

FDA DRUG AND DEVICE PRODUCT APPROVALS

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**Center for Drug Evaluation
and Research**

*George R. Scott (301) 443-3910

**Center for Biologics
Evaluation and Research**

Joseph Wilczek (301) 295-9012

**Center for Devices and
Radiological Health**

Mary Jo Robinson (301) 427-1186

Center for Veterinary Medicine

Melanie R. Berson, D.V.M.
(301) 295-8623

*To whom general inquiries should be directed.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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*****ORIGINAL AND SUPPLEMENTAL NDAs***
FOR NEW DRUG PRODUCTS**

20-123 01-08-93 (1 S)	OMNISCAN (INJECTABLE) 19246	STERLING WINTHROP COLLEGEVILLE, PA (DIAGNOSTIC RADIOPAQUE)	GADODIAMIDE 287MG/ML
19-084 01-27-93 (SUPPL)	NIZORAL (CREAM) 08854	JANSSEN PISCATAWAY, NJ (NEW INDICATION -- TREATMENT OF TINEA PEDIS)	KETOCONAZOLE 2%

*****ERRATA*****

19-899* 12-31-92 (5 S)	SINE-AID IB (TABLET) 19034	MCNEIL FORT WASHINGTON, PA PSEUDOEPHEDRINE HYDROCHLORIDE 30MG (NONSTEROIDAL ANTI-INFLAMMATORY/ DECONGESTANT) (OTC)	IBUPROFEN 200MG
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

* - Corrected Classification code

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

20-198 01-29-93	NIFEDIPINE (TABLET, EXTENDED RELEASE)	MILES WEST HAVEN, CT 06516 90MG (CALCIUM ION INFLUX INHIBITOR)	NIFEDIPINE 30MG 60MG
20-288 01-29-93	MONISTAT 7 COMBINATION PACK (SUPPOSITORY/CREAM)	ADVANCED CARE RARITAN, NJ 08869 (ANTIFUNGAL)	MICONAZOLE NITRATE 100MG-SUPPOSITORY 2%-CREAM
20-289 01-29-93	GYNE-LOTRIMIN COMBINATION PACK (INSERT/CREAM)	SCHERING LIBERTY CORNER, NJ 07938 (ANTIFUNGAL)	CLOTRIMAZOLE 100MG-INSERT 1%-CREAM

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

63-182	MEFOXIN	MERCK	CEFOXITIN SODIUM
01-25-93	IN PLASTIC CONTAINER (INJECTABLE)	WEST POINT, PA 19486	EQ 20MG BASE/ML EQ 40MG BASE/ML
		(ANTIBIOTIC, CEPHEM)	

70-998	K+8	ALRA	POTASSIUM CHLORIDE
01-25-93	(TABLET, EXTENDED RELEASE)	GURNEE, IL 60031	8MEQ (ELECTROLYTE REPLACEMENT)

73-466*	GEMFIBROZIL	MYLAN	GEMFIBROZIL
01-25-93	(CAPSULE)	MORGANTOWN, WV 26504	300MG (ANTHYPERLIPIDEMIC)

74-097*	ISOFLURANE	ABBOTT	ISOFLURANE
01-25-93	(LIQUID)	ABBOTT PARK, IL 60064	99.9% (GENERAL ANESTHETIC)

73-652	NITROFURANTOIN	ZENITH	NITROFURANTOIN,
01-28-93	(CAPSULE)	NORTHVALE, NJ 100MG	MACROCRYSTALLINE
	07647	(ANTIBACTERIAL)	

73-671	NITROFURANTOIN	ZENITH	NITROFURANTOIN,
01-28-93	(CAPSULE)	NORTHVALE, NJ 50MG	MACROCRYSTALLINE
	07647	(ANTIBACTERIAL)	

63-211	ERYTHROMYCIN	STIEFEL	ERYTHROMYCIN
01-29-93	(GEL)	CORAL GABLES, FL 33134	2% (ANTIBIOTIC, MACROLIDE)

64-022	NYSTATIN	TARO	NYSTATIN
01-29-93	(CREAM)	DOWNSVIEW, ONTARIO	100,000 UNITS/GM

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

(ANTIFUNGAL)

* - First Time Product Available Generically

72-370	DIAZEPAM	MARSAM	DIAZEPAM
01-29-93	(INJECTABLE)	CHERRY HILL, NJ	5MG/ML
	[VIAL]	08034	(ANXIOLYTIC)

72-371	DIAZEPAM	MARSAM	DIAZEPAM
01-29-93	(INJECTABLE)	CHERRY HILL, NJ	5MG/ML
	[AMPUL]	08034	(ANXIOLYTIC)

72-397	DIAZEPAM	MARSAM	DIAZEPAM
01-29-93	(INJECTABLE)	CHERRY HILL, NJ	5MG/ML
	[SYRINGE]	08034	(ANXIOLYTIC)

72-929	GEMFIBROZIL	PUREPAC	GEMFIBROZIL
01-29-93	(CAPSULE)	ELIZABETH, NJ	300MG
		07207	(ANTIHYPERTENSIVE)

74-014	KETOPROFEN	LEDERLE	KETOPROFEN
01-29-93	(CAPSULE)	PEARL RIVER, NY	25MG
		10965	50MG
			75MG
			(NONSTEROIDAL ANTI-INFLAMMATORY)

81-297*	BENZONATATE	PHARMACAPS	BENZONATATE
01-29-93	(CAPSULE)	ELIZABETH, NJ	100MG
		07207	(ANTITUSSIVE)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

* - First Time Product Available Generically

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
TENTATIVE	(DOSAGE FORM)		STRENGTH(S)
APPROVAL DATE			CLASSIFICATION(S)

ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

THERE ARE NO ORIGINAL ABBREVIATED AND 505(b)(2) NDA TENTATIVE APPROVALS FOR JANUARY 1993.

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

03-158 01-07-93	ORETON METHYL (TABLET) 07033	SCHERING KENILWORTH, NJ (REVISED LABELING -- PRECAUTIONS)	METHYLTESTOSTERONE 10MG
50-590 01-07-93	TIMENTIN (INJECTABLE) 19101	SMITHKLINE BEECHAM PHILADELPHIA, PA TICARCILLIN DISODIUM EQ 3GM BASE/VIAL (REVISED LABELING -- PRECAUTIONS)	CLAVULANATE POTASSIUM EQ 100MG ACID/VIAL
50-590 01-07-93	TIMENTIN (INJECTABLE) 19101	SMITHKLINE BEECHAM PHILADELPHIA, PA TICARCILLIN DISODIUM EQ 3GM BASE/VIAL (REVISED LABELING -- PRECAUTIONS)	CLAVULANATE POTASSIUM EQ 200MG ACID/VIAL
50-590 01-07-93	TIMENTIN (INJECTABLE) 19101	SMITHKLINE BEECHAM PHILADELPHIA, PA TICARCILLIN DISODIUM EQ 30GM BASE/VIAL (REVISED LABELING -- PRECAUTIONS)	CLAVULANATE POTASSIUM EQ 1GM ACID/VIAL
18-719 01-08-93	MODRASTANE (CAPSULE) 10016	STERLING NEW YORK, NY 60MG (REVISED LABELING -- PRECAUTIONS)	TRILOSTANE 30MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-901 01-08-93	ALTACE (CAPSULE)	HOECHST ROUSSEL SOMERVILLE, NJ	RAMIPRIL 1.25MG
	08876	2.5MG 5MG 10MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)	
18-922 01-12-93	LODINE (CAPSULE)	WYETH AYERST PHILADELPHIA, PA	ETODOLAC 200MG
	19101	300MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)	
19-667 01-12-93	SANDOSTATIN (INJECTABLE)	SANDOZ EAST HANOVER, NJ	OCTREOTIDE ACETATE EQ 50UGM BASE/ML
	07936	EQ 100UGM BASE/ML EQ 500UGM BASE/ML (REVISED LABELING -- DESCRIPTION; HOW SUPPLIED)	
17-386	ZAROXOLYN	FISONS	METOLAZONE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

01-13-93	(TABLET)	ROCHESTER, NY	2.5MG	
		14603	5MG	
			10MG	
			(REVISED LABELING --	
			PRECAUTIONS;	ADVERSE

REACTIONS)

19-532	MYKROX	FISONS	METOLAZONE	
01-13-93	(TABLET)	ROCHESTER, NY	0.5MG	
		14603	(REVISED LABELING --	
			PRECAUTIONS;	ADVERSE

REACTIONS)

50-482	KEFLIN	LILLY	CEPHALOTHIN SODIUM	
01-19-93	(INJECTABLE)	INDIANAPOLIS, IN	EQ 1GM BASE/VIAL	
		46285	EQ 2GM BASE/VIAL	
			EQ 20GM BASE/VIAL	
			(REVISED LABELING --	
			CLINICAL PHARMACOLOGY;	
			INDICATIONS AND USAGE;	
			OVERDOSAGE; HOW SUPPLIED)	

50-621	SUPRAX	LEDERLE	CEFIXIME	
01-19-93	(TABLET)	PEARL RIVER, NY	200MG	
		10965	400MG	
			(REVISED LABELING --	
			ADVERSE REACTIONS;	
			DOSAGE AND ADMINISTRATION)	

50-622	SUPRAX	LEDERLE	CEFIXIME	
01-19-93	(POWDER	PEARL RIVER, NY	100MG/5ML	
	FOR RECONSTITUTION)	10965	(REVISED LABELING --	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

ADVERSE REACTIONS;
DOSAGE AND ADMINISTRATION)

17-498 01-21-93	MICRONASE (TABLET)	UPJOHN KALAMAZOO, MI 49001	GLYBURIDE 1.25MG 2.5MG 5MG (REVISED LABELING -- PRECAUTIONS)
17-532 01-21-93	DIABETA (TABLET)	HOECHST ROUSSEL SOMERVILLE, NJ 08876	GLYBURIDE 1.25MG 2.5MG 5MG (REVISED LABELING -- PRECAUTIONS; DOSAGE AND ADMINISTRATION)
18-245 01-21-93	SYNTOCINON (INJECTABLE)	SANDOZ EAST HANOVER, NJ 07936	OXYTOCIN 10 USP UNITS/ML (REVISED LABELING -- DESCRIPTION; HOW SUPPLIED)
20-051 01-21-93	GLYNASE (TABLET)	UPJOHN KALAMAZOO, MI 49001	GLYBURIDE 1.5MG 3MG (REVISED LABELING -- PRECAUTIONS)
17-934	SEMILENTE ILETIN	LILLY	INSULIN ZINC SUSP

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

01-22-93	PROMPT INSULIN ZINC (SUSPENSION)	INDIANAPOLIS, IN 46285	PROMPT BEEF 100 UNITS/ML (REVISED LABELING -- PATIENT INFORMATION; PRODUCT TO BE DISCONTINUED 9/1/93) (OTC)
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17-935 01-22-93	ULTRALENTE ILETIN (BEEF-PORK) EXTENDED INSULIN ZINC (SUSPENSION)	LILLY INDIANAPOLIS, IN 46285	INSULIN ZINC SUSP EXTENDED 100 UNITS/ML (REVISED LABELING -- PATIENT INFORMATION; PRODUCT TO BE DISCONTINUED 9/1/93) (OTC)
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18-061 01-22-93	TIMOLIDE 10-25 (TABLET)	MSD WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 25MG TIMOLOL MALEATE 10MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
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18-477 01-22-93	LENTE ILETIN II (INJECTABLE)	LILLY INDIANAPOLIS, IN 46285	INSULIN ZINC SUSP PURIFIED BEEF 100 UNITS/ML (REVISED LABELING -- PATIENT INFORMATION; PRODUCT
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

TO BE DISCONTINUED 9/1/93)
(OTC)

18-478	REGULAR ILETIN II	LILLY	INSULIN PURIFIED BEEF
01-22-93	(INJECTABLE)	INDIANAPOLIS, IN	100 UNITS/ML
	46285		(REVISED LABELING -- PATIENT INFORMATION; PRODUCT TO BE DISCONTINUED 9/1/93) (OTC)

18-479	NPH ILETIN II	LILLY	INSULIN SUSP
01-22-93	(INJECTABLE)	INDIANAPOLIS, IN	ISOPHANE PURIFIED BEEF
	46285		100 UNITS/ML (REVISED LABELING -- PATIENT INFORMATION; PRODUCT TO BE DISCONTINUED 9/1/93) (OTC)

19-537	CIPRO	MILES	CIPROFLOXACIN HYDROCHLORIDE
01-22-93	(TABLET)	WEST HAVEN, CT	EQ 100MG BASE
	06516		EQ 250MG BASE EQ 500MG BASE EQ 750MG BASE (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; ANIMAL PHARMACOLOGY)

19-084	NIZORAL	JANSSEN	KETOCONAZOLE
01-27-93	(CREAM)	PISCATAWAY, NJ	2%

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

08854 (REVISED LABELING --
INDICATIONS AND USAGE)

50-605	CEFTIN	GLAXO	CEFUROXIME AXETIL
01-27-93	(TABLET)	RES TRIANGLE PK, NC	EQ 125MG BASE
		27709	EQ 250MG BASE
			EQ 500MG BASE
			(REVISED LABELING -- ADVERSE REACTIONS)

19-002	VASCOR	JOHNSON RW	BEPRIDIL HYDROCHLORIDE
01-28-93	(TABLET)	SPRING HOUSE, PA	200MG
		19477	300MG
			400MG
			(REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; WARNINGS; PRECAUTIONS)

19-357	ETHAMOLIN	REED AND CARNRICK	ETHANOLAMINE OLEATE
01-29-93	(INJECTABLE)	KENILWORTH, NJ	50MG/ML
		07033	(REVISED LABELING -- ADVERSE REACTIONS)

LICENSE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
LICENSE DATE	(DOSAGE FORM)		(DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

THERE ARE NO BIOLOGICAL PRODUCT LICENSES ISSUED FOR JANUARY 1993.

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE		(DESCRIPTION)	

BIOLOGICAL PRODUCT DEVICE APPROVALS

THERE ARE NO BIOLOGICAL PRODUCT DEVICE APPROVALS FOR JANUARY 1993.

NDA NUMBER	TRADE NAME	APPLICANT	PROPER NAME
APPROVAL DATE	(DOSAGE FORM)		(DESCRIPTION)

BIOLOGICAL PRODUCT NDA APPROVALS

19-862	INDICLOR	AMERSHAM	INDIUM IN ¹¹¹ CHLORIDE
12-29-92	(INJECTABLE)	ARLINGTON HEIGHTS, IL	N/A
	60005	(DIAGNOSTIC)	

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND
APPROVAL DATE			INDICATION OF DEVICE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

P890045	GELSEAL	CARBOMEDICS	APPROVAL FOR THE
01/11/93		AUSTIN, TX	GELSEAL VASCULAR
	78752-1793		GRAFT

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

P790018/S21 01/29/93	22 MM AORTIC MEDTRONIC HALL PROSTHETIC HEART VALVE	MEDTRONIC HEART VALVES MINNEAPOLIS, MN 55440	APPROVAL FOR PROTOCOL WHICH WILL BE USED IN THE POSTAPPROVAL STUDY ON THE 22 MM AORTIC MEDTRONIC HALL PROSTHETIC HEART VALVE
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P830026/S55 01/11/93	COSMOS PACING SYSTEM, COSMOS II, NOVA 11, AND QUANTUM II PULSE GENERATORS	INTERMEDICS, INC. ANGLETON, TX 77515	DISCONTINUATION OF ONGOING REAL-TIME LIFE TESTING
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P860007/S10 01/11/93	INTERTACH PACING SYSTEM, INTERTACH II PULSE GENERATORS MODELS 262-16 AND 262-16R	INTERMEDICS, INC. ANGLETON, TX 77515	DISCONTINUATION OF ONGOING REAL-TIME LIFE TESTING
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P910020/S02 01/11/93	RELAY/DASH PACING SYSTEM, RELAY/DASH FAMILY OF PULSE GENERATORS	INTERMEDICS, INC. ANGLETON, TX 77515	DISCONTINUATION OF ONGOING REAL-LIFE TESTING
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P830045/S41 01/22/93	AFP MODEL 203 PULSE GENERATOR WITH MODEL 370 PROGRAMMER, MODEL 3038	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	SOFTWARE MODIFICATIONS TO THE MODEL 3038 FUNCTION PACK FOR USE WITH THE APS II MODEL 3003
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APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
APPROVAL DATE			

MEDICAL DEVICE - PMA SUPPLEMENTALS

FUNCTION PACK

PROGRAMMER

P830055/S24	NEW JERSEY LCS	DEPUY	CHANGE IN MATERIAL
01/08/93	TOTAL KNEE SYSTEM 46580	WARSAW, IN	FOR THE ANCHORING PLATE PIN ON THE PATELLAR COMPONENT

P840040/S29	HEART TRAK	BOSTON SCIENTIFIC	APPROVAL FOR SYNERGY
01/12/93	CORONARY BALLOON DILATATION CATHETER SYSTEM, SYNERGY CONVERTIBLE RAPID EXCHANGE PTCA CATHETER	WATERTOWN, MA CORPORATION 02172	CONVERTIBLE RAPID EXCHANGE PTCA CATHETER

P840066/S30	SOFTMATE CONSEPT-1	SOLA/BARNES-HIND	ALTERNATE
01/07/93	CLEANING AND DISINFECTION SOLUTION	SUNNYVALE, CA 94086-5200	MANUFACTURING SITE

P850021/S18	HYBRID	BAXTER HEALTHCARE	APPROVAL FOR THE
01/22/93	PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, QUICK .14 PTCA CATHETER	CORPORATION SANTA ANA, CA 92711-1150	QUICK .14 PTCA CATHETER

P850021/S20	HYBRID	BAXTER HEALTHCARE	APPROVAL FOR THE
01/29/93	PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, BAXTER LONG REACH 30 MM	CORPORATION SANTA ANA, CA 92711-1150	BAXTER LONG REACH 30 MM PTCA CATHETER

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

PTCA CATHETER

P860004/S26 01/26/93	MEDTRONIC SYNCHROMED INFUSION SYSTEM, MEDTRONIC SYNCHROMED PUMPS (MODELS 8610H, 8611H, AND 8615)	MEDTRONIC NEUROLOGICAL MINNEAPOLIS, MN 55440-9087	MODIFICATIONS TO THE ELECTRONIC HYBRID MODULE OF THE SYNCHROMED IMPLANTABLE INFUSION PUMPS
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P860019/S53 01/28/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, SCIMED ACE AND SCIMED LONG ACE PTCA CATHETERS	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	ONE-PIECE MANIFOLD TO BE USED ON ALL MODELS OF SCIMED ACE AND SCIMED LONG ACE PTCA CATHETERS
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P860047/S03 01/11/93	OCCUCOAT, VISCOLON CLEARWATER, FL 34616	STORZ OPHTHALMICS, INC. AS A DISTRIBUTOR FOR OCCUCOAT AS AN ALTERNATE TO STORZ OPHTHALMICS, INC., LABELING CHANGE, NEW TOLL-FREE NUMBER	MDR MEDICAL CORPORATION
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P860047/S04 01/11/93	OCCUCOAT, CELLUCOAT CLEARWATER, FL 34616	STORZ OPHTHALMICS, INC. AS AN ALTERNATE TO STORZ	WORLD OPTICS, INC. AS DISTRIBUTOR FOR OCCUCOAT
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APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

OPHTHALMICS, INC.,
LABELING CHANGE, NEW
TOLL-FREE NUMBER

P860047/S05 01/11/93	OCCUCOAT, ZYCON CLEARWATER, FL 34616	STORZ OPHTHALMICS, INC. DGR, INC. AS A DISTRIBUTOR FOR OCCUCOAT AS AN ALTERNATE TO STORZ OPHTHALMICS, INC., LABELING CHANGE, NEW TOLL-FREE NUMBER
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P870024/S35 01/26/93	FLUOROPERM 92 (PAFLUFOCON A), FLUOROPERM 60 (PAFLUFOCON B) AND FLUOROPERM 30 (PAFLUFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PARAGON OPTICAL MESA, AZ 85204 LABORATORY	ADDITIONAL CONTACT LENS FINISHING
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P870078/S02 01/29/93	HANCOCK STABILIZED GLUTARALDEHYDE PROCESS BIOPROSTHESIS (MODELS 242, 342, 342C AND 342R)	MEDTRONIC HEART VALVES MINNEAPOLIS, MN 55440	ALTERNATE MILLING PROCESS
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P880006/S16 01/22/93	SENSOLOG MODEL 703 PULSE GENERATOR AND P700 PROGRAMMER,	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	SOFTWARE MODIFICATIONS TO THE MODEL 3038 FUNCTION PACK FOR USE WITH THE
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APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

MODEL 3038 FUNCTION PACK	APS II MODEL 3003 PROGRAMMER
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P880016/S04 01/13/93	ONCOR B/T GENE REARRANGEMENT TEST, ONCOR B/T BLUE	ONCOR, INCORPORATED GAITHERSBURG, MD 20884	APPROVAL FOR BONE MARROW AS A SAMPLE TYPE WHICH MAY BE TESTED WITH THE ONCOR B/T BLUE KIT
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P880038/S20 01/07/93	META MV PACING SYSTEM, META III PACING SYSTEM	TELECTRONICS, INC. ENGLEWOOD, CO 80112	INTRODUCTION OF THE META III MODEL 1206
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P890043/S16 01/12/93	SIMPSON CORONARY ATHEROCATH, MOTOR DRIVE UNIT WITH TORQUE CONTROLLER CIRCUIT	DEVICES FOR VASCULAR INTERVENTION, INC. REDWOOD CITY, CA 94063	MODIFICATION TO THE MOTOR DRIVE UNIT COMPONENT TO INCLUDE A TORQUE CONTROLLER CIRCUIT
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P890046/S19 01/14/93	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	IDEAL OPTICS, INC. ATLANTA, GA 30339	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES AS ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
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P900032/S13 01/08/93	AIS EXCIMER LASER ANGIOPLASTY SYSTEM IRVINE, CA 92718	ADVANCED INTERVENTIONAL SYSTEMS	NEW LASER SOURCE
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P900070/S02 01/07/93	META DDR PACING SYSTEM, V4.10UE SOFTWARE FOR THE MODEL 9600 NETWORK	TELECTRONICS, INC. ENGLEWOOD, CO 80112	INTRODUCTION OF THE VERSION V4.10UE SOFTWARE FOR THE MODEL 9600 NETWORK
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APPLICATION NO. TRADE NAME
APPROVAL DATE

APPLICANT
INDICATION OF DEVICE

DESCRIPTION AND
INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

PROGRAMMER

PROGRAMMER

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

140-848	VETEEZE	DOGS	ROCHE	DIAZEPAM
12-17-92	(INJECTABLE)	07110	NUTLEY, NJ	5MG/ML

ORIGINAL ABBREVIATED VETERINARY NADAs

200-030	SULFADIMETHOXINE	CATTLE,	AGRI LABS	SULFADIMETHOXINE
12-31-92	12.5%	CHICKENS,	ST JOSEPH, MO	3.75GM/OZ
	(SOLUTION)	TURKEYS	64503	

SUPPLEMENTAL VETERINARY NADAs

140-915	INTERCEPTOR	DOGS	CIBA GEIGY AN HLTH	MILBEMYCIN
12-29-92	(TABLET)	27419	GREENSBORO, NC	OXIME
			2.3MG	
			5.75MG	
			11.5MG	
			23MG	

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

Center for Drug Evaluation and Research
 *George R. Scott (301) 443-3910

Center for Devices and Radiological Health
 Mary Jo Robinson (301) 427-1186

Center for Biologics Evaluation and Research
 Joseph Wilczek (301) 295-9012

Center for Veterinary Medicine
 Melanie R. Berson, D.V.M.
 (301) 295-8623

*To whom general inquiries should be directed.

This report is compiled by the Division of Drug Information Resources, OM, CDER. It is available by subscription from the National Technical Information Service, Springfield, VA 22161.

Volume 16 (2) February 1993

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
 FOR NEW DRUG PRODUCTS

19-726 02-02-93 (SUPPL)	ZOLADEX (IMPLANT)	IMPERIAL CHEM CHESHIRE, ENGLAND	GOSERELIN ACETATE EQ 3.6MG BASE (NEW INDICATION -- MANAGEMENT OF ENDOMETRIOSIS)
20-007 02-02-93 (SUPPL)	ZOFRAN (INJECTABLE)	GLAXO RES TRIANGLE PK, NC 27709	ONDANSETRON HYDROCHLORIDE EQ 2MG BASE/ML (NEW DOSAGE REGIMEN -- ALTERNATE DOSAGE - SINGLE 32MG DOSE)
18-859 02-05-93 (SUPPL)	VIRAZOLE (POWDER FOR RECONSTITUTION)	VIRATEK COSTA MESA, CA 92626	RIBAVIRIN 6GM/VIAL (EXPANDED PATIENT POPULATION -- MECHANICALLY VENTILATED)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

INFANTS)

20-107	NOVAMINE 15%	BAXTER	AMINO ACIDS
02-05-93	SULFITE FREE	ROUND LAKE, IL	15%
(5 S)	IN PLASTIC CONTAINER	60073	(NUTRIENT REPLENISHER)
	(INJECTABLE)		

50-621	SUPRAX	LEDERLE	CEFIXIME
02-05-93	(TABLET)	PEARL RIVER, NY	200MG
(SUPPL)		10965	400MG
			(NEW INDICATIONS --
			UNCOMPLICATED URETHRAL
			AND CERVICAL GONORRHEA)

20-229	LEUSTATIN	JOHNSON RW	CLADRIBINE
02-26-93	(INJECTABLE)	RARITAN, NJ	1MG/ML
(1 P, V*)		08869	(ANTINEOPLASTIC)
			[HAIRY CELL LEUKEMIA]

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

V* - Designated Orphan Drug

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

*** APPROVABLE ORIGINAL NDAs ***

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

20-279 02-24-93	DERMATOP (CREAM)	HOECHST ROUSSEL SOMERVILLE, NJ 08876	PREDNICARBATE 0.1% (CORTICOSTEROID)
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

72-733 02-22-93	LEUCOVORIN CALCIUM (TABLET)	ROXANE COLUMBUS, OH 43216	LEUCOVORIN CALCIUM EQ 5MG BASE (FOLIC ACID ANTAGONIST ANTIDOTE)
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72-734 02-22-93	LEUCOVORIN CALCIUM (TABLET)	ROXANE COLUMBUS, OH 43216	LEUCOVORIN CALCIUM EQ 10MG BASE (FOLIC ACID ANTAGONIST ANTIDOTE)
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72-735 02-22-93	LEUCOVORIN CALCIUM (TABLET)	ROXANE COLUMBUS, OH 43216	LEUCOVORIN CALCIUM EQ 15MG BASE (FOLIC ACID ANTAGONIST ANTIDOTE)
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72-736 02-22-93	LEUCOVORIN CALCIUM (TABLET)	ROXANE COLUMBUS, OH 43216	LEUCOVORIN CALCIUM EQ 25MG BASE (FOLIC ACID ANTAGONIST ANTIDOTE)
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72-516 02-25-93	HALOPERIDOL (INJECTABLE) [AMP]	MARSAM CHERRY HILL, NJ 08034	HALOPERIDOL LACTATE EQ 5MG BASE/ML (ANTIPSYCHOTIC)
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72-517 02-25-93	HALOPERIDOL (INJECTABLE) [VIAL]	MARSAM CHERRY HILL, NJ 08034	HALOPERIDOL LACTATE EQ 5MG BASE/ML (ANTIPSYCHOTIC)
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40-057 02-26-93	LIDOCAINE HCL AND EPINEPHRINE (INJECTABLE)	STERLING WINTHROP NEW YORK, NY 10016	EPINEPHRINE 0.02MG/ML LIDOCAINE 2% (VASOCONSTRICTOR/
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

LOCAL ANESTHETIC)

40-057 02-26-93	LIDOCAINE HCL AND EPINEPHRINE (INJECTABLE)	STERLING WINTHROP NEW YORK, NY 10016	EPINEPHRINE 0.01MG/ML LIDOCAINE 2% (VASOCONSTRICTOR/ LOCAL ANESTHETIC)
64-035 02-26-93	CEFUROXIME (INJECTABLE) 08034	MARSAM CHERRY HILL, NJ	CEFUROXIME SODIUM EQ 750MG BASE/VIAL EQ 1.5GM BASE/VIAL (ANTIBIOTIC, CEPHEM)
64-036* 02-26-93	CEFUROXIME (INJECTABLE) 08034	MARSAM CHERRY HILL, NJ	CEFUROXIME SODIUM EQ 7.5GM BASE/VIAL (ANTIBIOTIC, CEPHEM)
72-233 02-26-93	VERAPAMIL HCL (INJECTABLE) 08034	MARSAM CHERRY HILL, NJ	VERAPAMIL HYDROCHLORIDE 2.5MG/ML (CALCIUM ION INFLUX INHIBITOR)
73-037 02-26-93	HALOPERIDOL (CONCENTRATE) 29636	PHARM ASSOC CONESTEE, SC	HALOPERIDOL LACTATE EQ 2MG BASE/ML (ANTIPSYCHOTIC)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

73-651 02-26-93	PIROXICAM (CAPSULE) 43216	ROXANE COLUMBUS, OH 20MG (NONSTEROIDAL ANTI-INFLAMMATORY)	PIROXICAM 10MG
73-683 02-26-93	CYCLOBENZAPRINE HCL (TABLET) 07004	INVAMED FAIRFIELD, NJ (SKELETAL MUSCLE RELAXANT)	CYCLOBENZAPRINE 10MG

* - First Time Product Available Generically

73-687 02-26-93	PINDOLOL (TABLET) 07647	ZENITH NORTHVALE, NJ 10MG (BETA ADRENERGIC BLOCKER)	PINDOLOL 5MG
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
TENTATIVE	(DOSAGE FORM)		STRENGTH(S)
APPROVAL DATE			CLASSIFICATION(S)

ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

74-207 02-26-93	NAPROXEN (TABLET)	COPLEY CANTON, MA 02021	NAPROXEN 250MG 375MG 500MG (NONSTEROIDAL ANTI-INFLAMMATORY)
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-715 01-05-93	DIPENTUM (CAPSULE)	KABI PISCATAWAY, NJ 08855	OLSALAZINE SODIUM 250MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; PRECAUTIONS; ADVERSE REACTIONS)
09-218 02-01-93	COUMADIN (TABLET)	DUPONT WILMINGTON, DE 19880	WARFARIN SODIUM 1MG 2MG 2.5MG 5MG 7.5MG 10MG (REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS; OVERDOSAGE)
19-726 02-02-93	ZOLADEX (IMPLANT)	IMPERIAL CHEM CHESHIRE, ENGLAND	GOSERELIN ACETATE EQ 3.6MG BASE (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
20-007 02-02-93	ZOFRAN (INJECTABLE)	GLAXO RES TRIANGLE PK, NC 27709	ONDANSETRON HYDROCHLORIDE EQ 2MG BASE/ML (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS;

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

DOSAGE AND ADMINISTRATION)

18-859	VIRAZOLE	VIRATEK	RIBAVIRIN
02-05-93	(POWDER FOR RECONSTITUTION)	COSTA MESA, CA 92626	6GM/VIAL (REVISED LABELING -- BOXED WARNINGS; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)

50-621	SUPRAX	LEDERLE	CEFIXIME
02-05-93	(TABLET)	PEARL RIVER, NY 10965	200MG 400MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)

19-264	PENTAM 300	FUJISAWA	PENTAMIDINE ISETHIONATE
02-09-93	(INJECTABLE)	DEERFIELD, IL 60015	300MG/VIAL (REVISED LABELING -- WARNINGS; ADVERSE REACTIONS)

19-926	HEXALEN	US BIOSCIENCE	ALTRETAMINE
02-10-93	(CAPSULE)	WEST CONSHOHOCKEN, PA 19428	50MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

17-016	CHORIONIC	STERIS	GONADOTROPIN, CHORIONIC
02-11-93	GONADOTROPIN (INJECTABLE)	PHOENIX, AZ 85063	2,000 UNITS/VIAL 5,000 UNITS/VIAL 10,000 UNITS/VIAL 15,000 UNITS/VIAL 20,000 UNITS/VIAL (REVISED LABELING -- ADVERSE REACTIONS)
17-067	CHORIONIC	LYPHOMED	GONADOTROPIN, CHORIONIC
02-11-93	GONADOTROPIN (INJECTABLE)	MELROSE PARK, IL 60160	5,000 UNITS/VIAL 10,000 UNITS/VIAL 20,000 UNITS/VIAL (REVISED LABELING -- DESCRIPTION; PRECAUTIONS)
19-465	SODIUM CHLORIDE 0.9%	ABBOTT	SODIUM CHLORIDE
02-16-93	IN PLASTIC CONTAINER (INJECTABLE)	ABBOTT PARK, IL 60064	900MG/100ML (REVISED LABELING -- DESCRIPTION; PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-466	DEXTROSE 5%	ABBOTT	DEXTROSE
02-16-93	IN PLASTIC CONTAINER (INJECTABLE)	ABBOTT PARK, IL 60064	5GM/100ML (REVISED LABELING -- DESCRIPTION; PRECAUTIONS; DOSAGE AND ADMINISTRATION;

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

HOW SUPPLIED)

19-759 02-16-93	SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE)	ABBOTT ABBOTT PARK, IL 60064	SODIUM CHLORIDE 450MG/100ML (REVISED LABELING -- DESCRIPTION; PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
08-248 02-17-93	WYAMINE SULFATE (INJECTABLE) 19101	WYETH AYERST PHILADELPHIA, PA	MEPHENTERMINE SULFATE EQ 15MG BASE/ML EQ 30MG BASE/ML (REVISED LABELING -- LABELING FORMAT REVISION PROGRAM)
18-154 02-17-93	LONITEN (TABLET) 49001	UPJOHN KALAMAZOO, MI	MINOXIDIL 2.5MG 10MG (REVISED LABELING -- PRECAUTIONS)
06-002 02-18-93	ARALEN (TABLET) 10016	STERLING NEW YORK, NY	CHLOROQUINE PHOSPHATE EQ 300MG BASE (REVISED LABELING -- ADVERSE REACTIONS)
20-103 02-22-93	ZOFRAN (TABLET) 27709	GLAXO RES TRIANGLE PK, NC	ONDANSETRON HYDROCHLORIDE EQ 4MG BASE EQ 8MG BASE (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
50-579	MONOCID	SMITHKLINE BEECHAM	CEFONICID SODIUM

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

02-22-93	(INJECTABLE)	PHILADELPHIA, PA	EQ 500MG BASE/VIAL
	19101	EQ 1GM BASE/VIAL	
		EQ 2GM BASE/VIAL	
		EQ 10GM BASE/VIAL	
		(REVISED LABELING --	
		DESCRIPTION;	
		DOSAGE AND ADMINISTRATION;	
		COMPATIBILITY AND STABILITY;	
		HOW SUPPLIED)	

50-624	ROCEPHIN W/ DEXTROSE	ROCHE	CEFTRIAXONE SODIUM
02-22-93	IN PLASTIC CONTAINER	NUTLEY, NJ	EQ 10MG BASE/ML
	(INJECTABLE)	07110	EQ 20MG BASE/ML
		EQ 40MG BASE/ML	
		(REVISED LABELING --	
		INDICATIONS AND USAGE)	

11-683	THIO-TEPA	LEDERLE	THIOTEPA
02-23-93	(INJECTABLE)	PEARL RIVER, NY	15MG/VIAL
	10965	(REVISED LABELING --	
		ADVERSE REACTIONS;	
		DOSAGE AND ADMINISTRATION)	

19-880	PARAPLATIN	BRISTOL MYERS SQUIBB	CARBOPLATIN
02-23-93	(INJECTABLE)	BUFFALO, NY	50MG/VIAL
	14213	150MG/VIAL	
		450MG/VIAL	
		(REVISED LABELING --	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

WARNINGS)

50-443	BLENOXANE	BRISTOL	BLEOMYCIN SULFATE
02-23-93	(INJECTABLE)	SYRACUSE, NY	EQ 15 UNITS BASE/VIAL
	13221	(REVISED LABELING --	ADMINISTRATION;
		STABILITY)	

10-402	PREMARIN	WYETH AYERST	ESTROGENS, CONJUGATED
02-24-93	(INJECTABLE)	PHILADELPHIA, PA	25MG/VIAL
	19101	(REVISED LABELING --	DESCRIPTION;
		PATIENT PACKAGE INSERT)	

18-998	VASOTEC	MERCK	ENALAPRIL MALEATE
02-24-93	(TABLET)	WEST POINT, PA	2.5MG
	19486	5MG	
		10MG	
		20MG	
		(REVISED LABELING --	WARNINGS; ADVERSE REACTIONS)

19-221	VASERETIC	MERCK	ENALAPRIL MALEATE
02-24-93	(TABLET)	WEST POINT, PA	10MG
	19486	HYDROCHLOROTHIAZIDE	
		25MG	
		(REVISED LABELING --	WARNINGS; PRECAUTIONS;
		ADVERSE REACTIONS)	

19-309	VASOTEC	MERCK	ENALAPRILAT
02-24-93	(INJECTABLE)	WEST POINT, PA	1.25MG/ML
	19486	(REVISED LABELING --	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

WARNINGS; ADVERSE REACTIONS)

19-882	TECHNESCAN MAG3	MALLINCKRODT	TECHNETIUM TC-99M
02-26-93	(INJECTABLE)	SAINT LOUIS, MO	MERTIATIDE KIT
	63134	N/A	
		(REVISED LABELING --	
		INSTRUCTIONS FOR	
		PREPARATION)	

LICENSE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
LICENSE DATE	(DOSAGE FORM)		(DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

0008	KOGENATE	MILES	ANTIHEMOPHILIC FACTOR
02-25-93	(INJECTABLE)	BERKELEY, CA	(RECOMBINANT)
	94701	*(B)	

LICENSE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
LICENSE DATE	(DOSAGE FORM)		(DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

* - New Product Manufactured Under License
(B) Product License Issued

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE		(DESCRIPTION)	

BIOLOGICAL PRODUCT DEVICE APPROVALS

BP860031	ETI-CORE	INCSTAR	ETI-CORE
02-22-93		STILLWATER, MN	(C)
	55082		

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE		(DESCRIPTION)	

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

P910001 02/19/93	SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM	SPECTRANETICS CORPORATION COLORADO SPRINGS, CO 80907	APPROVAL FOR THE SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM
P910053 02/19/93	AIA-PACK CEA S. SAN FRANCISCO, CA 94080	TOSOH MEDICS	APPROVAL FOR THE AIA-PACK CEA
P900067 02/25/93	ISPAN SULFUR HEXAFLUORIDE GAS 18949	SCOTT MEDICAL PRODUCTS PLUMSTEADVILLE, PA GAS FOR USE AS A SURGICAL AID IN THE TREATMENT OF UNCOMPLICATED RETINAL DETACHMENT BY PNEUMATIC RETINOPEXY	APPROVAL FOR ISPAN SULFUR HEXAFLUORIDE
P900066 02/25/93	ISPAN PERFLUOROPROPANE GAS 18949	SCOTT MEDICAL PRODUCTS PLUMSTEADVILLE, PA	APPROVAL FOR ISPAN PERFLUOROPROPANE GAS
P900061 02/11/93	MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR THE MEDTRONIC PCD TACHYARRHYTHMIA CONTROL SYSTEM

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND
APPROVAL DATE		INDICATION OF DEVICE	

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

N16895/S81 02/26/93	BAUSCH & LOMB MEDALIST (POLYMACON) VISIBILITY TINTED CONTACT LENS	BAUSCH & LOMB ROCHESTER, NY 14692-0450	REVISED LABELING TO CHANGE "FOR USE WITH PLANNED REPLACEMENT" TO "FOR PLANNED REPLACEMENT"
N18466/S14 02/19/93	CMW4 LONG SET BONE CEMENT 17405-0872	DENTSPLY INTERNATIONAL YORK, PA	APPROVAL FOR CMW4 BONE CEMENT
P790007/S10 02/02/93	HANCOCK MODIFIED ORIFICE (MO) BIOPROSTHESIS (MODEL 250)	MEDTRONIC HEART VALVES MINNEAPOLIS, MN 55440	ALTERNATE MILLING PROCESS
P810046/S129 02/11/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS RX STREAK .014 RX STREAK .010 AND ACS FLOWTRACK 40 CORONARY DILATATION CATHETERS	ADVANCED CARDIOVASCULAR SYSTEMS TEMECULA, CA 92591-4628	ADDITION OF A FLUSHING SHEATH, A COIL CLIP, AND A CUP CLIP TO THE ACS RX STREAK .014, ACS RX STREAK .010 AND ACS FLOWTRACK 40 CORONARY DILATATION CATHETERS
P810046/S135 02/11/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS RX STREAK .010	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	APPROVAL FOR THE ACS RX STREAK .010 CORONARY DILATATION CATHETER

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

CORONARY DILATATION
CATHETER

P820018/S56 02/05/93	MODEL 5603, 9600 PROGRAMMER NEW SOFTWARE, V4.10UE	TELECTRONICS PACING SYSTEMS ENGLEWOOD, CO 80112	APPROVAL FOR THE INTRODUCTION OF THE V.4.10UE SOFTWARE FOR MODEL 9600 NETWORK PROGRAMMER AND CHAPTER 0/V0.12 FOR MODEL 5603 PROGRAMMER
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P820051/S15 02/26/93	UNILENS 53 (OCUFILCON B) SOFT (HYDROPHILIC) ASPHERIC CONTACT LENS, MULTI-VUE 53 (OCUFILCON B) SOFT (HYDROPHILIC) ASPHERIC LENS	OCU-EASE OPTICAL PRODUCTS, INC. PINOLE, CA 94564	TRADE NAME CHANGE FROM UNILENS 53 TO MULTI-VUE 53 (OCUFILCON B) SOFT (HYDROPHILIC) ASPHERIC CONTACT LENS FOR DAILY WEAR
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P820076/S14 02/09/93	DIPLOS-03 PULSE GENERATOR AND MODEL EPR-400 PROGRAMMER, GEMNOS 04 PULSE GENERATOR	BIOTRONIK, INC. LAKE OSWEGO, OR 97035-5369	APPROVAL FOR THE GEMNOS 04 AND PMS 600 PROGRAMMER WITH MODULE SWM 600 VERSION C00U02
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P830045/S38	AFP MODEL 283	SIEMENS PACESETTER, INC.	APPROVAL FOR THE
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APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

02/05/93	PULSE GENERATOR WITH MODEL 370 PROGRAMMER, SOLUS II PULSE GENERATOR MODELS 2006K, 2006L, 2007K, AND 2007M/S	SYLMAR, CA 91392-9221	SOLUS II PULSE GENERATOR MODELS 2006K, 2006L, 2007K, AND 2007M/S
P840024/S44 02/26/93	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT 80112	COCHLEAR CORPORATION ENGLEWOOD, CO	APPROVAL TO DISTRIBUTE NEW 6.60 VERSION OF THE DIAGNOSTIC AND PROGRAMMING SYSTEM SOFTWARE
P840068/S18 02/05/93	DELTA PULSE GENERATOR, VISTA 55112-5798 PULSE GENERATOR MODELS 443/444, VISTA T PULSE GENERATOR MODELS 445/446/447, VISTA DDD PULSE GENERATOR MODELS 940/941	CARDIAC PACEMAKERS, INC. ST. PAUL, MN	MANUFACTURING MODIFICATIONS
P850020/S04 02/20/93	PROSORBA COLUMN SEATTLE, WA 98109-4517	IMRE CORPORATION	CHANGE IN MANUFACTURING FACILITY LOCATION
P850077/S17 02/10/93	SUNSOFT (METHAFILCON A)	SUNSOFT CORPORATION ALBUQUERQUE, NM	MANUFACTURING MODIFICATIONS

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

SOFT (HYDROPHILIC) 87109
 LENS, SEDUCTIONS
 AND REVOLUTION
 (METHAFILCON A)
 SOFT (HYDROPHILIC)
 LENSES

P860019/S54 SCIMED SCIMED LIFE SYSTEMS, INC. TWO NEW MODEL
 02/05/93 PERCUTANEOUS MAPLE GROVE, MN CATHETERS
 TRANSLUMINAL 55369-7503
 CORONARY ANGIOPLASTY
 CATHETER,
 LONG COBRA 30
 AND LONG COBRA 40

P860019/S55 SCIMED SCIMED LIFE SYSTEMS, INC. NEW MODEL CATHETER
 02/05/93 PERCUTANEOUS MAPLE GROVE, MN
 TRANSLUMINAL 55369-7503
 CORONARY ANGIOPLASTY
 CATHETER

P860019/S58 SCIMED SCIMED LIFE SYSTEMS, INC. NEW MODEL CATHETER
 02/05/93 PERCUTANEOUS MAPLE GROVE, MN
 TRANSLUMINAL 55369-7503
 CORONARY ANGIOPLASTY
 CATHETER

P860019/S65 SCIMED SCIMED LIFE SYSTEMS, INC. MINOR LABELING
 02/05/93 PERCUTANEOUS MAPLE GROVE, MN CHANGES TO THE
 TRANSLUMINAL 55369-7503 INSTRUCTIONS FOR USE
 CORONARY ANGIOPLASTY

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

(PTCA) CATHETER

P870036/S13	VERSAFLEX	MEDTRONIC INTERVENTIONAL	ALTERNATE
02/12/93	BUCHBINDER	SAN DIEGO, CA	MANUFACTURING
	OMNIFLEX PTCA	92121-2256	FACILITY
	CATHETER SYSTEM		

P880013/S01	HFV INFANT STAR	INFRASONICS, INC.	REPLACEMENT OF TWO
02/05/93	VENTILATOR	SAN DIEGO, CA	TYPES OF VALVES,
	92121	RESTRICTORS,	
		ACCUMULATORS AND AN	
		ORIFICE	

P880027/S25	SCHNEIDER	SCHNEIDER (USA) INC.	REDUCTION OF THE
02/12/93	MICROSOFTRAC PTCA	PLYMOUTH, MN	INCUBATION PERIOD FOR
	CATHETER	55442	THE AMSCO BIOLOGICAL
			INDICATORS FROM 7 TO
			5 DAYS FOR SOME OF
			THEIR PTCA CATHETERS

P880053/S06	BARNES-HIND	SOLA BARNES HIND	ADDITION OF THE
02/09/93	ENZYME +	SUNNYVALE, CA	BARNES HIND ENZYME +
	SURFACTANT CLEANER	94086-5200	SURFACTANT CLEANER
			FOR COMBINED ONE STEP
			ENZYME CLEANING AND
			DISINFECTION WITH
			SOFT MATE CONSEPT-1
			SOLUTION

P880086/S16	SYNCHRONY	SIEMENS PACESETTER, INC.	APPROVAL FOR THE
02/05/93	MODEL 2020T	SYLMAR, CA	SOLUS II PULSE

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

PULSE GENERATOR AND APS II MODEL 3000 PROGRAMMER, SOLUS II PULSE GENERATOR MODELS 2006K, 2006L, 2007K, AND 2007M/S	91392-9221	GENERATOR MODELS 2006K, 2006L, 2007K, AND 2007M/S
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P880086/S17 SYNCHRONY 02/05/93 MODEL 2020T PULSE GENERATOR AND APS II MODEL 3000 PROGRAMMER, SYNCHRONY III PULSE GENERATOR MODELS 2028T, 2028L, 2029K AND 2029M/S	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	APPROVAL FOR THE SYNCHRONY III PULSE GENERATOR MODELS 2028T, 2028L, 2029K, AND 2029M/S
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P890003/S19 SYNERGYST II 02/19/93 MODELS 7070 AND 7071, MODEL 9858E SOFTWARE DISKETTES FOR USE WITH THE MODEL 9760 PROGRAMMER SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR THE MODEL 9858E SOFTWARE DISKETTES FOR USE WITH THE MODEL 9760 PROGRAMMER SYSTEM
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P890027/S15 NUCLEUS 22 02/26/93 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	DISTRIBUTION OF THE NEW 6.60 VERSION OF THE DIAGNOSTIC AND PROGRAMMING SYSTEM SOFTWARE
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APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

P890039/S10 02/12/93	MAESTRO SAVVI MODEL 305 PACING SYSTEM/A-TRACK LEADS	32137	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL A-TRACK LEADS, INTRODUCTION OF A NEW FEEDTHROUGH, AND MODIFICATION OF THE INCOMING INSPECTION FOR FEEDTHROUGHS	EXTENSION OF THE "USE BEFORE." DATE ON
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P890043/S13 02/11/93	SIMPSON CORONARY ATHEROCATH REDWOOD CITY, CA 94063		DEVICES FOR VASCULAR INTERVENTION, INC. FACILITY AND A CHANGE IN THE STERILIZATION GAS MIXTURE	ALTERNATE STERILIZATION
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P890044/S24 02/05/93	TRANS-AIRE (AMSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR	95834	BENITEC ENGINEERING, INC. SACRAMENTO, CA LABORATORY	ADDITIONAL CONTACT LENS FINISHING
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P890044/S25 02/09/93	TRANS-AIRE (AMSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND BLUE TINT)	95834	BENITEC ENGINEERING, INC. SACRAMENTO, CA FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTING SITES	TWO ADDITIONAL CONTACT LENS
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APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

P890072/S06 ALBERTA LENS 'S' 02/09/93 (SULFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED WITH AN ULTRAVIOLET LIGHT ABSORBER)	PROGRESSIVE OPTICAL RESEARCH, LTD. ALBERTA, CANADA	FOUR ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTING SITES
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P900065/S03 TECHNICON 38 02/11/93 (POLYMACON) HYDROPHILIC CONTACT LENS	WESTCON CONTACT LENS COMPANY GRAND JUNCTION, CO 81506 DEVELOPMENT, SARASOTA, FL AS AN	APPROVAL FOR BENZ RESEARCH AND ALTERNATE SUPPLIER FOR THE POLYMACON MATERIAL
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APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND
APPROVAL DATE			INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

140-971	HEARTGARD-30 PLUS	DOGS	MERCK	IVERMECTIN
01-15-93	(TABLET)	RAHWAY, NJ	68MCG	
	07065	PYRANTEL		
		57MG		

140-971	HEARTGARD-30 PLUS	DOGS	MERCK	IVERMECTIN
01-15-93	(TABLET)	RAHWAY, NJ	136MCG	
	07065	PYRANTEL		
		114MG		

140-971	HEARTGARD-30 PLUS	DOGS	MERCK	IVERMECTIN
01-15-93	(TABLET)	RAHWAY, NJ	272MCG	
	07065	PYRANTEL		
		227MG		

140-874	ANTAGONIL	FREE	WILDLIFE	YOHIMBINE
02-03-93	(SOLUTION)	RANGING OR	FT COLLINS, CO	HYDROCHLORIDE
	CONFINED	80524	5MG/ML	
	MEMBERS OF			
	THE FAMILY			
	CERVIDAE			
	(ELK,			
	DEER)			

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR FEBRUARY 1993.

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

SUPPLEMENTAL VETERINARY NADAs

111-798	DRONCIT	CATS	MILES AGRI DIV	PRAZIQUANTEL
01-11-93	(TABLET)		AN HLTH PRODS	11.5MG
		SHAWNEE MISSION, KS		
		66201		

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

**Center for Drug Evaluation
and Research**
*George R. Scott (301) 443-3910

**Center for Devices and
Radiological Health**
Mary Jo Robinson (301) 427-1186

**Center for Biologics
Evaluation and Research**
Joseph Wilczek (301) 295-9012

Center for Veterinary Medicine
Melanie R. Berson, D.V.M.
(301) 295-8623

*To whom general inquiries should be directed.

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Springfield, VA 22161.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

18-936	PROZAC	LILLY	FLUOXETINE HYDROCHLORIDE
12-23-92	(CAPSULE)	INDIANAPOLIS, IN	EQ 10MG BASE
(SUPPL)		46285	(NEW STRENGTH)

19-627	DIPRIVAN	ZENECA PHARMS	PROPOFOL
03-08-93	(INJECTABLE)	WILMINGTON, DE	10MG/ML
(SUPPL)		19897	(NEW INDICATION-- INTENSIVE CARE UNIT SEDATION)

19-710	OPTIRAY 300	MALLINCKRODT	IOVERSOL
03-09-93	(INJECTABLE)	SAINT LOUIS, MO	64%
(SUPPL)		63134	(NEW INDICATION -- CONTRAST ENHANCED COMPUTED TOMOGRAPHIC IMAGING OF THE BODY AND INTRAVENOUS EXCRETORY UROGRAPHY)

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT CLASSIFICATION(S)	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-200 03-12-93 (3 S)	NALBUPHINE HYDROCHLORIDE (INJECTABLE)	ABBOTT ABBOTT PARK, IL 60064	NALBUPHINE HYDROCHLORIDE 1.5MG/ML (OPIOID RECEPTOR AGONIST/ANTAGONIST) [ANALGESIC]
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19-050 03-19-93 (SUPPL)	SUFENTA (INJECTABLE)	JANSSEN PISCATAWAY, NJ 08854	SUFENTANIL CITRATE EQ 0.05MG BASE/ML (NEW ROUTE/INDICATION -- EPIDURAL USE IN LABOR AND DELIVERY AS AN ANALGESIC ADJUNCT TO BUPIVACAINE)
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50-560 03-19-93 (SUPPL)	CEFIZOX (INJECTABLE)	FUJISAWA BALA CYNWYD, PA 19004	CEFTIZOXIME SODIUM EQ 10GM BASE/VIAL (NEW STRENGTH)
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19-898 03-22-93 (SUPPL)	PRAVACHOL (TABLET)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	PRAVASTATIN SODIUM 40MG (NEW STRENGTH)
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19-979 03-24-93 (SUPPL)	TICLID (TABLET)	SYNTEX PALO ALTO, CA 94303	TICLOPIDINE HYDROCHLORIDE 125MG* (NEW STRENGTH)
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20-186 03-26-93 (4 S)	ZIAC (TABLET)	LEDERLE PEARL RIVER, NY 10965	BISOPROLOL FUMARATE 2.5MG HYDROCHLOROTHIAZIDE 6.25MG (ANTIHYPERTENSIVE)
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20-186 03-26-93 (4 S)	ZIAC (TABLET)	LEDERLE PEARL RIVER, NY 10965	BISOPROLOL FUMARATE 5MG HYDROCHLOROTHIAZIDE 6.25MG
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

(ANTIHYPERTENSIVE)

20-186	ZIAC	LEDERLE	BISOPROLOL FUMARATE
03-26-93	(TABLET)	PEARL RIVER, NY	10MG
(4 S)		10965	HYDROCHLOROTHIAZIDE
			6.25MG
			(ANTIHYPERTENSIVE)
20-164	LOVENOX	RHONE POULENC RORER	ENOXAPARIN SODIUM
03-29-93	(INJECTABLE)	COLLEGEVILLE, PA	30MG/0.3ML
(1 P)		19426	(ANTICOAGULANT)
			[PREVENTION OF DEEP VEIN
			THROMBOSIS, WHICH MAY LEAD TO
			PULMONARY EMBOLISM, FOLLOWING
			HIP REPLACEMENT SURGERY]

* - Not Marketed at This Time

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

20-142	CATAFLAM	GEIGY	DICLOFENAC POTASSIUM
03-30-93	(TABLET)	SUMMIT, NJ	25MG
	07901	50MG	
		(NONSTEROIDAL	
		ANTI-INFLAMMATORY)	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

73-535 03-12-93	PIROXICAM (CAPSULE)	MUTUAL PHARM PHILADELPHIA, PA 19124	PIROXICAM 10MG (NONSTEROIDAL ANTI-INFLAMMATORY)
73-536 03-12-93	PIROXICAM (CAPSULE)	MUTUAL PHARM PHILADELPHIA, PA 19124	PIROXICAM 20MG (NONSTEROIDAL ANTI-INFLAMMATORY)
73-136 03-24-93	TRAZODONE HCL (TABLET)	MUTUAL PHARM PHILADELPHIA, PA 19124	TRAZODONE HYDROCHLORIDE 50MG (ANTIDEPRESSANT)
73-137 03-24-93	TRAZODONE HCL (TABLET)	MUTUAL PHARM PHILADELPHIA, PA 19124	TRAZODONE HYDROCHLORIDE 100MG (ANTIDEPRESSANT)
63-305 03-29-93	NYSTATIN AND TRIAMCINOLONE ACETONIDE (OINTMENT)	TARO DOWNSVIEW, ONTARIO 0.1% (ANTIFUNGAL/CORTICOSTEROID)	NYSTATIN 100,000 UNITS/GM TRIAMCINOLONE ACETONIDE
73-608 03-29-93	PINDOLOL (TABLET)	GENEVA BROOMFIELD, CO 80038	PINDOLOL 5MG (BETA ADRENERGIC BLOCKER)
73-609 03-29-93	PINDOLOL (TABLET)	GENEVA BROOMFIELD, CO 80038	PINDOLOL 10MG (BETA ADRENERGIC BLOCKER)
73-475	ATENOLOL	MUTUAL PHARM	ATENOLOL

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

03-30-93	(TABLET)	PHILADELPHIA, PA 19124	50MG (BETA ADRENERGIC BLOCKER)
73-476 03-30-93	ATENOLOL (TABLET)	MUTUAL PHARM PHILADELPHIA, PA 19124	ATENOLOL 100MG (BETA ADRENERGIC BLOCKER)
74-051 03-31-93	DILTIAZEM HCL (TABLET)	APOTHECON PRINCETON, NJ 08543	DILTIAZEM HYDROCHLORIDE 30MG 60MG 90MG 120MG (CALCIUM ION INFLUX INHIBITOR)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
TENTATIVE	(DOSAGE FORM)		STRENGTH(S)
APPROVAL DATE			CLASSIFICATION(S)

ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

73-138 03-23-93	TRAZODONE HCL (TABLET)	MUTUAL PHARM PHILADELPHIA, PA 19124	TRAZODONE HYDROCHLORIDE 150MG (ANTIDEPRESSANT)
73-653 03-30-93	METOPROLOL TARTRATE (TABLET)	MUTUAL PHARM PHILADELPHIA, PA 19124	METOPROLOL TARTRATE 50MG (BETA ADRENERGIC BLOCKER)
73-654 03-30-93	METOPROLOL TARTRATE (TABLET)	MUTUAL PHARM PHILADELPHIA, PA 19124	METOPROLOL TARTRATE 100MG (BETA ADRENERGIC BLOCKER)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-936	PROZAC	LILLY	FLUOXETINE HYDROCHLORIDE
12-23-92	(CAPSULE)	INDIANAPOLIS, IN	EQ 10MG BASE
	46285	EQ 20MG BASE	
		(REVISED LABELING --	
		DESCRIPTION; HOW SUPPLIED)	

17-557	DANOCRINE	STERLING	DANAZOL
03-01-93	(CAPSULE)	NEW YORK, NY	50MG
	10016	100MG	
		200MG	
		(REVISED LABELING --	
		CLINICAL PHARMACOLOGY)	

11-145	DIURIL	MSD	CHLOROTHIAZIDE
03-02-93	(TABLET)	WEST POINT, PA	250MG
	19486	500MG	
		(REVISED LABELING --	
		PRECAUTIONS;	
		DOSAGE AND ADMINISTRATION;	
		HOW SUPPLIED)	

11-145	DIURIL	MSD	CHLOROTHIAZIDE SODIUM
03-02-93	(INJECTABLE)	WEST POINT, PA	EQ 500MG BASE/MIAL
	19486	(REVISED LABELING --	
		PRECAUTIONS;	
		DOSAGE AND ADMINISTRATION;	
		HOW SUPPLIED)	

11-870	DIURIL	MSD	CHLOROTHIAZIDE
03-02-93	(SUSPENSION)	WEST POINT, PA	250MG/5ML
	19486	(REVISED LABELING --	
		PRECAUTIONS;	
		DOSAGE AND ADMINISTRATION;	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

HOW SUPPLIED)

12-193*	SER-AP-ES	CIBA	HYDRALAZINE HYDROCHLORIDE
03-03-93	(TABLET)	SUMMIT, NJ	25MG
		07901	HYDROCHLOROTHIAZIDE
			15MG
			RESERPINE
			0.1MG
			(REVISED LABELING --
			PRECAUTIONS; HOW SUPPLIED)

11-793	ESIDRIX	CIBA	HYDROCHLOROTHIAZIDE
03-10-93	(TABLET)	SUMMIT, NJ	25MG
		07901	50MG
			100MG
			(REVISED LABELING --
			PRECAUTIONS)

19-558	PRINIVIL	MERCK	LISINOPRIL
03-10-93	(TABLET)	WEST POINT, PA	5MG
		19486	10MG
			20MG
			40MG
			(REVISED LABELING --
			ADVERSE REACTIONS)

19-778	PRINZIDE 12.5	MERCK	HYDROCHLOROTHIAZIDE
03-10-93	(TABLET)	WEST POINT, PA	12.5MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19486 LISINOPRIL
 20MG
 (REVISED LABELING --
 WARNINGS; ADVERSE REACTIONS)

19-778 PRINZIDE 25 MERCK HYDROCHLOROTHIAZIDE
 03-10-93 (TABLET) WEST POINT, PA 25MG

19486 LISINOPRIL
 20MG
 (REVISED LABELING --
 WARNINGS; ADVERSE REACTIONS)

* - Permitted

17-576 OVCON-50 BRISTOL MYERS SQUIBB ETHINYL ESTRADIOL
 03-12-93 28-DAY EVANSVILLE, IN 0.05MG
 (TABLET) 47721 NORETHINDRONE

1MG
 (REVISED LABELING --
 PRECAUTIONS;
 DOSAGE AND ADMINISTRATION;
 PATIENT PACKAGE INSERT)

17-716 OVCON-35 BRISTOL MYERS ETHINYL ESTRADIOL
 03-12-93 28-DAY EVANSVILLE, IN 0.035MG
 (TABLET) 47721 NORETHINDRONE

0.4MG
 (REVISED LABELING --
 PRECAUTIONS;
 DOSAGE AND ADMINISTRATION;
 PATIENT PACKAGE INSERT)

18-127 OVCON-35 BRISTOL MEYERS SQUIBB ETHINYL ESTRADIOL

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

03-12-93	21-DAY (TABLET)	EVANSVILLE, IN 47721	0.035MG NORETHINDRONE 0.4MG (REVISED LABELING -- PRECAUTIONS; DOSAGE AND ADMINISTRATION; PATIENT PACKAGE INSERT)
18-128 03-12-93	OVCON-50 21-DAY (TABLET)	BRISTOL MYERS SQUIBB EVANSVILLE, IN 47721	ETHINYL ESTRADIOL 0.05MG NORETHINDRONE 1MG (REVISED LABELING -- PRECAUTIONS; DOSAGE AND ADMINISTRATION; PATIENT PACKAGE INSERT)
50-182 03-12-93	ERYTHROCIN (INJECTABLE) 60064	ABBOTT ABBOTT PARK, IL	ERYTHROMYCIN LACTOBIONATE EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
50-609 03-12-93	ERYTHROCIN (INJECTABLE) 60064	ABBOTT ABBOTT PARK, IL	ERYTHROMYCIN LACTOBIONATE EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL (REVISED LABELING -- PRECAUTIONS;

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

ADVERSE REACTIONS)

19-715	DIPENTUM	KABI	OLSALAZINE SODIUM
03-15-93	(CAPSULE)	PISCATAWAY, NJ	250MG
	08855		(REVISED LABELING -- ADVERSE REACTIONS)

09-599*	SUSTAC	KEY PHARMS	NITROGLYCERIN
03-18-93	(TABLET, EXTENDED RELEASE)	MIAMI, FL	2.6MG**
		33137	6.5MG**
		10MG**	
			(REVISED LABELING -- DESCRIPTION; PRECAUTIONS; ADVERSE REACTIONS)

11-642*	CARDIOQUIN	PURDUE FREDERICK	QUINIDINE POLYGALACTURONATE
03-18-93	(TABLET)	NORWALK, CT	275MG
	06856		(REVISED LABELING -- DESCRIPTION; WARNINGS; DOSAGE AND ADMINISTRATION)

50-617	ERYGEL	ALLERGAN HERBERT	ERYTHROMYCIN
03-18-93	(GEL)	IRVINE, CA	2%
	92713		(REVISED LABELING -- PATIENT INSTRUCTIONS)

* - Permitted

** - Not Marketed in U.S.A.

19-050	SUFENTA	JANSSEN	SUFENTANIL CITRATE
03-19-93	(INJECTABLE)	PISCATAWAY, NJ	EQ 0.05MG BASE/ML
	08854		(REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY;

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

CLINICAL STUDIES;
INDICATIONS AND USAGE;
WARNINGS; PRECAUTIONS;
ADVERSE REACTIONS;
OVERDOSAGE;
DOSAGE AND ADMINISTRATION)

19-898	PRAVACHOL	BRISTOL MYERS SQUIBB	PRAVASTATIN SODIUM
03-22-93	(TABLET)	PRINCETON, NJ	10MG
	08543	20MG	

40MG
(REVISED LABELING --
DESCRIPTION;
INDICATIONS AND USAGE;
WARNINGS; PRECAUTIONS;
ADVERSE REACTIONS;
DOSAGE AND ADMINISTRATION;
HOW SUPPLIED)

19-842	CHILDREN'S MOTRIN	MCNEIL	IBUPROFEN
03-23-93	(SUSPENSION)	FORT WASHINGTON, PA	100MG/5ML
	19034	(REVISED LABELING -- ADDITIONAL TRADE NAME)	

13-401	ALDOMET	MSD	METHYLDOPATE HYDROCHLORIDE
03-24-93	(INJECTABLE)	WEST POINT, PA	50MG/ML
	19486	(REVISED LABELING -- PRECAUTIONS)	

13-402	ALDORIL 15	MSD	HYDROCHLOROTHIAZIDE
03-24-93	(TABLET)	WEST POINT, PA	15MG
	19486	METHYLDOPA	
		250MG	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

(REVISED LABELING --
PRECAUTIONS)

13-402	ALDORIL 25	MSD	HYDROCHLOROTHIAZIDE
03-24-93	(TABLET)	WEST POINT, PA	25MG
	19486	METHYLDOPA	250MG
		(REVISED LABELING --	PRECAUTIONS)

13-402	ALDORIL D30	MSD	HYDROCHLOROTHIAZIDE
03-24-93	(TABLET)	WEST POINT, PA	30MG
	19486	METHYLDOPA	500MG
		(REVISED LABELING --	PRECAUTIONS)

13-402	ALDORIL D50	MSD	HYDROCHLOROTHIAZIDE
03-24-93	(TABLET)	WEST POINT, PA	50MG
	19486	METHYLDOPA	500MG
		(REVISED LABELING --	PRECAUTIONS)

18-107	MDP-SQUIBB	SQUIBB	TECHNETIUM TC-99M
03-24-93	(INJECTABLE)	PRINCETON, NJ	MEDRONATE KIT
	08543	N/A	
		(REVISED LABELING --	LABELING FORMAT
		REVISION PROGRAM)	

18-963	CHOLETEC	SQUIBB	TECHNETIUM TC-99M
03-24-93	(INJECTABLE)	PRINCETON, NJ	MEBROFENIN KIT

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

08543		N/A (REVISED LABELING -- ADVERSE REACTIONS)	
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19-011	GOLYTELY	BRAINTREE	POLYETHYLENE GLYCOL 3350
03-24-93	(POWDER FOR RECONSTITUTION)	BRAINTREE, MA 02184	236GM/BOT POTASSIUM CHLORIDE
		2.97GM/BOT	
		SODIUM BICARBONATE	
		6.74GM/BOT	
		SODIUM CHLORIDE	
		5.86GM/BOT	
		SODIUM SULFATE, ANHYDROUS	
		22.74GM/BOT	
		(REVISED LABELING -- HOW SUPPLIED)	

19-011	GOLYTELY	BRAINTREE	POLYETHYLENE GLYCOL 3350
03-24-93	(POWDER FOR RECONSTITUTION)	BRAINTREE, MA 02184	227.1GM/PACKET POTASSIUM CHLORIDE
		2.82GM/PACKET	
		SODIUM BICARBONATE	
		6.36GM/PACKET	
		SODIUM CHLORIDE	
		5.53GM/PACKET	
		SODIUM SULFATE, ANHYDROUS	
		21.5GM/PACKET	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

(REVISED LABELING --
HOW SUPPLIED)

18-057 03-25-93	PLATINOL (INJECTABLE) 47721	BRISTOL MYERS EVANSVILLE, IN 50MG/VIAL	CISPLATIN 10MG/VIAL
(REVISED LABELING -- WARNINGS; ADVERSE REACTIONS; OVERDOSAGE)			
18-057 03-25-93	PLATINOL-AQ (INJECTABLE) 47721	BRISTOL MYERS EVANSVILLE, IN	CISPLATIN 1MG/ML
(REVISED LABELING -- WARNINGS; ADVERSE REACTIONS; OVERDOSAGE)			
18-936 03-25-93	PROZAC (CAPSULE) 46285	LILLY INDIANAPOLIS, IN EQ 20MG BASE	FLUOXETINE HYDROCHLORIDE EQ 10MG BASE
(REVISED LABELING -- CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; PRECAUTIONS; OVERDOSAGE)			
20-101 03-25-93	PROZAC (SOLUTION) 46285	LILLY INDIANAPOLIS, IN	FLUOXETINE HYDROCHLORIDE EQ 20MG BASE/5ML
(REVISED LABELING -- CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; PRECAUTIONS; OVERDOSAGE)			
17-808	MIACALCIN	SANDOZ	CALCITONIN, SALMON

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

03-26-93	(INJECTABLE) 07936	EAST HANOVER, NJ 200 IU/ML (REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)	100 IU/ML
19-529 03-26-93	HUMULIN BR (INJECTABLE) 46285	LILLY INDIANAPOLIS, IN (REVISED LABELING -- PATIENT INFORMATION; PRODUCT TO BE DISCONTINUED SEPTEMBER 1, 1993) (OTC)	INSULIN BIOSYNTHETIC HUMAN 100 UNITS/ML
19-938 03-26-93	NOVOLIN R (INJECTABLE) 08540	NOVO NORDISK PRINCETON, NJ (REVISED LABELING -- PATIENT PACKAGE INSERT) (OTC)	INSULIN BIOSYNTHETIC HUMAN 100 UNITS/ML
19-959 03-26-93	NOVOLIN N (INJECTABLE) 08540	NOVO NORDISK PRINCETON, NJ 100 UNITS/ML (REVISED LABELING -- PATIENT PACKAGE INSERT) (OTC)	INSULIN SUSP ISOPHANE BIOSYNTHETIC HUMAN
19-991 03-26-93	NOVOLIN 70/30 (INJECTABLE)	NOVO NORDISK PRINCETON, NJ	INSULIN BIOSYNTHETIC HUMAN 30 UNITS/ML

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

08540 INSULIN SUSP ISOPHANE
 BIOSYNTHETIC HUMAN
 70 UNITS/ML
 (REVISED LABELING --
 PATIENT PACKAGE INSERT)
 (OTC)

20-088 NORPLANT SYSTEM WYETH AYERST LEVONORGESTREL
 03-26-93 (IMPLANT) PHILADELPHIA, PA 36MG/IMPLANT
 19101 (REVISED LABELING --
 INDICATIONS AND USAGE;
 WARNINGS; PRECAUTIONS;
 INSERTION PROCEDURE;
 PATIENT PACKAGE INSERT)

10-060 FLORINEF SQUIBB FLUDROCORTISONE ACETATE
 03-31-93 (TABLET) NEW BRUNSWICK, NJ 0.1MG
 08903 (REVISED LABELING --
 WARNINGS; PRECAUTIONS)

12-283* HYGROTON RHONE POULENC RORER CHLORTHALIDONE
 03-31-93 (TABLET) FORT WASHINGTON, PA 25MG
 19034 50MG
 (REVISED LABELING --
 PRECAUTIONS)

18-538 LOZOL RHONE POULENC RORER INDAPAMIDE
 03-31-93 (TABLET) FORT WASHINGTON, PA 2.5MG
 19034 (REVISED LABELING --
 PRECAUTIONS)

* - Permitted

19-777 ZESTRIL IMPERIAL CHEM LISINOPRIL
 03-31-93 (TABLET) CHESHIRE, ENGLAND 5MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

10MG
 20MG
 40MG
 (REVISED LABELING --
 PRECAUTIONS;
 ADVERSE REACTIONS)

19-888 03-31-93	ZESTORETIC 20/12.5 (TABLET)	IMPERIAL CHEM CHESHIRE, ENGLAND	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL 20MG (REVISED LABELING -- PRECAUTIONS; WARNINGS; ADVERSE REACTIONS)
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19-888 03-31-93	ZESTORETIC 20/25 (TABLET)	IMPERIAL CHEM CHESHIRE, ENGLAND	HYDROCHLOROTHIAZIDE 25MG LISINOPRIL 20MG (REVISED LABELING -- PRECAUTIONS; WARNINGS; ADVERSE REACTIONS)
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LICENSE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
LICENSE DATE	(DOSAGE FORM)		(DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

0017	TETRAMUNE	LEDERLE LABS	DIPHThERIA AND TETANUS TOXOIDS
03-30-93	(INJECTABLE)	DIV AM CYANAMID	AND PERTUSSIS VACCINE ADSORBED
	PEARL RIVER, NY	AND HAEMOPHILUS B CONJUGATE	
	10965	VACCINE (DIPHThERIA CRM197	
		PROTEIN CONJUGATE)	
		*(B)	
0384	ACTHIB	PASTEUR MERIEUX	HAEMOPHILUS B CONJUGATE
03-30-93	(INJECTABLE)	SERUMS ET VACCINS SA	VACCINE (TETANUS TOXOID
	LYON, FRANCE	CONJUGATE)	
		*(B)	

LICENSE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
LICENSE DATE	(DOSAGE FORM)		(DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

* - New Product Manufactured Under License
(B) Product License Issued

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE		(DESCRIPTION)	

BIOLOGICAL PRODUCT DEVICE APPROVALS

BP910003 03-11-93	CRYOGENIC LAKEWOOD, NJ 08701	CHARTERMED (C)	CRYOGENIC STORAGE CONTAINER USING HEMOFLEX FILM
BP920009 03-25-93	NONE CANOGA PARK, CA 91303	ONE LAMBDA ANTIBODY (C)	ANTI-B27 FITC CONJUGATED MONOCLONAL
BP920019 03-26-93	INVERNESS AUTOMATED ANTIBODY SCREENING	IBG SYS LAYTONSVILLE, MD 20882 (C)	AUTOMATED BLOOD GROUPING AND ANTIBODY TEST SYSTEM

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE		(DESCRIPTION)	

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

P920040 03/24/93	CIBA VISION DISINFECTING SOLUTION	CIBA VISION CORPORATION DULUTH, GA 30136-1518	APPROVAL FOR CIBA VISION DISINFECTING SOLUTION
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APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

P800018/S19	SOFT MATE	SOLA BARNES HIND	ALTERNATE
03/25/93	COMFORT DROPS FOR SENSITIVE EYES AND BARNES-HIND GAS PERMEABLE COMFORT DROPS	SUNNYVALE, CA 94086-5200	MANUFACTURING SITE

P810046/S134	SIMPSON-ROBERT	ADVANCED	MODIFIED ACS STACK
03/18/93	CORONARY BALLOON DILATATION CATHETER, ACS STACK 40-S CORONARY DILATATION CATHETER WITH QUARTER SIZE BALLOONS	SANTA CLARA, CA 95052-8167	40-S CORONARY DILATATION CATHETER WITH QUARTER SIZE BALLOONS

P810046/S136	SIMPSON-ROBERT	ADVANCED	APPROVAL FOR THE
03/19/93	CORONARY BALLOON DILATATION CATHETER, ACS PRISM AND PINKERTON .018 CORONARY DILATATION CATHETERS	SANTA CLARA, CA 95052-8167	CONTENT OF CARBON BLACK IN THE ACS PRISM AND PINKERTON .018 CORONARY DILATATION CATHETERS

P830026/S57	COSMOS PACING	INTERMEDICS, INC.	INTRODUCTION OF THE
03/03/93	SYSTEM 77515	ANGLETON, TX	RX222 MODEL 522-10 POCKET PROGRAMMER

P840001/S28	ITREL TOTALLY	MEDTRONIC, INC.	MODIFICATION OF THE
03/31/93	IMPLANTED SPINAL	MINNEAPOLIS, MN	REED SWITCH

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

CORD STIMULATION SYSTEM, ITREL AND ITREL II IMPLANTABLE PULSE GENERATOR, MODEL 7424	55432-3576	SPECIFICATION FOR THE ITREL IMPLANTABLE PULSE GENERATOR, MODEL 7424
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P840008/S40 03/08/93	DORNIER LITHOTRIPTER, MODEL HM3, DORNIER MFL5000 LITHOTRIPTER	DORNIER MEDICAL SYSTEMS, INC. KENNESAW, GA 30144	APPROVAL FOR THE DORNIER MFL5000 LITHOTRIPTER
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P840024/S47 03/19/93	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT 80112	COCHLEAR CORPORATION ENGLEWOOD, CO	CHANGE IN THE SPECIFICATIONS FOR THE HEADSET CABLE OF THE NUCLEUS 22 CHANNEL COCHLEAR IMPLANT
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P840039/S34 03/31/93	MODELS P323UV, P328UV, P329UV, P351UV, P356UV, AND P359UV ULTRAVIOLET- ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	APPROVAL FOR THE REFERENCED INTRAOCULAR LENSES
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P850074/S08 03/03/93	GORE-TEX CRUCIATE LIGAMENT PROSTHESIS	W.L. GORE & ASSOCIATES, INC. FLAGSTAFF, AZ 86003-2200	NEW MANUFACTURING FACILITY
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P850079/S17	HYDRASOFT	COASTVISION, INC.	EXPANSION OF THE
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APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

03/11/93	(METHAFILCON A) HYDROPHILIC CONTACT LENS, HYDRASOFT XW AND HYDRASOFT TORIC XW (METHAFILCON B) HYDROPHILIC CONTACT LENSES FOR EXTENDED WEAR	HUNTINGTON BEACH, CA 92648 INCLUDE THE CORRECTION OF VISUAL ACUITY IN APHAKIC PERSONS	INDICATIONS TO
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P850079/S21 03/11/93	HYDRASOFT, HYDRASOFT XW, HYDRASOFT TORIC XW, HYDRASOFT XW EZC AND HYDRASOFT TORIC XW EZC (METHAFILCON A OR METHAFILCON B) HYDROPHILIC CONTACT LENSES	COASTVISION, INC. HUNTINGTON BEACH, CA 92648	ADDITIONAL PARAMETERS IN LENS INDICATIONS ALREADY APPROVED FOR EXTENDED WEAR
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P850088/S28 03/09/93	LENS PLUS OXYSEPT DISINFECTION SYSTEM, OXYSEPT 1 DISINFECTION SOLUTION AND ULTRACARE DISINFECTING	ALLERGAN OPTICAL IRVINE, CA 92713-9534	ALTERNATE SUPPLIER OF THE HYDROGEN PEROXIDE RAW MATERIAL USED TO MANUFACTURE OXYSEPT 1 DISINFECTION SOLUTION AND ULTRACARE DISINFECTING SOLUTION
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APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

SOLUTION

P860035/S05 03/10/93	IVAC TITRATOR KIT- MODEL T1000 92186-5335	IVAC CORP. SAN DIEGO, CA	CHANGE IN THE MANUFACTURING, PROCESSING, AND PACKAGING SITE OF THE TITRATOR KIT - MODEL T1000
P870049/S14 03/12/93	MICROSCAN RAPID PANELS 95691	BAXTER DIAGNOSTICS, INC. WEST SACRAMENTO, CA	EXTEND THE READ TIME FROM 3 1/2 - 7 HOURS TO 3 1/2 - 15 HOURS
P880001/S37 03/31/93	FLOUREX 700 (FLUSILFOCON A), FLOUREX 500 (FLUSILFOCON B) AND FLOUREX 300 (FLUSILFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	G.T. LABORATORIES, INC. CHICAGO, IL 60602	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTING SITES
P880027/S24 03/23/93	SCHNEIDER MICROSOFTRAC PTCA CATHETER, SCHNEIDER MYSTIC PTCA CATHETERS MODELS: MYS-015, MYS-020, MYS-225, MYS-025, MYS-275, MYS-030, MYS-325, MYS-035, MYS-040	SCHNEIDER (USA) INC. PLYMOUTH, MN 55442	APPROVAL FOR AN ALTERNATIVE DESIGN TO THE CURRENTLY MARKETED XLP PTCA CATHETER

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P880098/S06 03/23/93	MENICON SF-P (MELAFICON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	MENICON CO., LTD. NAKA-KU, JAPAN	RELOCATION OF THE FINISHING LABORATORY
P890027/S17 03/19/93	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	CHANGE IN THE SPECIFICATIONS FOR THE HEADSET CABLE OF THE NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS
P890072/S07 03/23/93	ALBERTA LENS 'S' (SULFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED) WITH AN ULTRAVIOLET LIGHT ABSORBER	PROGRESSIVE OPTICAL RESEARCH, LTD. ALBERTA, CANADA	FIVE ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P900032/S16 03/18/93	AIS EXCIMER LASER ANGIOPLASTY SYSTEM IRVINE, CA 92718	ADVANCED INTERVENTIONAL SYSTEMS	REVISED LABELING

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

065-505	MICROCILLIN-AG	CATTLE	ANTHONY PRODS	PENICILLIN G PROCAINE
01-29-93	(LIQUID, SUSPENSION)	HORSES	ARCADIA, CA	300,000 UNITS/ML
	SHEEP	91006		
	SWINE			

140-916	DENAGARD	SWINE	FERMENTA AN HLTH	TIAMULIN HYDROGEN
01-29-93	CONCENTRATE		KANSAS CITY, MO	FUMARATE
	(LIQUID)	64153	12.3% W/V	

ORIGINAL ABBREVIATED VETERINARY NADAs

200-037	GENTAMICIN	HORSES	AGRI LABS	GENTAMICIN SULFATE
02-08-93	SULFATE		ST JOSEPH, MO	100 MG/ML
	(LIQUID)	64503		

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR MARCH 1993.

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

Center for Drug Evaluation and Research
 *George R. Scott (301) 443-3910

Center for Devices and Radiological Health
 Mary Jo Robinson (301) 427-1186

Center for Biologics Evaluation and Research
 Joseph Wilczek (301) 295-9012

Center for Veterinary Medicine
 Melanie R. Berson, D.V.M.
 (301) 295-8623

*To whom general inquiries should be directed.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
 FOR NEW DRUG PRODUCTS

17-970 04-01-93 (SUPPL)	NOLVADEX (TABLET)	STUART WILMINGTON, DE 19897	TAMOXIFEN CITRATE EQ 10MG BASE (EXPANDED USE -- TREATMENT OF METASTATIC BREAST CANCER IN MALES)
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19-658 04-12-93 (1 S)	CLARITIN (TABLET)	SCHERING KENILWORTH, NJ 07033	LORATADINE 10MG (ANTIHISTAMINE)
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20-263 04-16-93 (5 S, V)	LUPRON (INJECTABLE)	TAP DEERFIELD, IL 60015	LEUPROLIDE ACETATE 5MG/ML (GONADOTROPIN RELEASING HORMONE ANALOG) [TREATMENT OF CHILDREN WITH CENTRAL PRECOCIOUS PUBERTY]
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-263 04-16-93 (5 S, V)	LUPRON DEPOT-PED (INJECTABLE) 60015	TAP DEERFIELD, IL 3.75MG/VIAL & 7.5MG/VIAL	LEUPROLIDE ACETATE 7.5MG/VIAL 7.5MG/VIAL & 7.5MG/VIAL (GONADOTROPIN RELEASING HORMONE ANALOG) [TREATMENT OF CHILDREN WITH CENTRAL PRECOCIOUS PUBERTY]
16-020 04-19-93 (SUPPL)	SYMMETREL (CAPSULE) 19880	DUPONT WILMINGTON, DE (NEW DOSAGE REGIMEN --	AMANTADINE HYDROCHLORIDE 100MG DOSING OF 100MG DAILY FOR PROPHYLAXIS OF INFLUENZA A VIRUS INFECTION IN ADULTS WHO ARE UNABLE TO TOLERATE 200MG DAILY)
16-023 04-19-93 (SUPPL)	SYMMETREL (SYRUP) 19880	DUPONT WILMINGTON, DE (NEW DOSAGE REGIMEN --	AMANTADINE HYDROCHLORIDE 50MG/5ML DOSING OF 100MG DAILY FOR PROPHYLAXIS OF INFLUENZA A VIRUS INFECTION IN ADULTS WHO ARE UNABLE TO TOLERATE 200MG DAILY)
18-101 04-19-93 (SUPPL)	SYMMETREL (TABLET) 19880	DUPONT WILMINGTON, DE (NEW DOSAGE REGIMEN --	AMANTADINE HYDROCHLORIDE 100MG* DOSING OF 100MG DAILY FOR PROPHYLAXIS OF INFLUENZA A VIRUS INFECTION IN ADULTS WHO ARE UNABLE TO TOLERATE 200MG DAILY)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-198	ADALAT CC	MILES	NIFEDIPINE
04-21-93	(TABLET,	WEST HAVEN, CT	30MG
(5 S)	EXTENDED RELEASE)	06516	60MG
		90MG	
		(CALCIUM ION	
		INFLUX INHIBITOR)	
17-450	MONISTAT 7	ADVANCED CARE	MICONAZOLE NITRATE
04-26-93	(CREAM)	RARITAN, NJ	2%
(SUPPL)		08869	(NEW INDICATION --
			RELIEF OF EXTERNAL VULVAR
			ITCHING AND IRRITATION
			ASSOCIATED WITH A YEAST
			INFECTION)
			(OTC)

* - Not Marketed at Present Time

18-052	GYNE-LOTRIMIN	SCHERING	CLOTRIMAZOLE
04-26-93	(CREAM)	KENILWORTH, NJ	1%
(SUPPL)		07033	(NEW INDICATION --
			RELIEF OF EXTERNAL VULVAR
			ITCHING AND IRRITATION
			ASSOCIATED WITH A YEAST
			INFECTION)
			(OTC)
20-288	MONISTAT 7	ADVANCED CARE	MICONAZOLE NITRATE
04-26-93	COMBINATION PACK	RARITAN, NJ	100MG-SUPPOSITORY

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT CLASSIFICATION(S)	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

(3 S)	(SUPPOSITORY AND CREAM)	08869 (ANTIFUNGAL) (OTC)	2%-CREAM
20-289 04-26-93 (3 S)	GYNE-LOTRIMIN COMBINATION PACK (SUPPOSITORY AND CREAM)	SCHERING PLOUGH LIBERTY CORNER, NJ 07938 (ANTIFUNGAL) (OTC)	CLOTRIMAZOLE 100MG-SUPPOSITORY 1%-CREAM
19-757 04-27-93 (SUPPL)	CHIBROXIN (SOLUTION/DROPS)	MERCK WEST POINT, PA 19486 (EXPANDED USE -- ADDITIONAL ORGANISM, PSEUDOMONAS AERUGINOSA)	NORFLOXACIN 0.3%
18-538 04-29-93 (SUPPL)	LOZOL (TABLET)	RHONE POULENC RORER FORT WASHINGTON, PA 19034 (NEW STRENGTH)	INDAPAMIDE 1.25MG
18-538 04-29-93 (SUPPL)	LOZOL (TABLET)	RHONE POULENC RORER FORT WASHINGTON, PA 19034 2.5MG (NEW DOSAGE REGIMEN -- LOWER INITIAL AND MAINTENANCE DOSING)	INDAPAMIDE 1.25MG
19-777 04-29-93 (SUPPL)	ZESTRIL (TABLET)	ZENECA WILMINGTON, DE 19897 (NEW STRENGTH)	LISINOPRIL 2.5MG
50-671 04-29-93 (3 S)	VANCOCIN HCL IN PLASTIC CONTAINER (INJECTABLE)	LILLY INDIANAPOLIS, IN 46285 (ANTIBIOTIC, GLYCOPEPTIDE)	VANCOMYCIN HYDROCHLORIDE EQ 500MG BASE/100ML

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE (DOSAGE FORM)		CLASSIFICATION(S)	STRENGTH(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

19-843 03-16-93	ISOLYTE S W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE 5GM/100ML MAGNESIUM CHLORIDE 30MG/100ML POTASSIUM CHLORIDE 37MG/100ML SODIUM ACETATE 370MG/100ML SODIUM CHLORIDE 530MG/100ML SODIUM GLUCONATE 500MG/100ML REPLENISHER)
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(ELECTROLYTE/NUTRIENT

19-844 03-16-93	ISOLYTE H W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE 5GM/100ML MAGNESIUM CHLORIDE 30MG/100ML POTASSIUM CHLORIDE 97MG/100ML SODIUM ACETATE
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE (DOSAGE FORM)		CLASSIFICATION(S)	STRENGTH(S)

APPROVABLE ORIGINAL NDAs

220MG/100ML
 SODIUM CHLORIDE
 140MG/100ML
 (ELECTROLYTE/NUTRIENT
 REPLENISHER)

19-864	ISOLYTE R	MCGAW	CALCIUM CHLORIDE
03-16-93	W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	IRVINE, CA 92713	37MG/100ML DEXTROSE 5GM/100ML MAGNESIUM CHLORIDE 31MG/100ML POTASSIUM CHLORIDE 120MG/100ML SODIUM ACETATE 330MG/100ML SODIUM CHLORIDE 88MG/100ML (ELECTROLYTE/NUTRIENT REPLENISHER)

19-870	ISOLYTE M	MCGAW	DEXTROSE
03-16-93	W/ DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	IRVINE, CA 92713	5GM/100ML POTASSIUM CHLORIDE 150MG/100ML POTASSIUM PHOSPHATE, DIBASIC 130MG/100ML SODIUM ACETATE 280MG/100ML SODIUM CHLORIDE 91MG/100ML

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE (DOSAGE FORM)		CLASSIFICATION(S)	STRENGTH(S)

APPROVABLE ORIGINAL NDAs

(ELECTROLYTE/NUTRIENT
REPLENISHER)

19-873	ISOLYTE P	MCGAW	DEXTROSE
03-16-93	W/ DEXTROSE 5%	IRVINE, CA	5GM/100ML
	IN PLASTIC CONTAINER	92713	MAGNESIUM CHLORIDE
	(INJECTABLE)		31MG/100ML
			POTASSIUM CHLORIDE
			130MG/100ML
			POTASSIUM PHOSPHATE, DIBASIC
			26MG/100ML
			SODIUM ACETATE
			320MG/100ML
			(ELECTROLYTE/NUTRIENT REPLENISHER)
20-210	PROPULSID	JANSSEN	CISAPRIDE MONOHYDRATE
04-09-93	(TABLET)	PISCATAWAY, NJ	EQ 10MG/BASE
	08855		EQ 20MG/BASE
			(UPPER GI TRACT MOTILITY STIMULATOR)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE (DOSAGE FORM)		CLASSIFICATION(S)	STRENGTH(S)

APPROVABLE ORIGINAL NDAs

20-095 04-30-93	ZANTAC 150 (CAPSULE)	GLAXO RES TRIANGLE PK, NC 27709	RANITIDINE HYDROCHLORIDE EQ 150MG BASE (HISTAMINE H-2 RECEPTOR ANTAGONIST)
20-095 04-30-93	ZANTAC 300 (CAPSULE)	GLAXO RES TRIANGLE PK, NC 27709	RANITIDINE HYDROCHLORIDE EQ 300MG BASE (HISTAMINE H-2 RECEPTOR ANTAGONIST)
50-693 04-30-93	ZITHROMAX (SUSPENSION)	PFIZER GROTON, CT 06340	AZITHROMYCIN DIHYDRATE EQ 1GM BASE/PACKET (ANTIBIOTIC, MACROLIDE)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

40-050 04-15-93	METHADOSE (TABLET) 63017	MALLINCKRODT CHESTERFIELD, MO 10MG (NARCOTIC ANALGESIC)	METHADONE HYDROCHLORIDE 5MG
62-772 04-15-93	AMPICILLIN SODIUM (INJECTABLE) 13201	HANFORD SYRACUSE, NY (ANTIBIOTIC, PENICILLIN)	AMPICILLIN SODIUM EQ 1GM BASE/VIAL
63-139 04-15-93	AMPICILLIN SODIUM (INJECTABLE) 13201	HANFORD SYRACUSE, NY (ANTIBIOTIC, PENICILLIN)	AMPICILLIN SODIUM EQ 1GM BASE/VIAL
63-140 04-15-93	AMPICILLIN SODIUM (INJECTABLE) 13201	HANFORD SYRACUSE, NY (ANTIBIOTIC, PENICILLIN)	AMPICILLIN SODIUM EQ 2GM BASE/VIAL
63-141 04-15-93	AMPICILLIN SODIUM (INJECTABLE) 13201	HANFORD SYRACUSE, NY (ANTIBIOTIC, PENICILLIN)	AMPICILLIN SODIUM EQ 2GM BASE/VIAL
63-142 04-15-93	AMPICILLIN SODIUM (INJECTABLE) 13201	HANFORD SYRACUSE, NY (ANTIBIOTIC, PENICILLIN)	AMPICILLIN SODIUM EQ 10GM BASE/VIAL
63-143 04-15-93	AMPICILLIN SODIUM (INJECTABLE) 13201	HANFORD SYRACUSE, NY (ANTIBIOTIC, PENICILLIN)	AMPICILLIN SODIUM EQ 125MG BASE/VIAL
63-145 04-15-93	AMPICILLIN SODIUM (INJECTABLE) 13201	HANFORD SYRACUSE, NY (ANTIBIOTIC, PENICILLIN)	AMPICILLIN SODIUM EQ 250MG BASE/VIAL

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

63-146 04-15-93	AMPICILLIN SODIUM (INJECTABLE) 13201	HANFORD SYRACUSE, NY (ANTIBIOTIC, PENICILLIN)	AMPICILLIN SODIUM EQ 500MG BASE/VIAL
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63-147 04-15-93	AMPICILLIN SODIUM (INJECTABLE) 13201	HANFORD SYRACUSE, NY (ANTIBIOTIC, PENICILLIN)	AMPICILLIN SODIUM EQ 500MG BASE/VIAL
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71-536 04-28-93	METOCLOPRAMIDE HCL (TABLET) 19124	MUTUAL PHARM PHILADELPHIA, PA (UPPER GI TRACT MOTILITY STIMULATOR)	METOCLOPRAMIDE HYDROCHLORIDE EQ 10MG BASE
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74-125 04-28-93	PINDOLOL (TABLET) 07207	PUREPAC ELIZABETH, NJ 10MG (BETA ADRENERGIC BLOCKER)	PINDOLOL 5MG
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40-015 04-29-93	NEOSAR (INJECTABLE) 43216	ADRIA COLUMBUS, OH 200MG/VIAL 500MG/VIAL 1GM/VIAL 2GM/VIAL (ANTINEOPLASTIC)	CYCLOPHOSPHAMIDE 100MG/VIAL
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63-221 04-29-93	CEFTAZIDIME SODIUM IN PLASTIC CONTAINER (INJECTABLE)	BAXTER ROUND LAKE, IL 60073 EQ 20MG BASE/ML EQ 40MG BASE/ML (ANTIBIOTIC, CEPHEM)	CEFTAZIDIME SODIUM EQ 10MG BASE/ML
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63-293	CEFOTAN	ZENECA	CEFOTETAN DISODIUM
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

04-29-93	(INJECTABLE) 19897	WILMINGTON, DE	EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL (ANTIBIOTIC, CEPHAM)
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73-165 04-29-93	ALBUTEROL SULFATE (SYRUP) 91720	WATSON CORONA, CA	ALBUTEROL SULFATE EQ 2MG BASE/5ML (BRONCHODILATOR)
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73-581 04-29-93	ATENOLOL AND CHLORTHALIDONE (TABLET) 19124	MUTUAL PHARM PHILADELPHIA, PA	ATENOLOL 50MG CHLORTHALIDONE 25MG (ANTIHYPERTENSIVE)
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73-582 04-29-93	ATENOLOL AND CHLORTHALIDONE (TABLET) 19124	MUTUAL PHARM PHILADELPHIA, PA	ATENOLOL 100MG CHLORTHALIDONE 25MG (ANTIHYPERTENSIVE)
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74-184 04-29-93	METHADOSE (TABLET, DISPERSIBLE) 63017	MALLINCKRODT CHESTERFIELD, MO	METHADONE HYDROCHLORIDE 40MG (NARCOTIC ANALGESIC)
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81-310 04-29-93	FLUPHENAZINE HYDROCHLORIDE (ELIXIR) 02021	COPLEY CANTON, MA	FLUPHENAZINE HYDROCHLORIDE 2.5MG/5ML (ANTIPSYCHOTIC)
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81-318 04-29-93	LIDOCAINE HCL (JELLY) 02021	COPLEY CANTON, MA	LIDOCAINE HYDROCHLORIDE 2% (LOCAL ANESTHETIC)
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
TENTATIVE	(DOSAGE FORM)		STRENGTH(S)
APPROVAL DATE			CLASSIFICATION(S)

*****ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS*****

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

THERE ARE NO ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS FOR APRIL 1993.

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-710 03-09-93	OPTIRAY 160 (INJECTABLE) 63134	MALLINCKRODT SAINT LOUIS, MO (REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)	IOVERSOL 34%
19-710 03-09-93	OPTIRAY 240 (INJECTABLE) 63134	MALLINCKRODT SAINT LOUIS, MO (REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)	IOVERSOL 51%
19-710 03-09-93	OPTIRAY 300 (INJECTABLE) 63134	MALLINCKRODT SAINT LOUIS, MO (REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)	IOVERSOL 64%
19-710 03-09-93	OPTIRAY 320 (INJECTABLE) 63134	MALLINCKRODT SAINT LOUIS, MO (REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)	IOVERSOL 68%
19-710 03-09-93	OPTIRAY 350 (INJECTABLE) 63134	MALLINCKRODT SAINT LOUIS, MO (REVISED LABELING -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)	IOVERSOL 74%
18-186 03-24-93	SODIUM LACTATE 0.167 MOLAR IN PLASTIC CONTAINER	MCGAW IRVINE, CA 92713	SODIUM LACTATE 1.87GM/100ML (REVISED LABELING --

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

(INJECTABLE)	DESCRIPTION; PRECAUTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
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18-931	TRAVASOL 10%	BAXTER	AMINO ACIDS
03-24-93	IN PLASTIC CONTAINER	ROUND LAKE, IL	10%
	(INJECTABLE)	60073	(REVISED LABELING -- DESCRIPTION; PRECAUTIONS; HOW SUPPLIED)

17-970	NOLVADEX	STUART	TAMOXIFEN CITRATE
04-01-93	(TABLET)	WILMINGTON, DE	EQ 10MG BASE
	19897		(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION)

19-471	CARDIZEM SR	MARION MERRELL DOW	DILTIAZEM HYDROCHLORIDE
04-01-93	(CAPSULE, EXTENDED RELEASE)	KANSAS CITY, MO	60MG
		64137	90MG 120MG (REVISED LABELING -- PRECAUTIONS)

50-477	NEBCIN	LILLY	TOBRAMYCIN SULFATE
04-01-93	(INJECTABLE)	INDIANAPOLIS, IN	EQ 10MG BASE/ML

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

46285 (REVISED LABELING --
PRECAUTIONS)

50-519 NEBCIN LILLY TOBRAMYCIN SULFATE
04-01-93 (INJECTABLE) INDIANAPOLIS, IN EQ 1.2GM BASE/VIAL

46285 (REVISED LABELING --
PRECAUTIONS)

18-841 DAYPRO SEARLE OXAPROZIN
04-02-93 (TABLET) SKOKIE, IL 600MG

60077 (REVISED LABELING --
CLINICAL PHARMACOLOGY;
PRECAUTIONS)

07-073 AZULFIDINE KABI SULFASALAZINE
04-05-93 (TABLET) PISCATAWAY, NJ 500MG

08855 (REVISED LABELING --
CLINICAL PHARMACOLOGY;
ADVERSE REACTIONS)

07-073 AZULFIDINE EN-TABS KABI SULFASALAZINE
04-05-93 (TABLET, PISCATAWAY, NJ 500MG
EXTENDED RELEASE) 08855 (REVISED LABELING --

CLINICAL PHARMACOLOGY;
ADVERSE REACTIONS)

18-703 ZANTAC 150 GLAXO RANITIDINE HYDROCHLORIDE
04-05-93 (TABLET) RES TRIANGLE PK, NC EQ 150MG BASE

27709 (REVISED LABELING --
CONTRAINDICATIONS;
PRECAUTIONS;

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

ADVERSE REACTIONS)

18-703	ZANTAC 300	GLAXO	RANITIDINE HYDROCHLORIDE
04-05-93	(TABLET)	RES TRIANGLE PK, NC	EQ 300MG BASE
	27709		(REVISED LABELING -- CONTRAINDICATIONS; PRECAUTIONS; ADVERSE REACTIONS)

19-081	ESTRADERM	CIBA	ESTRADIOL
04-05-93	(FILM, EXTENDED RELEASE)	SUMMIT, NJ	0.05MG/24HR
		07901	0.1MG/24HR (REVISED LABELING -- CONTRAINDICATIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; PATIENT PACKAGE INSERT)

19-090	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
04-05-93	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 25MG BASE/ML
	27709		(REVISED LABELING -- DESCRIPTION; DOSAGE AND ADMINISTRATION; PRECAUTIONS; ADVERSE REACTIONS)

19-593	ZANTAC	GLAXO	RANITIDINE HYDROCHLORIDE
04-05-93	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 1MG BASE/100ML

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

27709 (REVISED LABELING --
DESCRIPTION;
DOSAGE AND ADMINISTRATION;
PRECAUTIONS;
ADVERSE REACTIONS)

19-675 04-05-93	ZANTAC (SYRUP)	GLAXO RES TRIANGLE PK, NC	RANITIDINE HYDROCHLORIDE EQ 15MG BASE/ML
		27709	(REVISED LABELING -- CONTRAINDICATIONS; PRECAUTIONS; ADVERSE REACTIONS)

17-362 04-06-93	PROGESTERONE (INJECTABLE)	STERIS PHOENIX, AZ	PROGESTERONE 50MG/ML
	85063		(REVISED LABELING -- WARNINGS; PATIENT PACKAGE INSERT)

50-674 04-08-93	VANTIN (TABLET)	UPJOHN KALAMAZOO, MI	CEFPODOXIME PROXETIL EQ 100MG BASE
		49001	EQ 200MG BASE (REVISED LABELING -- ADVERSE REACTIONS)

50-675 04-08-93	VANTIN (GRANULE, FOR RECONSTITUTION)	UPJOHN KALAMAZOO, MI	CEFPODOXIME PROXETIL EQ 50MG BASE/5ML EQ 100MG BASE/5ML
		49001	(REVISED LABELING -- ADVERSE REACTIONS)

50-687 04-08-93	BANAN (TABLET)	SANKYO NEW YORK, NY	CEFPODOXIME PROXETIL EQ 100MG BASE**
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

10017 EQ 200MG BASE**
 (REVISED LABELING --
 ADVERSE REACTIONS)

50-688 04-08-93	BANAN (GRANULE, FOR RECONSTITUTION)	SANKYO NEW YORK, NY 10017	CEFPODOXIME PROXETIL EQ 50MG BASE/5ML** EQ 100MG BASE/5ML** (REVISED LABELING -- ADVERSE REACTIONS)
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50-579 04-12-93	MONOCID (INJECTABLE)	SMITHKLINE BEECHAM PHILADELPHIA, PA 19101	CEFONICID SODIUM EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL EQ 10GM BASE/VIAL (REVISED LABELING -- WARNINGS; ADVERSE REACTIONS)
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18-342 04-14-93	WELLCOVORIN (TABLET)	BURROUGHS WELLCOME RES TRIANGLE PK, NC 27709	LEUCOVORIN CALCIUM EQ 5MG BASE EQ 25MG BASE (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
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17-857 04-16-93	STADOL (INJECTABLE)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	BUTORPHANOL TARTRATE 1MG/ML 2MG/ML (REVISED LABELING -- PRECAUTIONS;
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

ADVERSE REACTIONS)

** - Not Marketed in USA At This Time

18-869 04-16-93	NIMOTOP (CAPSULE)	MILES WEST HAVEN, CT	NIMODIPINE 30MG
	06516	(REVISED LABELING -- CLINICAL PHARMACOLOGY; DOSAGE AND ADMINISTRATION)	
19-890 04-16-93	STADOL (SPRAY, METERED)	BRISTOL MYERS SQUIBB WALLINGFORD, CT	BUTORPHANOL TARTRATE 1MG/INH
	06492	(REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)	
16-020 04-19-93	SYMMETREL (CAPSULE)	DUPONT WILMINGTON, DE	AMANTADINE HYDROCHLORIDE 100MG
	19880	(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; DOSAGE AND ADMINISTRATION)	
16-023 04-19-93	SYMMETREL (SYRUP)	DUPONT WILMINGTON, DE	AMANTADINE HYDROCHLORIDE 50MG/5ML
	19880	(REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS;	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

WARNINGS; PRECAUTIONS;
DOSAGE AND ADMINISTRATION)

18-101	SYMMETREL	DUPONT	AMANTADINE HYDROCHLORIDE
04-19-93	(TABLET)	WILMINGTON, DE	100MG*
	19880	(REVISED LABELING --	CLINICAL PHARMACOLOGY;
		INDICATIONS AND USAGE;	CONTRAINDICATIONS;
		WARNINGS; PRECAUTIONS;	DOSAGE AND ADMINISTRATION)

* - Not Marketed at Present Time

18-701	HALDOL DECANOATE 50	JOHNSON RW	HALOPERIDOL DECANOATE
04-21-93	(INJECTABLE)	RARITAN, NJ	EQ 50MG BASE/ML
	08869	(REVISED LABELING --	PRECAUTIONS;
		ADVERSE REACTIONS;	OVERDOSAGE)

18-057	PLATINOL	BRISTOL MYERS	CISPLATIN
04-22-93	(INJECTABLE)	EVANSVILLE, IN	10MG/VIAL
	47721	50MG/VIAL	(REVISED LABELING --
		INDICATIONS;	DOSAGE AND ADMINISTRATION)

18-057	PLATINOL-AQ	BRISTOL MYERS	CISPLATIN
04-22-93	(INJECTABLE)	EVANSVILLE, IN	1MG/ML
	47721	(REVISED LABELING --	INDICATIONS;
		DOSAGE AND ADMINISTRATION)	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-603	ZOVIRAX	BURROUGHS WELLCOME	ACYCLOVIR SODIUM
04-22-93	(INJECTABLE)	RES TRIANGLE PK, NC	EQ 500MG BASE/VIAL
	27709	(REVISED LABELING --	
		PRECAUTIONS;	
		ADVERSE REACTIONS;	
		OVERDOSAGE;	
		DOSAGE AND ADMINISTRATION;	
		HOW SUPPLIED)	

18-828	ZOVIRAX	BURROUGHS WELLCOME	ACYCLOVIR
04-22-93	(CAPSULE)	RES TRIANGLE PK, NC	200MG
	27709	(REVISED LABELING --	
		CLINICAL PHARMACOLOGY;	
		INDICATIONS; PRECAUTIONS;	
		ADVERSE REACTIONS;	
		OVERDOSAGE;	
		DOSAGE AND ADMINISTRATION;	
		HOW SUPPLIED)	

19-909	ZOVIRAX	BURROUGHS WELLCOME	ACYCLOVIR
04-22-93	(SUSPENSION)	RES TRIANGLE PK, NC	200MG/5ML
	27709	(REVISED LABELING --	
		CLINICAL PHARMACOLOGY;	
		INDICATIONS; PRECAUTIONS;	
		ADVERSE REACTIONS;	
		OVERDOSAGE;	
		DOSAGE AND ADMINISTRATION;	
		HOW SUPPLIED)	

20-089	ZOVIRAX	BURROUGHS WELLCOME	ACYCLOVIR
04-22-93	(TABLET)	RES TRIANGLE PK, NC	400MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

27709		800MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)	
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50-484	CERUBIDINE	WYETH AYERST	DAUNORUBICIN HYDROCHLORIDE
04-22-93	(INJECTABLE)	RADNOR, PA	EQ 20MG BASE/VIAL
	19087	(REVISED LABELING -- WARNINGS)	

17-450	MONISTAT 7	ADVANCED CARE	MICONAZOLE NITRATE
04-26-93	(CREAM)	RARITAN, NJ	2%
	08869	(REVISED LABELING -- PATIENT LABELING) (OTC)	

18-052	GYNE-LOTRIMIN	SCHERING	CLOTRIMAZOLE
04-26-93	(CREAM)	KENILWORTH, NJ	1%
	07033	(REVISED LABELING -- PATIENT LABELING) (OTC)	

18-701	HALDOL DECANOATE 50	JOHNSON RW	HALOPERIDOL DECANOATE
04-27-93	(INJECTABLE)	RARITAN, NJ	EQ 50MG BASE/ML
	08869	(REVISED LABELING -- DOSAGE AND ADMINISTRATION)	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-757 04-27-93	CHIBROXIN (SOLUTION/DROPS) 19486	MERCK WEST POINT, PA (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE)	NORFLOXACIN 0.3%
12-122 04-28-93	GLUCAGON (INJECTABLE) 46285	LILLY INDIANAPOLIS, IN EQ 10MG BASE/VIAL (REVISED LABELING -- DOSAGE AND ADMINISTRATION; PATIENT PACKAGE INSERT)	GLUCAGON HYDROCHLORIDE EQ 1MG BASE/VIAL
16-927 04-28-93	DEMULEN 1/50-21 (TABLET) 00936	SEARLE SAN JUAN, PR ETHYNODIOL DIACETATE 1MG (REVISED LABELING -- PATIENT PACKAGE INSERT)	ETHINYL ESTRADIOL 0.05MG
16-936 04-28-93	DEMULEN 1/50-28 (TABLET) 00936	SEARLE SAN JUAN, PR ETHYNODIOL DIACETATE 1MG (REVISED LABELING -- PATIENT PACKAGE INSERT)	ETHINYL ESTRADIOL 0.05MG
18-160 04-28-93	DEMULEN 1/35-28 (TABLET) 00936	SEARLE SAN JUAN, PR ETHYNODIOL DIACETATE 1MG (REVISED LABELING -- PATIENT PACKAGE INSERT)	ETHINYL ESTRADIOL 0.035MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-168 04-28-93	DEMULEN 1/35-21 (TABLET)	SEARLE SAN JUAN, PR	ETHINYL ESTRADIOL 0.035MG
	00936	ETHYNODIOL DIACETATE 1MG (REVISED LABELING -- PATIENT PACKAGE INSERT)	
20-007 04-28-93	ZOFRAN (INJECTABLE)	GLAXO RES TRIANGLE PK, NC	ONDANSETRON HYDROCHLORIDE EQ 2MG BASE/ML
	27709	(REVISED LABELING -- ADVERSE REACTIONS)	
20-027 04-28-93	CARDIZEM (INJECTABLE)	MARION MERRELL DOW KANSAS CITY, MO	DILTIAZEM HYDROCHLORIDE 5MG/ML
	64134	(REVISED LABELING -- PRECAUTIONS; DOSAGE AND ADMINISTRATION)	
20-062 04-28-93	CARDIZEM CD (CAPSULE, EXTENDED RELEASE)	MARION MERRELL DOW KANSAS CITY, MO	DILTIAZEM HYDROCHLORIDE 120MG 180MG
		64134 240MG 300MG (REVISED LABELING -- PRECAUTIONS)	
13-553 04-29-93	ESIMIL (TABLET)	CIBA SUMMIT, NJ	GUANETHIDINE MONOSULFATE 10MG
	07901	HYDROCHLOROTHIAZIDE 25MG (REVISED LABELING --	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

PRECAUTIONS)

18-240 04-29-93	TENORMIN (TABLET)	ICI WILMINGTON, DE 19897	ATENOLOL 25MG 50MG 100MG (REVISED LABELING -- WARNINGS; PRECAUTIONS)
18-538 04-29-93	LOZOL (TABLET)	RHONE POULENC RORER FORT WASHINGTON, PA 19034	INDAPAMIDE 1.25MG 2.5MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; WARNINGS; PRECAUTIONS; DRUG INTERACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
18-760 04-29-93	TENORETIC 50 (TABLET)	ICI WILMINGTON, DE 19897	ATENOLOL 50MG CHLORTHALIDONE 25MG (REVISED LABELING -- WARNINGS; PRECAUTIONS)
18-760 04-29-93	TENORETIC 100 (TABLET)	ICI WILMINGTON, DE 19897	ATENOLOL 100MG CHLORTHALIDONE 25MG (REVISED LABELING -- WARNINGS; PRECAUTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-058 04-29-93	TENORMIN (INJECTABLE) 19897	ICI WILMINGTON, DE	ATENOLOL 0.5MG/ML (REVISED LABELING -- WARNINGS; PRECAUTIONS)
19-190 04-29-93	TRIPHASIL-28 (TABLET) 19101	WYETH AYERST PHILADELPHIA, PA	ETHINYL ESTRADIOL 0.03MG,0.04MG,0.03MG LEVONORGESTREL 0.05MG,0.075MG,0.125MG (REVISED LABELING -- INDICATIONS AND USAGE; PATIENT PACKAGE INSERT)
19-192 04-29-93	TRIPHASIL-21 (TABLET) 19101	WYETH AYERST PHILADELPHIA, PA	ETHINYL ESTRADIOL 0.03MG,0.04MG,0.03MG LEVONORGESTREL 0.05MG,0.075MG,0.125MG (REVISED LABELING -- INDICATIONS AND USAGE; PATIENT PACKAGE INSERT)
19-668 04-29-93	CARDURA (TABLET) 10017	PFIZER NEW YORK, NY	DOXAZOSIN MESYLATE EQ 1MG BASE EQ 2MG BASE EQ 4MG BASE EQ 8MG BASE (REVISED LABELING -- CLINICAL PHARMACOLOGY; PRECAUTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-777	ZESTRIL	ZENECA	LISINOPRIL
04-29-93	(TABLET)	WILMINGTON, DE	2.5MG
	19897	5MG	
		10MG	
		20MG	
		40MG	
		(REVISED LABELING --	
		DESCRIPTION;	
		HOW SUPPLIED)	

50-578	FORTAZ	GLAXO	CEFTAZIDIME
04-29-93	(INJECTABLE)	RES TRIANGLE PK, NC	500MG/VIAL
	27709	1GM/VIAL	
		2GM/VIAL	
		6GM/VIAL	
		(REVISED LABELING --	
		PRECAUTIONS;	
		ADVERSE REACTIONS;	
		DOSAGE AND ADMINISTRATION)	

17-533	KLONOPIN	ROCHE	CLONAZEPAM
04-30-93	(TABLET)	NUTLEY, NJ	0.5MG
	07100	1MG	
		2MG	
		(REVISED LABELING --	
		WARNINGS; PRECAUTIONS;	
		ADVERSE REACTIONS;	
		DRUG ABUSE AND DEPENDENCE;	
		HOW SUPPLIED)	

LICENSE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
LICENSE DATE	(DOSAGE FORM)	(DESCRIPTION)	

BIOLOGICAL PRODUCT LICENSES ISSUED

1165 04-01-93	NONE (INJECTABLE) 35205	SOUTHERN BLOOD SRVCS BIRMINGHAM, AL (B)	PLASMA (TRANSFUSION)
1165 04-01-93	NONE (INJECTABLE) 35205	SOUTHERN BLOOD SRVCS BIRMINGHAM, AL (B)	PLATELETS (TRANSFUSION)
1165 04-01-93	NONE (INJECTABLE) 35205	SOUTHERN BLOOD SRVCS BIRMINGHAM, AL (B)	RED BLOOD CELLS (TRANSFUSION)
1165 04-01-93	NONE (INJECTABLE) 35205	SOUTHERN BLOOD SRVCS BIRMINGHAM, AL (A&B)	WHOLE BLOOD (TRANSFUSION)

LICENSE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
LICENSE DATE	(DOSAGE FORM)		(DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

- (A) Establishment License Issued
- (B) Product License Issued

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE		(DESCRIPTION)	

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK920035	RAD-SURE	INTL SPECIALTY PRODS	BLOOD IRRADIATION LABEL
04-01-93	WAYNE, NJ	(C)	
	07470		

BP850001/25	AUTOPHERESIS-C	BAXTER HLTHCARE	AUTOMATED BLOOD SEPARATORS
04-06-93	PLASMAPHERESIS	ROUND LAKE, IL	(C)
	SYSTEM	60073	

BK920036	COBE SPECTRA	COBE BCT	BLOOD COMPONENT
04-06-93	SINGLE NEEDLE	LAKWOOD, CO	SEPARATOR
	EXTENDED LIFE	80215	(C)
	PLATELET (ELP)		
	SET		

BK920027	PLASMA	MILES	EMPTY CONTAINERS FOR
04-13-93	POOLING BAG	BERKELEY, CA	COLLECTION AND PROCESSING
	94701	(C)	

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE		(DESCRIPTION)	

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND
APPROVAL DATE			INDICATION OF DEVICE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

P910023	CADENCE	VENTRITEX, INC.	CADENCE TIERED
04/30/93	TIERED THERAPY	SUNNYVALE, CA	THERAPY DEFIBRILLATOR
	DEFIBRILLATOR SYSTEM	94086	SYSTEM FOR USE IN
		PATIENTS WITH	
		HEMODYNAMICALLY	
		COMPROMISING	
		VENTRICULAR	
		TACHYARRHYTHMIAS	

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

P780007/S38 04/12/93	HYDRON (POLYMACON) HYDROPHILIC CONTACT LENSES, OCULAR SCIENCES/AMERICAN HYDRON CAST MOLDED POLYMACON SOFT HYDROPHILIC LENSES	OSI CORPORATION SO. SAN FRANCISCO, CA 07746	ALTERNATE MANUFACTURING SITE
P790002/S13 04/12/93	EBI BI-OSTEOGEN BONE HEALING SYSTEM	ELECTRO-BIOLOGY, INC. PARSIPPANY, NJ 07054-1079	MODIFIED VERSION OF THE EBI BONE HEALING SYSTEM, MODEL 1020 TO BE DESIGNATED THE EBI BONE HEALING SYSTEM, MODEL 1026
P800002/S09 04/09/93	AVITENE MICROFIBRILLAR COLLAGEN HEMOSTAT (MCH) NON-WOVEN WEB (NWW)	MEDCHEM PRODUCTS, INC. WOBURN, MA 01801	ALTERNATE BULK MANUFACTURING FACILITY
P800022/S38 04/12/93	ZYDERM AND ZYPLAST COLLAGEN IMPLANTS	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	REVISED LABELING
P810046/S137 04/28/93	SIMPSON-ROBERT CORONARY BALLOON	ADVANCED CARDIOVASCULAR SYSTEMS	ACS TEN (.010) CORONARY DILATATION

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

P820018/S57	AUTIMA ACS TEN (.010) CORONARY DILATATION CATHETER WITH 2.25 MM, 2.75 MM, 3.25 MM, AND 3.75 MM BALLOONS	SANTA CLARA, CA 95052-8167	CATHETER WITH 2.25 MM, 2.75 MM, 3.25 MM AND 3.75 MM BALLOONS
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P820018/S57	AUTIMA PACING SYSTEM, AUXILIARY INSTRUMENTS INTERFACE CABLE MODEL 042-034	TELECTRONICS, INC. ENGLEWOOD, CO 80112	APPROVAL FOR AUXILIARY INSTRUMENTS INTERFACE CABLE, MODEL 042-034
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P820018/S59	AUTIMA PACING SYSTEM, PATIENT BOOKLET	TELECTRONICS, INC. ENGLEWOOD, CO 80112	NEW PATIENT BOOKLET
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P820034/S03	REPRO-MED THD (TESTICULAR HYPOTHERMIA DEVICE)	MIDDLETOWN, NY 10940	REPRO-MED SYSTEMS, INC. SITE OF ALL MANUFACTURING OPERATIONS OF THE REPRO-MED THD
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P820034/S04	REPRO-MED THD (TESTICULAR HYPOTHERMIA DEVICE)	MIDDLETOWN, NY 10940	REPRO-MED SYSTEMS, INC. MANUFACTURING, ASSEMBLY, DESIGN, MATERIALS AND OTHER CHANGES
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P820056/S54	OPTACRYL 60 (KOLFOCON A) RIGID GAS PERMEABLE CONTACT LENSES	MESA, AZ 85204	PARAGON OPTICAL ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
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APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

P820063/S53	PARAPERM 02 (PASIFOCON A)	PARAGON OPTICAL MESA, AZ	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
04/14/93	RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	85204	

P840001/S26	ITREL TOTALLY IMPLANTABLE	MEDTRONIC NEUROLOGICAL MINNEAPOLIS, MN	MEDTRONIC MODEL 7497 NEUROMED ADAPTER
04/05/93	SPINAL CORD STIMULATION SYSTEM, MEDTRONIC MODEL 7497 NEUROMED ADAPTER	55440-9087	

P840024/S38	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO	MODIFICATION OF THE IMPLANTED RECEIVER ANTENNA COIL AND THE ADDITION OF A WARNING STATEMENT TO THE PACKAGE INSERT AND THE PATIENT IDENTIFICATION CARD
04/05/93	80112		

P840039/S35	MODEL P399UV POSTERIOR CHAMBER ULTRAVIOLET ABSORBING INTRAOCULAR LENS	STORZ OPHTHALMICS, INC. CLEARWATER, FL	MODEL P399UV POSTERIOR CHAMBER ULTRAVIOLET-ABSORBING INTRAOCULAR LENS
04/28/93	34616		

P840039/S38	POSTERIOR CHAMBER ULTRAVIOLET- ABSORBING	STORZ OPHTHALMICS, INC. CLEARWATER, FL	APPROVAL FOR MDR MEDICAL CORPORATION TO DISTRIBUTE THE
04/28/93	34616		

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

INTRAOCCULAR LENSES: PRIVATE DISTRIBUTION REQUEST	STORZ MODEL 72NUV ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCCULAR LENS
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P840040/S32 04/28/93	SLIDER ST/SUPER THIN CORONARY BALLOON DILATATION CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	SLIDER ST/SUPER THIN CORONARY BALLOON DILATATION CATHETER
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P840050/S48 04/14/93	OCUSIL (NEFOCON A) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	OSI CORPORATION SO. SAN FRANCISCO, CA 94080	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
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P850038/S21 04/14/93	PARAPERME EW (PASIFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PARAGON OPTICAL MESA, AZ 85204	ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
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P850051/S37 04/21/93	MEDTRONIC MICRO MINIX MODEL 8360 AND LEGEND MODELS 8416, 8417, 8418, AND 8419 AND THE CPI TRIUMPH VR PULSE GENERATORS MODELS 1123, 1124, 1125, AND 1126	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFICATIONS TO THE TECHNICAL MANUALS
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APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

P850064/S09 04/02/93	LIFE PULSE HIGH FREQUENCY JET VENTILATOR	BUNNELL INCORPORATED SALT LAKE CITY, UT 84115	MANUFACTURING MODIFICATIONS
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P850079/S24 04/06/93	HYDRASOFT (METHAFILCON A OR METHAFILCON B) HYDROPHILIC CONTACT LENSES	COASTVISION HUNTINGTON BEACH, CA 92648	REVISED LABELING
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P860019/S59 04/28/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER, BIOSLIDE HYDROPHILIC COATING	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	MANUFACTURING MODIFICATIONS
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P860019/S63 04/28/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER, ACE, LONG ACE AND GRAFT ACE	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	MANUFACTURING MODIFICATIONS
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P860019/S64 04/28/93	SCIMED PERCUTANEOUS TRANSLUMINAL	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	USE OF THE HYPO-SEAL ACCESSORY ON ALL SCIMED'S PTCA
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APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

CORONARY ANGIOPLASTY CATHETER, HYPO-SEAL ACCESSORY		CATHETERS WHICH HAVE 1.8F HYPOTUBE PROXIMAL SHAFTS
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P870007/S06 04/14/93	STERILE PRESERVED SALINE SOLUTION FAIRTON, NJ 08320-0210	OPTOPICS LABORATORIES CORPORATION FOR THE SOLUTION	APPROVAL FOR A 24-MONTH SHELF-LIFE
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P870024/S37 04/02/93	FLUOROPERM 92, 60, AND 30 MESA, AZ (PAFLUFOCON A, B, AND C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PARAGON OPTICAL MODIFICATIONS	MANUFACTURING
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P870024/S38 04/14/93	FLUOROPERM 92, 60 AND 30 MESA, AZ (PAFLUFOCON A, B, AND C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PARAGON OPTICAL MANUFACTURING AND DISTRIBUTION SITE	ALTERNATE
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P870036/S19 04/28/93	MEDTRONIC 14K CORONARY DILATION CATHETER 92121-2256	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA THE CURRENT BALLOON DIAMETERS	ADDITION OF ANOTHER BALLOON DIAMETER TO
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P870073/S07 04/28/93	POSTERIOR CHAMBER INTRAOCULAR LENSES: PRIVATE DISTRIBUTION REQUEST 34616	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34616 STORZ	APPROVAL FOR MDR MEDICAL CORPORATION TO DISTRIBUTE THE
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APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
			ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES
P880038/S22 04/19/93	META MV PACING SYSTEM, AUXILIARY INSTRUMENTS INTERFACE CABLE MODEL 042-034	TELECTRONICS, INC. ENGLEWOOD, CO 80112	APPROVAL FOR AUXILIARY INSTRUMENTS INTERFACE CABLE, MODEL 042-034
P880038/S24 04/19/93	META MV PACING SYSTEM PATIENT BOOKLET	TELECTRONICS, INC. ENGLEWOOD, CO 80112	NEW PATIENT BOOKLET
P890027/S09 04/05/93	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MODIFICATION OF THE IMPLANTED RECEIVER ANTENNA COIL AND ADDITION OF A WARNING STATEMENT TO THE PACKAGE INSERT AND PATIENT IDENTIFICATION CARD
P890039/S07 04/05/93	MAESTRO SAVVI MODEL 305 VDD PACING SYSTEM, MOLDED CABLE ASSEMBLY AND MODIFICATION OF THE MODEL 1401 DAA	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	MANUFACTURING MODIFICATIONS AND DISTRIBUTION OF SYSTEM COMPONENTS AS SEPARATELY PACKAGED ACCESSORIES
P840039/S39 04/28/93	POSTERIOR CHAMBER ULTRAVIOLET- ABSORBING	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34616	APPROVAL FOR WORLD OPTICS, INC. TO DISTRIBUTE THE STORZ

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

INTRAOCULAR LENSES: PRIVATE DISTRIBUTION REQUEST	MODEL 72NUV ULTRAVIOLET-ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENS
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P890058/S11 NOVALENS 04/06/93 (ROSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND BLUE TINTED)	OCUTEC CORPORATION MORRISVILLE, NC 27560	ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
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P900023/S02 ABIOMED BVS 5000 04/08/93 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923 PACKAGE	INCLUSION OF A REMINDER SHEET IN THE BVS BLOOD PUMP
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P900070/S03 META DDDR 04/19/93 PACING SYSTEM, AUXILIARY INSTRUMENTS INTERFACE CABLE MODEL 042-034	TELECTRONICS, INC ENGLEWOOD, CO 80112	APPROVAL FOR AUXILIARY INSTRUMENTS INTERFACE CABLE, MODEL 024-034
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P900070/S04 META DDDR 04/21/93 PACING SYSTEM PATIENT BOOKLET	TELECTRONICS, INC. ENGLEWOOD, CO 80112	NEW PATIENT BOOKLET
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NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

200-070	ISOFLU	DOGS	ABBOTT LABS	ISOFLURANE
04-02-93	(GAS/INHALATION)	HORSES	N CHICAGO, IL	99.9%
		60064		

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR APRIL 1993.

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR APRIL 1993.

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

Center for Drug Evaluation and Research

*George R. Scott (301) 443-3910

Center for Biologics Evaluation and Research

Joseph Wilczek (301) 295-9012

Center for Devices and Radiological Health

Mary Jo Robinson (301) 427-1186

Center for Veterinary Medicine

Melanie R. Berson, D.V.M.
(301) 295-8623

*To whom general inquiries should be directed.

This report is compiled by the Division of Drug Information Resources, OM, CDER. It is available by subscription from the National Technical Information Service, Springfield, VA 22161.

Volume 16 (5) May 1993

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

18-057 22-APR-93 (SUPPL)	PLATINOL (INJECTABLE)	BRISTOL MYERS EVANSVILLE, IN 47721	CISPLATIN 10MG/VIAL 50MG/VIAL (NEW DOSAGE REGIMEN -- USE IN COMBINATION WITH CYCLOPHOSPHAMIDE FOR METASTATIC OVARIAN TUMORS) [DELETE COMBINATION USE WITH DOXORUBICIN HYDROCHLORIDE FOR METASTATIC OVARIAN TUMORS]
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

18-057 22-APR-93 (SUPPL)	PLATINOL-AQ (INJECTABLE)	BRISTOL MYERS EVANSVILLE, IN 47721	CISPLATIN 1MG/ML (NEW DOSAGE REGIMEN -- USE IN COMBINATION WITH CYCLOPHOSPHAMIDE FOR METASTATIC OVARIAN TUMORS) [DELETE COMBINATION USE WITH DOXORUBICIN HYDROCHLORIDE FOR METASTATIC OVARIAN TUMORS]
19-855 05-MAY-93 (SUPPL)	ELIMITE (CREAM)	BURROUGHS WELLCOME RES TRIANGLE PK, NC 27709	PERMETHRIN 5% (NEW DOSAGE REGIMEN -- ADDITION OF A RETREATMENT REGIMEN)
20-036 06-MAY-93 (SUPPL)	AREDIA (INJECTABLE)	CIBA GEIGY SUMMMIT, NJ 07901	PAMIDRONATE DISODIUM 60MG/VIAL 90MG/VIAL (NEW STRENGTH)
20-049 10-MAY-93 (3 P)	PENTASA (CAPSULE, EXTENDED RELEASE)	MARION MERRELL DOW KANSAS CITY, MO 64134	MESALAMINE 250MG (NONSTEROIDAL ANTI-INFLAMMATORY) [ULCERATIVE COLITIS]
17-783 11-MAY-93 (SUPPL)	GLUCOTROL (TABLET)	PFIZER NEW YORK, NY 10017	GLIPIZIDE 2.5MG (NEW STRENGTH)

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT CLASSIFICATION(S)	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

19-032 11-MAY-93 (SUPPL)	TENEX (TABLET)	ROBINS PHILADELPHIA, PA 19101	GUANFACINE HYDROCHLORIDE 1MG 2MG (NEW INDICATION -- USE AS MONOTHERAPY IN HYPERTENSION)
19-660 18-MAY-93 (SUPPL)	TILADE (AEROSOL, METERED)	FISONS ROCHESTER, NY 14603	NEDOCROMIL SODIUM 1.75MG/INH (COMPARATIVE EFFICACY CLAIM -- PRESENTLY AVAILABLE DATA ON THE RELATIVE EFFICACY OF TILADE AND CROMOLYN SODIUM ARE INCONCLUSIVE)
19-531 28-MAY-93 (5 S)	NUTRILIPID 10% (INJECTABLE)	MCGAW IRVINE, CA 92713	SOYBEAN OIL 10% (CALORIC SUPPLEMENT)
19-531 28-MAY-93 (5 S)	NUTRILIPID 20% (INJECTABLE)	MCGAW IRVINE, CA 92713	SOYBEAN OIL 20% (CALORIC SUPPLEMENT)
50-585 28-MAY-93 (SUPPL)	ROCEPHIN (INJECTABLE)	ROCHE NUTLEY, NJ 07110	CEFTRIAZONE SODIUM EQ 250MG BASE/VIAL EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL EQ 10GM BASE/VIAL (NEW DOSAGE REGIMEN -- ONCE DAILY USE IN THE TREATMENT OF MENINGITIS IN PEDIATRIC PATIENTS AT A DOSE OF 100MG/KG/DAY)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

50-674	VANTIN	UPJOHN	CEFPODOXIME PROXETIL
28-MAY-93	(TABLET)	KALAMAZOO, MI	EQ 100MG BASE
(SUPPL)		49001	EQ 200MG BASE
			(NEW INDICATION --
			ACUTE BACTERIAL EXACERBATION
			OF CHRONIC BRONCHITIS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE (DOSAGE FORM)		CLASSIFICATION(S)	STRENGTH(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

20-215 05-MAY-93	MONOKET (TABLET)	SCHWARZ PHARMA MILWAUKEE, WI 53201	ISOSORBIDE MONONITRATE 10MG 20MG (VASODILATOR)
20-070 10-MAY-93	COGNEX (CAPSULE)	PARKE DAVIS ANN ARBOR, MI 48105	TACRINE HYDROCHLORIDE EQ 10MG BASE EQ 20MG BASE EQ 30MG BASE EQ 40MG BASE (ENZYME INHIBITOR) [TREATMENT OF MILD TO MODERATE DEMENTIA OF THE ALZHEIMER'S TYPE]

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

71-446 21-MAY-93	TEMAZEPAM (CAPSULE)	DANBURY DANBURY, CT 06810	TEMAZEPAM 15MG (SEDATIVES AND HYPNOTICS)
71-447 21-MAY-93	TEMAZEPAM (CAPSULE)	DANBURY DANBURY, CT 06810	TEMAZEPAM 30MG (SEDATIVES AND HYPNOTICS)
73-393 27-MAY-93	TOLMETIN SODIUM (CAPSULE)	MYLAN MORGANTOWN, WV 26505	TOLMETIN SODIUM EQ 400MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)
73-630* 27-MAY-93	SULFACETAMIDE SODIUM AND PREDNISOLONE SODIUM PHOSPHATE (SOLUTION/DROPS)	STERIS PHOENIX, AZ 85043	PREDNISOLONE SODIUM PHOSPHATE EQ 0.23% PHOSPHATE SULFACETAMIDE SODIUM 10% (CORTICOSTEROID/ ANTI-INFECTIVE)
73-062 28-MAY-93	LOPERAMIDE HCL (SOLUTION)	WATSON LABS CORONA, CA 91720	LOPERAMIDE HYDROCHLORIDE 1MG/5ML (ANTIDIARRHEAL) (OTC)
73-315 28-MAY-93	ATENOLOL (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	ATENOLOL 50MG (BETA BLOCKERS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

73-316 28-MAY-93	ATENOLOL (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	ATENOLOL 100MG (BETA BLOCKERS)
* - First Time Product Available Generically			
73-495 28-MAY-93	ALBUTEROL SULFATE (SOLUTION/ INHALATION)	COPLEY PHARM CANTON, MA 02021	ALBUTEROL SULFATE EQ 0.083% BASE (BRONCHODILATOR)
73-497 28-MAY-93	EVALOSE (SOLUTION)	COPLEY PHARM CANTON, MA 02021	LACTULOSE 10GM/15ML (LAXATIVE/AMMONIA DETOXICANT)
73-504 28-MAY-93	HEPTALAC (SOLUTION)	COPLEY PHARM CANTON, MA 02021	LACTULOSE 10GM/15ML (LAXATIVE/AMMONIA DETOXICANT)
73-685 28-MAY-93	ACILAC (SOLUTION)	TECHNILAB SAINT LAURENT, QUEBEC CANADA	LACTULOSE 10GM/15ML (LAXATIVE/AMMONIA DETOXICANT)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

73-686 28-MAY-93	LAXILOSE (SOLUTION)	TECHNILAB SAINT LAURENT, QUEBEC CANADA	LACTULOSE 10GM/15ML (LAXATIVE/AMMONIA DETOXICANT)
81-203 28-MAY-93	HYDROCORTISONE (OINTMENT)	FOUGERA MELVILLE, NY 11747	HYDROCORTISONE 2.5% (STEROIDAL SKIN PRODUCTS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
TENTATIVE	(DOSAGE FORM)		STRENGTH(S)
APPROVAL DATE			CLASSIFICATION(S)

ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

74-199 27-MAY-93	ALPRAZOLAM (TABLET)	ROXANE COLUMBUS, OH 43216	ALPRAZOLAM 0.25MG 0.5MG 1MG (ANXIOLYTIC)
74-201 27-MAY-93	NAPROXEN (TABLET)	LEMMON SELLERSVILLE, PA 18960	NAPROXEN 250MG 375MG 500MG (NONSTEROIDAL ANTI-INFLAMMATORY)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-859 01-APR-93	VIRAZOLE (INHALATION)	ICN COSA MESA, CA 92626	RIBAVIRIN 6GM/VIAL (REVISED LABELING -- DESCRIPTION; OVERDOSAGE)
19-855 05-MAY-93	ELIMITE (CREAM)	BURROUGHS WELLCOME RES TRIANGLE PK, NC 27709	PERMETHRIN 5% (REVISED LABELING -- DESCRIPTION; INDICATION AND USAGE; DOSAGE AND ADMINISTRATION)
19-402 06-MAY-93	HISMANAL (TABLET)	JANSSEN PISCATAWAY, NJ 08854	ASTEMIZOLE 10MG (REVISED LABELING -- CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

11-909* 07-MAY-93	NARDIL (TABLET)	PARKE DAVIS MORRIS PLAINS, NJ 07950	PHENELZINE SULFATE EQ 15MG BASE (REVISED LABELING -- DESCRIPTION; CONTRAINDICATIONS; WARNINGS; ADVERSE REACTIONS; OVERDOSAGE; HOW SUPPLIED)
14-684 10-MAY-93	AVENTYL HCL (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE EQ 25MG BASE (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
* - Permitted 14-685 10-MAY-93	AVENTYL HCL (SOLUTION)	LILLY INDIANAPOLIS, IN 46285	NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE/5ML (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
17-968 10-MAY-93	DEPO-TESTADIOL (INJECTABLE)	UPJOHN KALAMAZOO, MI 49001	ESTRADIOL CYPIONATE 2MG/ML TESTOSTERONE CYPIONATE 50MG/ML (REVISED LABELING -- CONTRAINDICATIONS; PRECAUTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

17-783 11-MAY-93	GLUCOTROL (TABLET)	PFIZER NEW YORK, NY 10017	GLIPIZIDE 2.5MG 5MG 10MG (REVISED LABELING -- DESCRIPTION; HOW SUPPLIED)
19-032 11-MAY-93	TENEX (TABLET)	WYETH AYERST PHILADELPHIA, PA 19101	GUANFACINE HYDROCHLORIDE 1MG 2MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
18-938 12-MAY-93	DDAVP (INJECTABLE)	RHONE POULENC RORER FORT WASHINGTON, PA 19034	DESMOPRESSIN ACETATE 0.004MG/ML (REVISED LABELING -- WARNINGS; PRECAUTIONS)
19-508 13-MAY-93	AXID (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	NIZATIDINE 150MG 300MG (REVISED LABELING -- ADVERSE REACTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-057 17-MAY-93	PLATINOL (INJECTABLE)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	CISPLATIN 10MG/VIAL 50MG/VIAL (REVISED LABELING -- PRECAUTIONS)
18-057 17-MAY-93	PLATINOL AQ (INJECTABLE)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	CISPLATIN 1MG/ML (REVISED LABELING -- PRECAUTIONS)
08-693 18-MAY-93	FURADANTIN (TABLET)	P AND G NORWICH, NY 13815	NITROFURANTOIN 50MG 100MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
09-175 18-MAY-93	FURADANTIN (SUSPENSION)	P AND G NORWICH, NY 13815	NITROFURANTOIN 25MG/5ML (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
19-660 18-MAY-93	TILADE (AEROSOL, METERED)	FISONS ROCHESTER, NY 14603	NEDOCROMIL SODIUM 1.75MG/INH (REVISED LABELING -- CLINICAL STUDIES; DOSAGE AND ADMINISTRATION;

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

HOW SUPPLIED)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-611 18-MAY-93	PCE (TABLET, COATED PARTICLES)	ABBOTT LABS ABBOTT PARK, IL 60064	ERYTHROMYCIN 333MG 500MG (REVISED LABELING -- DESCRIPTION; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS)
16-620 18-MAY-93	MACRODANTIN (CAPSULE)	P AND G NORWICH, NY 13815	NITROFURANTOIN, MACROCRYSTALLINE 25MG 50MG 100MG (REVISED LABELING -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
17-783 19-MAY-93	GLUCOTROL (TABLET)	PFIZER NEW YORK, NY 10017	GLIPIZIDE 2.5MG 5MG 10MG (REVISED LABELING -- PRECAUTIONS)
18-182 24-MAY-93	MYCELEX G (TABLET)	MILES WEST HAVEN, CT 06516	CLOTRIMAZOLE 100MG (REVISED LABELING -- USAGE IN PREGNANCY)
50-589 24-MAY-93	CEFIZOX IN DEXTROSE 5% IN	FUJISAWA PHARM BALA CYNWYD, PA	CEFTIZOXIME SODIUM EQ 20MG BASE/ML

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

	PLASTIC CONTAINER (INJECTABLE)	19004	EQ 40MG BASE/ML (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; DOSAGE AND ADMINISTRATION)
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18-716 27-MAY-93	TRANDATE (TABLET)	GLAXO RES TRIANGLE PK, NC 27709	LABETALOL HYDROCHLORIDE 100MG 200MG 300MG (REVISED LABELING -- DESCRIPTION; CLINICAL PHARMACOLOGY; WARNINGS; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
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19-425 27-MAY-93	TRANDATE (INJECTABLE)	GLAXO RES TRIANGLE PK, NC 27709	LABETALOL HYDROCHLORIDE 5MG/ML (REVISED LABELING -- DESCRIPTION; WARNINGS; PRECAUTIONS)
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19-651 27-MAY-93	ASACOL (TABLET, DELAYED RELEASE)	P AND G NORWICH, NY 13815	MESALAMINE 400MG (REVISED LABELING -- PRECAUTIONS; ADVERSE REACTIONS)
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

17-016 28-MAY-93	CHORIONIC GONADOTROPIN (INJECTABLE)	STERIS PHOENIX, AZ 85063	GONADOTROPIN, CHORIONIC 2,000 UNITS/VIAL 5,000 UNITS/VIAL 10,000 UNITS/VIAL 15,000 UNITS/VIAL 20,000 UNITS/VIAL (REVISED LABELING -- PRECAUTIONS)
50-521 28-MAY-93	CECLOR (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	CEFACLOR EQ 250MG BASE EQ 500MG BASE (REVISED LABELING -- ADVERSE REACTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-522 28-MAY-93	CECLOR (POWDER FOR RECONSTITUTION)	LILLY INDIANAPOLIS, IN 46285	CEFACLOR EQ 125MG BASE/5ML EQ 250MG BASE/5ML (REVISED LABELING -- ADVERSE REACTIONS)
50-585 28-MAY-93	ROCEPHIN (INJECTABLE)	ROCHE NUTLEY, NJ 07110	CEFTRIAZONE SODIUM EQ 250MG BASE/VIAL EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL EQ 10GM BASE/VIAL (REVISED LABELING -- DOSAGE AND ADMINISTRATION)
50-674 28-MAY-93	VANTIN (TABLET)	UPJOHN KALAMAZOO, MI 49001	CEFPODOXIME PROXETIL EQ 100MG BASE EQ 200MG BASE (REVISED LABELING -- INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)

LICENSE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
LICENSE DATE	(DOSAGE FORM)		(DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

THERE ARE NO BIOLOGICAL PRODUCT LICENSES ISSUED FOR MAY 1993.

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE		(DESCRIPTION)	

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK920015	VIROCHEQC 1	N AM BIOL	QUALITY CONTROL KITS FOR
05-20-93	MIAMI, FL		BLOOD BANKING REAGENTS
	33169	(C)	
BK920040	VENOJECT II	TERUMO MED	BLOOD BANK SUPPLY (HOLDER)
05-20-93	ELKTON, MD	(C)	
	21921		

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE		(DESCRIPTION)	

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT INDICATION OF DEVICE	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

P900039/ 05/28/93	COLLAGRAFT BONE GRAFT MATRIX	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	COLLAGRAFT BONE GRAFT MATRIX FOR USE IN ACUTE LONG BONE FRACTURES AND TRAUMATIC OSSEOUS DEFECTS TO PROVIDE A MATRIX FOR THE REPAIR PROCESS OF BONE
P900056/ 05/28/93	ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM	HEART TECHNOLOGY, INC. BELLEVUE, WA 98005	ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM FOR USE IN PATIENTS WITH CORONARY ARTERY DISEASE
P910019/ 05/18/93	IVT CORONARY ATHERECTOMY SYSTEM (TEC)	INTERVENTIONAL TECHNOLOGIES, INC. SAN DIEGO, CA 92123	APPROVAL FOR THE IVT CORONARY ATHERECTOMY SYSTEM (TEC)
P910030/ 05/28/93	GIANTURCO-ROUBIN FLEX-STENT CORONARY STENT	COOK, INC. BLOOMINGTON, IN 47402	TO BE USED FOR CHRONIC PLACEMENT IN A CORONARY ARTERY OR GRAFT TO OBTAIN VESSEL PATENCY IN THE TREATMENT OF ACUTE OR THREATENED CLOSURE
P910064/ 05/07/93	REALITY FEMALE CONDOM	WISCONSIN PHARMACAL COMPANY, INC. CHICAGO, IL 60611	REALITY FEMALE CONDOM FOR USE IN PREVENTION OF PREGNANCY AND SEXUALLY TRANSMITTED DISEASES

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT INDICATION OF DEVICE	DESCRIPTION AND
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MEDICAL DEVICE - PMA SUPPLEMENTALS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

N18073/S23 05/18/93	SOFT MATE DAILY CLEANER FOR SENSITIVE EYES AND SOFT MATE HANDS OFF DAILY CLEANER	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE MANUFACTURING SITE
N18078/S48 05/18/93	SOFT MATE SALINE SOLUTION FOR SENSITIVE EYES	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE MANUFACTURING SITE
P780013/S07 05/19/93	GBF V/X ASPHERIC (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENS	GBF CONTACT LENSES, INC. VIRGINIA BEACH, VA 23452	TWO SITES TO DO ADDITIONAL MANUFACTURING PROCEDURES
P790017/S46 05/20/93	USCI SOLITAIRE RAPID EXCHANGE BALLOON DILATATION CATHETER WITH PRO/PEL COATING	C.R. BARD, INC. BILLERICA, MA 01821	NEW MODEL CATHETER
P790017/S47 05/20/93	USCI GRUNTZIG DILACA CORONARY ARTERY BALLOON DILATATION CATHETER, USCI XPRT BALLOON DILATATION CATHETER WITH PRO/PEL COATING	C.R. BARD, INC. BILLERICA, MA 01821	NEW MODEL CATHETER

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT INDICATION OF DEVICE	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P800022/S42 05/13/93	ZYPLAST COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	ASSIST DEVICE AND ITS ASSOCIATED LABELING TO BE MADE AVAILABLE FOR USE WITH THE ZYPLAST COLLAGEN IMPLANT SYRINGE
P810006/S17 05/13/93	COLLASTAT MICROFIBRILLAR COLLAGEN, INSTAT MCH MICROFIBRILLAR COLLAGEN HEMOSTAT	VITAPHORE CORPORATION MENLO PARK, CA 94025	JOHNSON AND JOHNSON MEDICAL, INC. AS DISTRIBUTOR OF COLLASTAT MICROFIBRILLAR HEMOSTAT
P810039/S17 05/28/93	BAUSCH & LOMB SENSITIVE EYES DROPS	BAUSCH & LOMB ROCHESTER, NY 14692-0450	2 ML PROFESSIONAL SAMPLE SIZE IN A 7.5 ML LOW DENSITY POLYETHYLENE CONTAINER TO BE INCLUDED IN KITS DISTRIBUTED BY EYE CARE PRACTITIONERS
P810046/S138 05/04/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS RX PERFUSION CATHETER .30 MM BALLOON AND MODIFIED DISTAL JUNCTION	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	ADDITIONAL BALLOON LENGTH FOR THE ACS RX PERFUSION CATHETER AND MODIFICATION TO THE LUMEN JUNCTION UNDER THE BALLOON
P820053/S21 05/18/93	BARNES-HIND GAS PERMEABLE DAILY CLEANER	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE MANUFACTURING SITE

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT INDICATION OF DEVICE	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P820060/S07 05/13/93	ABBOTT AFP-EIA	ABBOTT LABORATORIES ABBOTT PARK, IL 60064	REVISED PACKAGE INSERT
P840004/S06 05/13/93	SATURN II (SYNERGICON A) CONTACT LENS	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	STABILITY TESTING PROTOCOL TO EXTEND THE EXPIRATION DATING
P840024/S35 05/20/93	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MANUFACTURING MODIFICATIONS
P840024/S39 05/20/93	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MODIFICATION OF THE MAGNET OPTION LABELING AND DISTRIBUTION OF THE NEW MAGNET OPTION
P840029/S04 05/17/93	HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	100 CM LENGTH OF THE SIZES 6, 8, AND 10 MM DIAMETER STRAIGHT SIZES OF THE HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT
P840029/S05 05/11/93	HEMASHIELD WOVEN DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	ADDITION OF THE HEMASHIELD WOVEN DOUBLE VELOUR GRAFT TO THE HEMASHIELD PRODUCT LINE
P840029/S06 05/17/93	HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	12 X 6 MM BIFURCATED SIZE OF THE HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT INDICATION OF DEVICE	DESCRIPTION AND
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P840029/S07 05/17/93	HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	7 MM X 100 CM SIZE OF THE HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT
P840029/S08 05/11/93	HEMASHIELD WOVEN DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	MODIFICATION OF THE LENGTH OF THE BIFURCATED SIZES OF THE HEMASHIELD WOVEN DOUBLE VELOUR GRAFT
P840029/S09 05/11/93	HEMASHIELD WOVEN DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	ADDITIONAL PACKAGE FOR THE 60 CM LENGTHS OF THE HEMASHIELD WOVEN DOUBLE VELOUR GRAFT
P840029/S10 05/11/93	HEMASHIELD WOVEN DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	MODIFICATION OF THE ACCEPTABLE LIMITS FOR THE SHRINK TEMPERATURE
P840029/S11 05/17/93	HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	MODIFICATION OF THE ACCEPTABLE LIMITS FOR THE SHRINK TEMPERATURE FOR THE HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT
P840029/S14 05/17/93	HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	ALTERNATE METHOD (AIR POROSITY) TO MEASURE POROSITY OF THE HEMASHIELD MICROVEL DOUBLE VELOUR GRAFT
P840029/S15 05/11/93	HEMASHIELD WOVEN DOUBLE VELOUR GRAFT	MEADOX MEDICALS, INC. OAKLAND, NJ 07436	USE OF AN ALTERNATE METHOD TO MEASURE POROSITY

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT INDICATION OF DEVICE	DESCRIPTION AND
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P840055/S31 05/27/93	SGP (TELEFOCON A) AND SGP II (TELEFOCON B) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR, BLUE AND GREEN TINTED)	PERMEABLE CONTACT LENSES, INC. MORGANVILLE, NJ 07751	ADDITIONAL CONTACT LENS FINISHING LABORATORY AS AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P850051/S38 05/18/93	ACTIVITRAX PACING SYSTEM, INTEGRATED CIRCUIT REVISION ON MEDTRONIC LEGEND AND CPI TRIUMPH VR PULSE GENERATORS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	REVISIONS TO THE L74 INTEGRATED CIRCUIT IN THE LEGEND PULSE GENERATOR MODELS 8416-8418, AND THE CPI TRIUMPH VR PULSE GENERATOR MODELS 1123-1125
P860019/S60 05/04/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER, RALLY PTCA CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	NEW MODEL EXCHANGE CATHETER TO BE MARKETED UNDER THE TRADE NAME RALLY
P860019/S61 05/04/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER, TRAPPER EXCHANGE DEVICE	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	REVISED LABELING
P870002/S10 05/11/93	APPLIED BUFFERED STERILE SALINE SOLUTION (AEROSOL)	APPLIED LABORATORIES, INC. COLUMBUS, IN 47202-0448	15 FL. OZ. SIZE AEROSOL PEERLESS CONTAINER WITH AN ARMITAGE 203 LINER

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT INDICATION OF DEVICE	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P870036/S20 05/04/93	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC 14K AND 18K PTCA CATHETERS	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	MANUFACTURING MODIFICATION
P880001/S38 05/11/93	FLUOREX 700 (FLUSILFOCON A), FLUOREX 500 (FLUSILFOCON B) AND FLUOREX 300 (FLUSILFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	G.T. LABORATORIES, INC. CHICAGO, IL 60602	THREE ALTERNATE MANUFACTURING AND DISTRIBUTING SITES
P880003/S07 05/04/93	HELIX PTCA DILATATION CATHETER, SLEUTH PTCA DILATATION CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	FINAL LABELING
P880009/S05 05/17/93	VIRAPAP HUMAN PAPILLOMAVIRUS DNA DETECTION KIT	DIGENE DIAGNOSTICS, INC. SILVER SPRING, MD 20904	CHANGE IN MANUFACTURING SITE
P880035/S02 05/19/93	VISTA OPTICS, OPTACRYL 18 (KOLFOCON A) AND VISTA OPTICS, OPTACRYL 32 (KOLFOCON B) RIGID GAS PERMEABLE CONTACT LENSES	VISTA OPTICS LIMITED BRADBURY, UK	ADDITION OF 17 FINISHING LABORATORIES AS ALTERNATE MANUFACTURERS AND DISTRIBUTORS

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT INDICATION OF DEVICE	DESCRIPTION AND
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P880078/S10 05/21/93	VH8500 HYPERTHERMIA TREATMENT SYSTEM	COOK INCORPORATED BLOOMINGTON, IN 47402	SOFTWARE REVISION
P880102/S02 05/05/93	LOMBART (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENSES, LL-38 (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENSES	LOMBART LENSES LTD. NORFOLK, VA 23507	ALTERNATE MANUFACTURING SITE
P890001/S05 05/04/93	LEOCOR PTCA CATHETER, MODEL 5S, LEOCOR PTCA CATHETER MODEL PICO-ST (COATED)	LEOCOR, INC. HOUSTON, TX 77058	ADDITION OF A SILICONE COATING TO THE LEOCOR PICO-CATH PTCA CATHETER
P890001/S07 05/04/93	LEOCOR PTCA CATHETER, MODEL 5S, LEOCOR PTCA CATHETER CORFLO MODEL 7.5PT (COATED)	LEOCOR, INC. HOUSTON, TX 77058	ADDITION OF A SILICONE COATING TO THE LEOCOR PTCA CATHETER CORFLO MODEL 7.5PT
P890027/S06 05/20/93	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MANUFACTURING MODIFICATIONS

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT INDICATION OF DEVICE	DESCRIPTION AND
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P890027/S10 05/20/93	NUCLEUS 22 CHANNEL COCHLEAR IMPLANT FOR USE IN CHILDREN AGES 2 THROUGH 17 YEARS	COCHLEAR CORPORATION ENGLEWOOD, CO 80112	MODIFICATION OF THE MAGNET OPTION LABELING AND DISTRIBUTION OF THE NEW MAGNET OPTION
P890043/S17 05/04/93	SIMPSON CORONARY ATHEROCATH, SCA-LP AND SCA-EX DEVICES	DEVICES FOR VASCULAR INTERVENTION, INC. REDWOOD CITY, CA 94063	MANUFACTURING MODIFICATION
P890044/S26 05/27/93	TRANS-AIRE (AMSILFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	BENITEC INCORPORATED SACRAMENTO, CA 95834	TWO ADDITIONAL CONTACT LENS FINISHING LABORATORIES AS ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P890064/S01 05/17/93	VIRATYPE HUMAN PAPILLOMAVIRUS DNA TYPING KIT	DIGENE DIAGNOSTICS, INC. SILVER SPRING, MD 20904	CHANGE IN MANUFACTURING SITE
P890072/S08 05/27/93	ALBERTA LENS 'S' (SULFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED WITH AN ULTRAVIOLET LIGHT ABSORBER)	PROGRESSIVE OPTICAL RESEARCH, LTD. ALBERTA, CANADA	THREE ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTING SITES

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT INDICATION OF DEVICE	DESCRIPTION AND
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MEDICAL DEVICE - PMA SUPPLEMENTALS

P900001/S09 05/27/93	SGP 3 (UNIFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR, BLUE AND GREEN TINTED)	PERMEABLE CONTACT LENSES, INC. MORGANVILLE, NJ 07751	ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY AS AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
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NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

140-958	EQUIPHEN	HORSES	LUITPOLD PHARM	PHENYLBUTAZONE
05-14-93	(PASTE)		SHIRLEY, NY	6GM/30GM
		11967		12GM/60GM

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR MAY 1993.

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR MAY 1993.

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

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Center for Drug Evaluation
and Research
*George R. Scott (301) 443-3910

Center for Devices and
Radiological Health
Mary Jo Robinson (301) 594-21

Center for Biologics
Evaluation and Research
Joseph Wilczek (301) 594-2012

Center for Veterinary Medicine
Melanie R. Berson, D.V.M.
(301) 594-1643

*To whom general inquiries should be directed.

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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL AND SUPPLEMENTAL NDAs FOR NEW DRUG PRODUCTS			
19-777 09-JUN-93 (SUPPL)	ZESTRIL (TABLET)	ZENECA WILMINGTON, DE 19897	LISINOPRIL 2.5MG 5MG 10MG 20MG 40MG (NEW INDICATION -- ADJUNCTIVE THERA MANAGEMENT OF HI
19-844 10-JUN-93 (5 S)	ISOLYTE H IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE 5GM/100ML MAGNESIUM CHLOR 30MG/100ML POTASSIUM CHLORI 97MG/100ML SODIUM ACETATE 220MG/100ML SODIUM CHLORIDE 140MG/100ML (NUTRITION/ELECTR REPLENISHER)

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE (DOSAGE FORM)				STRENGTH(S)

ORIGINAL VETERINARY NADAs

19-864 10-JUN-93 (5 S)	ISOLYTE R IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)		MCGAW IRVINE, CA 92713	CALCIUM CHLORIDE 37MG/100ML DEXTROSE 5GM/100ML MAGNESIUM CHLOR 31MG/100ML POTASSIUM CHLORI 120MG/100ML SODIUM ACETATE 330MG/100ML SODIUM CHLORIDE 88MG/100ML (NUTRITION/ELECTR REPLENISHER)
19-870 10-JUN-93 (5 S)	ISOLYTE M IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)		MCGAW IRVINE, CA 92713	DEXTROSE 5GM/100ML POTASSIUM CHLORIDE 150MG/100ML POTASSIUM PHOSPHATE, DIBA 130MG/100ML SODIUM ACETATE 280MG/100ML SODIUM CHLORIDE 91MG/100ML (NUTRITION/ELECTROLYTE REPLENISHER)

NUMBER DOVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL AND SUPPLEMENTAL NDAs FOR NEW DRUG PRODUCTS			
19-873 10-JUN-93 (5 S)	ISOLYTE P IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE 5GM/100ML MAGNESIUM CHLORIDE 31MG/100ML POTASSIUM CHLORIDE 130MG/100ML POTASSIUM PHOSPHATE, DIBAS 26MG/100ML SODIUM ACETATE 320MG/100ML (NUTRITION/ELECTROLYTE REPLENISHER)
18-155 11-JUN-93 (SUPPL)	OPTICROM (SOLUTION/DROPS)	FISONS ROCHESTER, NY 14603	CROMOLYN SODIUM 4% (REMOVAL OF INDICATION -- GIANT PAPILLARY CONJUNCTIVITIS)
19-558 14-JUN-93 (SUPPL)	PRINIVIL (TABLET)	MERCK WEST POINT, PA 19486	LISINOPRIL 5MG 10MG 20MG 40MG (NEW INDICATION -- ADJUNCTIVE THERAPY IN THE MANAGEMENT OF HEART FAILURE)
19-287 18-JUN-93 (3 S)	DIZAC (INJECTABLE)	KABI PHARMACIA CLAYTON, NC 27520	DIAZEPAM 5MG/ML (ANTI-ANXIETY AGENTS/ ANXIOLYTICS)
20-134 18-JUN-93 (1 P)	METASTRON (INJECTABLE)	MEDI PHYSICS ARLINGTON HEIGHTS, IL 60005	STRONTIUM CHLORIDE, SR-89 1MCI/ML (RADIOPHARMACEUTICALS) [RELIEF OF BONE PAIN IN PATIENTS WITH PAINFUL SKELETAL METASTASES]

NUMBER DOVAL DATE CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL AND SUPPLEMENTAL NDAs FOR NEW DRUG PRODUCTS			
20-215 30-JUN-93 (5 S)	MONOKET (TABLET)	SCHWARZ PHARMA MILWAUKEE, WI 53201	ISOSORBIDE MONONITRATE 10MG 20MG (VASODILATORS)
50-617 30-JUN-93 (SUPPL)	ERYGEL (GEL)	ALLERGAN IRVINE, CA 92713	ERYTHROMYCIN 2% (NEW DOSAGE REGIMEN -- ONCE OR TWICE DAILY APPLICATION)

NDA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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APPROVABLE ORIGINAL NDAs

An *approvable letter* indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters *may not be* legally *marketed* until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

20-136 07-JUN-93	DEMADEX (TABLET)	BOEHRINGER MANNHEIM ROCKVILLE, MD 20850	TORSEMIDE 5MG 10MG 20MG 100MG (DIURETICS AND RENAL TUBULE INHIBITORS) [HYPERTENSION/EDEMA]
20-137 07-JUN-93	DEMADEX (INJECTABLE)	BOEHRINGER MANNHEIM ROCKVILLE, MD 20850	TORSEMIDE 10MG/ML (DIURETICS AND RENAL TUBULE INHIBITORS) [HYPERTENSION/EDEMA]
20-330 24-JUN-93	TIMOPTIC-XE (SOLUTION/DROPS)	MERCK WEST POINT, PA 19486	TIMOLOL MALEATE EQ 0.25% BASE EQ 0.5% BASE (BETA BLOCKERS)
19-746 30-JUN-93	CHLORPHENIRAMINE MALEATE (TABLET, EXTENDED RELEASE)	ALZA PALO ALTO, CA 94303	CHLORPHENIRAMINE MALEATE 16MG (ANTIHISTAMINE) (OTC)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL ABBREVIATED NDAS			
72-801 15-JUN-93	METOCLOPRAMIDE HCL (TABLET)	BIOCRAFT FAIR LAWN, NJ 07410	METOCLOPRAMIDE HYDROCHLOR EQ 5MG BASE (MOTILITY STIMULANTS)
74-116 15-JUN-93	PIROXICAM (CAPSULE)	MEPHA AG SWITZERLAND	PIROXICAM 10MG (NSAID)
74-118 15-JUN-93	PIROXICAM (CAPSULE)	MEPHA AG SWITZERLAND	PIROXICAM 20MG (NSAID)
72-648 16-JUN-93	TIMOLOL MALEATE (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	TIMOLOL MALEATE 5MG (BETA BLOCKERS)
72-649 16-JUN-93	TIMOLOL MALEATE (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	TIMOLOL MALEATE 10MG (BETA BLOCKERS)
72-650 16-JUN-93	TIMOLOL MALEATE (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	TIMOLOL MALEATE 20MG (BETA BLOCKERS)
73-038 22-JUN-93	SULINDAC (TABLET)	MYLAN MORGANTOWN, WV 26504	SULINDAC 150MG (NSAID)
73-039 22-JUN-93	SULINDAC (TABLET)	MYLAN MORGANTOWN, WV 26504	SULINDAC 200MG (NSAID)
71-402 25-JUN-93	METOCLOPRAMIDE HCL (SOLUTION)	LIQUIPHARM LOS ANGELES, CA 90034	METOCLOPRAMIDE HYDROCHLOR EQ 5MG BASE/5ML (MOTILITY STIMULANTS)
72-779 25-JUN-93	ALBUTEROL SULFATE (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	ALBUTEROL SULFATE EQ 2MG BASE (BETA-2 AGONIST)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL ABBREVIATED NDAS			
72-780 25-JUN-93	ALBUTEROL SULFATE (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	ALBUTEROL SULFATE EQ 4MG BASE (BETA-2 AGONIST)
74-028 28-JUN-93	AMANTADINE HCL (SYRUP)	MIKART ATLANTA, GA 30318	AMANTADINE HYDROCHLORIDE 50MG/5ML (ANTIVIRAL - ANTI-INFLUENZA)
72-923 29-JUN-93	VERAPAMIL HCL (TABLET)	WATSON LABS CORONA, CA 91720	VERAPAMIL HYDROCHLORIDE 40MG (CALCIUM CHANNEL BLOCKERS)
72-924 29-JUN-93	VERAPAMIL HCL (TABLET)	WATSON LABS CORONA, CA 91720	VERAPAMIL HYDROCHLORIDE 40MG (CALCIUM CHANNEL BLOCKERS)
73-484 29-JUN-93	VALPROIC ACID (CAPSULE)	PHARMACAPS ELIZABETH, NJ 07207	VALPROIC ACID 250MG (ANTICONVULSANTS)
40-001* 30-JUN-93	METHAZOLAMIDE (TABLET)	COPLEY PHARM CANTON, MA 02021	METHAZOLAMIDE 25MG 50MG (CARBONIC ANHYDRASE INHIBITO
40-036* 30-JUN-93	METHAZOLAMIDE (TABLET)	GENEVA BROOMFIELD, CO 80038	METHAZOLAMIDE 25MG 50MG (CARBONIC ANHYDRASE INHIBITO
71-315 30-JUN-93	METOCLOPRAMIDE HCL (SOLUTION)	LEMMON SELLERSVILLE, PA 18960	METOCLOPRAMIDE HYDROCHLOR EQ 5MG BASE/5ML (MOTILITY STIMULANTS)
81-295* 30-JUN-93	ESTRACE (TABLET)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	ESTRADIOL 0.5MG (ESTROGENS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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ORIGINAL ABBREVIATED NDAS

* - First Time Product Available Generically

NDA NUMBER TENTATIVE APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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ORIGINAL ABBREVIATED NDAs WITH TENTATIVE APPROVALS

A *tentative approval* indicates that FDA has given an abbreviated new drug application (ANDA) provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Generic drug products that are the subjects of tentative approvals **may not be** legally **marketed** until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the ANDA receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluation" list published by FDA. Additional information on these ANDAs will become available to the public when the applications receive final approval.

74-198 22-JUN-93	NAPROXEN SODIUM (TABLET)	LEMMON SELLERSVILLE, PA 18960	NAPROXEN SODIUM 275MG 550MG (NSAID)
74-162 29-JUN-93	NAPROXEN SODIUM (TABLET)	GENEVA BROOMFIELD, CO 80038	NAPROXEN SODIUM 275MG 550MG (NSAID)
74-140 30-JUN-93	NAPROXEN (TABLET)	GENEVA BROOMFIELD, CO 80038	NAPROXEN 250MG 375MG 500MG (NSAID)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
20-036 06-MAY-93	AREZIA (INJECTABLE)	CIBA SUMMIT, NJ 07901	PAMIDRONATE DISODIUM 30MG/VIAL 60MG/VIAL 90MG/VIAL (LABELING REVISION -- DESCRIPTION; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
17-694 01-JUN-93	IMODIUM (CAPSULE)	JANSSEN PISCATAWAY, NJ 08854	LOPERAMIDE HYDROCHLORIDE 2MG (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; DRUG ABUSE AND DEPENDENCE)
18-760 04-JUN-93	TENORETIC 50 (TABLET)	ICI PHARMS WILMINGTON, DE 19897	ATENOLOL 50MG CHLORTHALIDONE 25MG (LABELING REVISION -- ADVERSE REACTIONS; POTENTIAL ADVERSE EFFECTS)
18-760 04-JUN-93	TENORETIC 100 (TABLET)	ICI PHARMS WILMINGTON, DE 19897	ATENOLOL 100MG CHLORTHALIDONE 25MG (LABELING REVISION -- ADVERSE REACTIONS; POTENTIAL ADVERSE EFFECTS)
17-831 07-JUN-93	DIDRONEL (TABLET)	P AND G NORWICH, NY 13815	ETIDRONATE DISODIUM 200MG 400MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
*** LABELING SUPPLEMENTS TO ORIGINAL NDAs ***			
09-218 08-JUN-93	COUMADIN (TABLET)	DUPONT WILMINGTON, DE 19880	WARFARIN SODIUM 1MG 2MG 2.5MG 5MG 7.5MG 10MG (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; ADVERSE REACTIONS DOSAGE AND LABORATORY CONT
18-469 08-JUN-93	BSS PLUS (SOLUTION)	ALCON LABS FORT WORTH, TX 76134	CALCIUM CHLORIDE 0.154MG/ML DEXTROSE 0.92MG/ML GLUTATHIONE DISULFIDE 0.184MG/ML MAGNESIUM CHLORIDE 0.2MG/ML POTASSIUM CHLORIDE 0.38MG/ML SODIUM BICARBONATE 2.1MG/ML SODIUM CHLORIDE 7.14MG/ML SODIUM PHOSPHATE 0.42MG/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
***** LABELING SUPPLEMENTS TO ORIGINAL NDAs *****			
19-777 09-JUN-93	ZESTRIL (TABLET)	ZENECA PHARMS WILMINGTON, DE 19897	LISINAPRIL 2.5MG 5MG 10MG 20MG 40MG (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
20-036 09-JUN-93	ARELIA (INJECTABLE)	CIBA GEIGY SUMMIT, NJ 07901	PAMIDRONATE DISODIUM 30MG/VIAL 60MG/VIAL 90MG/VIAL (LABELING REVISION -- ADVERSE REACTIONS)
18-155 11-JUN-93	OPTICROM (SOLUTION/DROPS)	FISONS BEDFORD, MA 01730	CROMOLYN SODIUM 4% (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
19-558 14-JUN-93	PRINIVIL (TABLET)	MERCK WEST POINT, PA 19486	LISINOPRIL 5MG 10MG 20MG 40MG (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
50-420 18-JUN-93	RIFADIN (CAPSULE)	MERRELL DOW PHARMS CINCINNATI, OH 45215	RIFAMPIN 300MG (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; ADVERSE REACTIONS)
50-504 18-JUN-93	MANDOL (INJECTABLE)	LILLY INDIANAPOLIS, IN 46285	CEFAMANDOLE NAFATE EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL (LABELING REVISION -- INDICATIONS AND USAGE)
50-627 18-JUN-93	RIFADIN (INJECTABLE)	MERRELL DOW PHARMS CINCINNATI, OH 45215	RIFAMPIN 600MG/VIAL (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; ADVERSE REACTIONS)
18-401 25-JUN-93	BUPRENEX (INJECTABLE)	RECKITT AND COLMAN RICHMOND, VA 23235	BUPRENORPHINE HYDROCHLORIDE EQ 0.3MG BASE/ML (LABELING REVISION -- PRECAUTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
***** LABELING SUPPLEMENTS TO ORIGINAL NDAs *****			
18-484 26-JUN-93	PROSTIN VR PEDIATRIC (INJECTABLE)	UPJOHN KALAMAZOO, MI 49001	ALPROSTADIL 0.5MG/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
19-574 26-JUN-93	THALITONE (TABLET)	HORUS ROCHESTER, NY 14623	CHLORTHALIDONE 15MG (LABELING REVISION -- PRECAUTIONS; DOSAGE AND ADMINISTRATION)
50-614 28-JUN-93	KEFTAB (TABLET)	LILLY INDIANAPOLIS, IN 46285	CEPHALEXIN HYDROCHLORIDE EQ 250MG BASE EQ 500MG BASE (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS)
19-384 29-JUN-93	NOROXIN (TABLET)	MERCK WEST POINT, PA 19486	NORFLOXACIN 400MG (LABELING REVISION -- ADVERSE REACTIONS)
50-606 30-JUN-93	VANCOCIN HCL (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	VANCOMYCIN HYDROCHLORIDE EQ 125MG/BASE EQ 250MG/BASE (LABELING REVISION -- ADVERSE REACTIONS)
50-617 30-JUN-93	ERYGEL (GEL)	ALLERGAN HERBERT IRVINE, CA 92713	ERYTHROMYCIN 2% (LABELING REVISION -- DOSAGE AND ADMINISTRATION)

LICENCE NUMBER LICENCE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
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BIOLOGICAL PRODUCT LICENCES ISSUED

0202 07-JUN-93	NONE (INJECTABLE)	TACOMA PIERCE CNTY BLOOD BANK TACOMA, WA 98405	CRYOPRECIPITATED AHF (TRANSFUSION) (B)
1106 22-JUN-93	CHIRON RIBA HCV 2.0 SIA (IN VITRO TEST)	CHIRON EMERYVILLE, CA 94608	HEPATITIS C VIRUS ENCODED ANTIGEN RECOMBINANT (RIBA) (QUALITATIVE STRIP IMMUNOBLOT ASSAY) (B)

LICENCE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
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BIOLOGICAL PRODUCT LICENCES ISSUED

(B) Product License Issued

DEVICE NUMBER APPROVABLE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
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BIOLOGICAL PRODUCT DEVICE APPROVALS

BK910032 07-JUN-93	OPTIPRESS	BAXTER HLTHCARE ROUND LAKE, IL 60073	BLOOD BANK SUPPLIES (C)
BK920022 07-JUN-93	RCM-MB-30 PLASMA STORAGE BAG	STERICON BROADVIEW, IL 60153	TRANSFER SETS (C)
BK920024 07-JUN-93	MUREX PEG POTENTIATOR FOR ANTIBODY DETECTION	MUREX BIOLGS CONROE, TX 77305	POTENTIATING MEDIA FOR IN VITRO DIAGNOSTIC USE (C)
BK920028 07-JUN-93	VIROTROL HIV-2	BLACKHAWK BIOSYSTEMS SAN RAMON, CA 94583	QUALITY CONTROL KITS FOR BLOOD BANKING REAGENTS (C)
BK920032 07-JUN-93	SEPACELL PRE-STORAGE LEUKOCYTE DEPLETION SET FOR RED CELL	BAXTER HLTHCARE ROUND LAKE, IL 60073	EMPTY CONTAINERS FOR COLLECTIVE PROCESSING OF BLOOD AND BLOOD COMPONENTS (C)

DEVICE NUMBER APPROVABLE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
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BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

****THERE ARE NO PREMARKET APPROVAL APPLICATIONS FOR JUNE 1993.****

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

N17003/S04 06/08/93	SURGICAL SIMPLEX P BONE CEMENT	HOWMEDICA, INC. RUTHERFORD, NJ 07070-2584	ALTERNATE FACILITY TO MANUFACTURE THE POWDER COMPONENT OF THE SURGICAL SIMPLEX P BONE CEMENT
N17987/S24 06/22/93	CSI COLOURS (CROFILCON A) CONTACT LENS	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	STABILITY TESTING PROTOCOL TO EXTEND THE EXPIRATION DATING THE CSI COLOURS (CROFILCON A) CONTACT LENS
N18020/S38 06/29/93	ALLERGAN PRESERVED SALINE SOLUTION	ALLERGAN OPTICAL IRVINE, CA 92713-9534	MODIFIED SPECIFICATIONS FOR SODIUM CHLORIDE AND OSMOLAL FOR THE ALLERGAN PRESERVED SALINE SOLUTION
N50510/S52 06/24/93	VITEK SYSTEMS GENERAL SUSCEPTIBILITY CARD	BIOMERIEUX VITEK, INC. HAZELWOOD, MO 63042	ADDITION OF OFLOXACIN (1, 2, AND 8 MCG/ML) TO THE VITEK GRAM-POSITIVE ANTIMICROBIAL SUSCEPTIBILITY PANELS
P790002/S14 06/14/93	EBI BI-OSTEOGEN BONE HEALING SYSTEM	ELECTRO-BIOLOGY, INC. PARSIPPANY, NJ 07054-1079	MODIFIED VERSION OF THE EBI BI HEALING SYSTEM, MODEL 1020 TO DESIGNATED THE EBI BONE HEAL SYSTEM MODEL 123
P790017/S43 06/04/93	USCI GRUNTZIG DILACA CORONARY ARTERY BALLOON DILATATION CATHETER, USCI SPRINT BALLOON DILATATION CATHETER	C.R. BARD, INC. BILLERICA, MA 01821	TAPERED BALLOON CATHETER INDICATED FOR PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY
P800036/S29 06/17/93	MODEL 400 IMPLANTABLE PUMP	INFUSAID INC. NORWOOD, MA 02062	RESUMPTION OF COMMERCIAL DISTRIBUTION OF THE MODEL 400 IMPLANTABLE PUMP WITH SEPTUM MATERIAL P/N 36290

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

P820018/S58 06/18/93	AUTIMA MODEL 2251 PULSE GENERATOR AND MODEL 2600 PROGRAMMER, MODEL 9600 NETWORK PROGRAMMER SOFTWARE VERSION 4.50UE	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	APPROVAL FOR THE MODEL 9600 NETWORK PROGRAMMER SOFTWARE VERSION 4.50UE
P830045/S42 06/04/93	AFP MODEL 283 PULSE GENERATOR W/MODEL 370 PROGRAMMER, PARAGON MODELS 2010/2011, PARAGON II MODEL 2016, PHOENIX MODELS 2005/2008/2009	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	APPROVAL FOR AN ADDITIONAL QUARTZ CRYSTAL COMPONENT TEST
P830055/S23 06/08/93	POSTERIOR CRUCIATE RETAINING DEVICE, CONFIGURATION OF THE LCS TOTAL KNEE SYSTEM WITH POROCOAT	DEPUY INC. WARSAW, IN 46581-0988	CHANGE IN THE POST APPROVAL STUDY; REDUCTION FROM 350 TO OF THE NUMBER OF CASES ENTER THE STUDY
P830055/S25 06/04/93	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	CHANGE IN THE RADIUS OF THE SULCUS ANGLE OF THE FEMORAL COMPONENTS
P830055/S27 06/04/93	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	ADDITION OF TIBIAL TRAYS
P830055/S28 06/04/93	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	ADDITION OF TIBIAL TRAYS
P830055/S29 06/04/93	NEW JERSEY LCS TOTAL KNEE SYSTEM	DEPUY, INC. WARSAW, IN 46581-0988	ADDITIONAL SUPPLIER OF LIDSTOCK PACKAGING

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS			
P840062/S04 06/24/93	COLLACOTE, COLLATAPE, COLLAPLUG, ABSORBABLE COLLAGEN WOUND DRESSINGS FOR DENTAL SURGERY	COLLA-TEC, INC. PLAINSBORO, NJ 08536	CHANGE OF DISTRIBUTOR
P850010/S14 06/08/93	HELISTAT ABSORBABLE COLLAGEN HEMOSTATIC AGENT AND HELITENE ABSORBABLE COLLAGEN HEMOSTATIC AGENT--FIBRILLAR FORM	COLLA-TEC, INC. PLAINSBORO, NJ 08536	CALGON VESTAL LABORATORIES DISTRIBUTOR
P850088/S26 06/09/93	ULTRACARE NEUTRALIZING TABLETS	ALLERGAN OPTICAL IRVINE, CA 92713-9534	ALTERNATE SITE FOR PLACING NEUTRALIZING TABLETS INTO "CHECKBOOKS" BEFORE FINAL ASSEMBLY INTO COMBINATION CARTONS
P860019/S56 06/15/93	SC SHADOW	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	APPROVAL FOR A "PATENTED TAP TECHNOLOGY" LABEL
P860019/S66 06/15/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, NC COBRA 14	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	NEW MODEL CATHETER
P860019/S67 06/14/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, ACE, QUANTUM, GRAFT ACE, EXPRESS, RALLY AND COBRA 10	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	REVISED LABELING

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS			
P860027/S09 06/03/93	MAESTRO SERIES 500 PULSE GENERATOR, MODELS 501, 505, 509, MAESTRO MODEL 1006/1006P PROGRAMMER RELEASE III SOFTWARE	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	APPROVAL FOR THE MAESTRO MO 1006/1006P PROGRAMMER RELEA SOFTWARE
P870024/S29 06/22/93	FLUOROPERM (PAFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS, FLUOROPERM ST BIFOCAL (PAFLUFOCON B) RIGID GAS PERMEABLE CONTACT LENS	PARAGON OPTICAL MESA, AZ 85204	MANUFACTURING MODIFICATIONS
P880003/S10 06/17/93	CORDIS PTCA DILATATION CATHETERS, CORDIS SLEEK PTCA DILATATION CATHETERS	CORDIS CORPORATION MIAMI, FL 33102-5700	APPROVAL FOR CORDIS SLEEK PT DILATATION CATHETERS
P880003/S11 06/17/93	CORDIS PTCA DILATATION CATHETERS, OLYMPIX AND SLEUTH XT PTCA DILATATION CATHETERS (WITH 3 CM LONG BALLOONS)	CORDIS CORPORATION MIAMI, FL 33102-5700	APPROVAL FOR A 3 CM LONG BAL
P880003/S12 06/17/93	CORDIS PTCA DILATATION CATHETERS, OLYMPIX AND SLEUTH XT PTCA DILATATION CATHETERS (WITH 4 CM LONG BALLOONS)	CORDIS CORPORATION MIAMI, FL 33102-5700	APPROVAL FOR A 4 CM LONG BAL

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS			
P880038/S23 06/18/93	META-MV CARDIAC PACING SYSTEM, MODEL 9600 NETWORK PROGRAMMER SOFTWARE VERSION 4.50UE	TELECTRONICS PACING SYSTEMS, INC. ENGLEWOOD, CO 80112	APPROVAL FOR THE MODEL 9600 NETWORK PROGRAMMER SOFTWARE VERSION 4.50UE
P880086/S21 06/04/93	SYNCHRONY MODEL 2020T, SOLUS MODELS 2002/2003, SOLUS II MODELS 2006/2007, SYNCHRONY II MODELS 2022/2023, SYNCHRONY III MODELS 2028/2029 PULSE GENERATORS	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	APPROVAL FOR AN ADDITIONAL QUARTZ CRYSTAL COMPONENT T
P890003/S20 06/03/93	SYNERGYST II MODELS 7070 AND 7071, MODEL 9858A SOFTWARE DISKETTES FOR USE WITH THE MODEL 9760 PROGRAMMER SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR THE MODEL 9858A SOFTWARE DISKETTES FOR USE WITH THE MODEL 9760 PROGRAMMER SYSTEM
P890032/S14 06/17/93	CORDIS ORION STEERABLE PTCA BALLOON CATHETER, CORDIS LIGHTNING STEERABLE PTCA BALLOON CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	APPROVAL FOR THE ORION II STEERABLE PTCA BALLOON CATH
P890039/S08 06/24/93	MAESTRO II SAVVI MODEL 333 PACING SYSTEM	CARDIAC CONTROL SYSTEM, INC. PALM COAST, FL 32137	APPROVAL FOR THE MAESTRO II MODEL 333 VDD PACING SYSTEM
P900032/S01 06/22/93	DYMER 200+ EXCIMER LASER SYSTEM, LAIS MODEL PC4010 MULTIFIBER LASER CATHETER	ADVANCED INTERVENTIONAL SYSTEMS IRVINE, CA 92718	APPROVAL FOR THE MODEL PC4010 (1.3MM) LASER CATHETER
P900032/S02 06/22/93	DYMER 200+ EXCIMER LASER SYSTEM, LAIS MODEL PC4021 MULTIFIBER LASER CATHETER	ADVANCED INTERVENTIONAL SYSTEMS IRVINE, CA 92718	APPROVAL FOR THE MODEL PC4021 (1.6MM) LASER CATHETER

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS			
P900050/S01 06/14/93	ACCESS MOBILITY SYSTEM	QUEST TECHNOLOGIES CORPORATION SUNNYVALE, CA 94086-9716	ADDITION OF THE ACCESS MOBIL SYSTEM ATTENDANT CONTROL
P900070/S01 06/29/93	META DDDR PACING SYSTEM MODELS 1250H AND 1254 WITH MODEL 9600 PROGRAMMER SOFTWARE VERSION 4.5	TELECTRONICS PACING SYSTEMS ENGLEWOOD, CO 80112	INTRODUCTION OF THE META DDDR MODEL 1254 PULSE GENER AND A MODIFIED VERSION OF THE MODEL 1250H AND 9600 PROGRAMMER SOFTWARE VERSION 4.5
P910016/S02 06/08/93	NEW JERSEY UNICOMPARTMENTAL LCS KNEE	DEPUY WARSAW, IN 46580	ADDITION OF PAPER MANUFACTU COMPANY AS A SUPPLIER OF TYV LIDSTOCK PACKAGING
P910029/S01 06/29/93	BLANCHARD SOFT (POLYMACON) CONTACT LENS, ESSTECH PS ASPHERIC (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENS	LES LABORATORIES BLANCHARD QUEBEC, CANADA	APPROVAL TO MANUFACTURE AND DISTRIBUTE AN ALTERNATE DESIGN CONFIGURATION OF THE BLANCHARD SOFT LENS

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL VETRINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR JUNE 1993.

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR JUNE 1993.

SUPPLEMENTAL VETERINARY NADAs

065-269 29-JUN-93	POLYOTIC SOLUBLE (POWDER)	CALVES, SWINE	AM CYANAMID WAYNE, NJ 07470	TETRACYCLINE HYDROCHLORIDE 25GM/LB
065-441 29-JUN-93	POLYOTIC SOLUBLE CONCENTRATE (POWDER)	CALVES, SWINE	AM CYANAMID WAYNE, NJ 07470	TETRACYCLINE HYDROCHLORIDE 102.4GM/LB

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL VETRINARY NADAs

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL VETRINARY NADAs

**FDA DRUG AND DEVICE
PRODUCT APPROVALS**

**VOLUME 16 (07)
JULY 1993**

**Center for Drug Evaluation
and Research**
*George R. Scott (301) 443-3910

**Center for Devices and
Radiological Health**
Mary Jo Robinson (301) 594-21

**Center for Biologics
Evaluation and Research**
Joseph Wilczek (301) 594-2012

Center for Veterinary Medicine
Norman Turner
(301) 594-1623

*To whom general inquiries should be directed.

This report is compiled by the Division of Drug Information Resources, OM, CDER.
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Springfield, VA 22161.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL AND SUPPLEMENTAL NDAs FOR NEW DRUG PRODUCTS			
18-602 01-JUL-93 (SUPPL)	CARDIZEM (TABLET)	MARION MERRELL DOW KANSAS CITY, MO 64137	DILTIAZEM HYDROCHLORIDE 30MG 60MG 90MG 120MG (INDICATION CHANGE -- REMOVAL OF SECOND LINE RESTRICTIONS FOR USE IN ANGINA PATIENTS; REFERENCE TO STUDIES DELE

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
ORIGINAL VETRINARY NADAs			
20-315 09-JUL-93 (1 P, V*)	ORLAAM (CONCENTRATE)	BIOMETRIC RES ARLINGTON, VA 22209	LEVOMETHADYL ACETATE HYDROCHLORIDE 10MG/ML (OPIATE AGONIST) [MANAGEMENT OF OPIATE DEPENDENCE]
18-956 13-JUL-93 (SUPPL)	OMNIPAQUE 180 (INJECTABLE)	STERLING NEW YORK, NY 10016	IOHEXOL 38.8% (NEW ROUTE -- ORAL OR RECTAL USE IN CHILDREN FOR THE EXAMINAT OF THE GASTROINTESTINAL TR
18-956 13-JUL-93 (SUPPL)	OMNIPAQUE 240 (SOLUTION)	STERLING NEW YORK, NY 10016	IOHEXOL 51.8% (NEW ROUTE -- ORAL OR RECTAL USE IN CHILDREN FOR THE EXAMINAT OF THE GASTROINTESTINAL TR
V* - Designated Orphan Drug			
18-956 13-JUL-93 (SUPPL)	OMNIPAQUE 300 (SOLUTION)	STERLING NEW YORK, NY 10016	IOHEXOL 64.7% (NEW ROUTE -- ORAL OR RECTAL USE IN CHILDREN FOR THE EXAMINAT OF THE GASTROINTESTINAL TR
18-473 20-JUL-93 (SUPPL)	VENTOLIN (AEROSOL, METERED)	GLAXO RES TRIANGLE PK, NC 27709	ALBUTEROL 0.09MG/INH (NEW INDICATION -- PREVENTION OF EXERCISE - INDUCED BRONCHOSPASM IN CHILDREN AGES 4-11 YEARS)
19-489 20-JUL-93 (SUPPL)	VENTOLIN ROTACAPS (CAPSULE)	GLAXO RES TRIANGLE PK, NC 27709	ALBUTEROL SULFATE EQ 0.2MG BASE (NEW INDICATION -- PREVENTION OF EXERCISE - INDUCED BRONCHOSPASM IN CHILDREN AGES 4-11 YEARS)
20-006 26-JUL-93 (5 S)	MANNITOL 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	MANNITOL 5GM/100ML (OSMOTIC DIURETICS)

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL AND SUPPLEMENTAL NDAs FOR NEW DRUG PRODUCTS			
20-006 26-JUL-93 (5 S)	MANNITOL 10% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	MANNITOL 10GM/100ML (OSMOTIC DIURETICS)
20-006 26-JUL-93 (5 S)	MANNITOL 15% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	MANNITOL 15GM/100ML (OSMOTIC DIURETICS)
20-006 26-JUL-93 (5 S)	MANNITOL 20% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	MANNITOL 20GM/100ML (OSMOTIC DIURETICS)
19-710 27-JUL-93 (SUPPL)	OPTIRAY 350 (INJECTABLE)	MALLINCKRODT SAINT LOUIS, MO 63134	IOVERSOL 74% (NEW INDICATION -- PEDIATRIC ANGIOCARDIOGRA
20-189 29-JUL-93 (1 P, V*)	FELBATOL (SUSPENSION)	WALLACE LABS CRANBURY, NJ 08512	FELBAMATE 600MG/5ML (ANTICONSULTANTS)
20-189 29-JUL-93 (1 P, V*)	FELBATOL (TABLET)	WALLACE LABS CRANBURY, NJ 08512	FELBAMATE 400MG 600MG (ANTICONSULTANTS)
20-210 29-JUL-93 (1 S)	PROPULSID (TABLET)	JANSSEN PISCATAWAY, NJ 08855	CISAPRIDE MONOHYDRATE EQ 10MG BASE EQ 20MG BASE (UPPER GI TRACT MOTILITY STIMULATOR) [SYMPTOMATIC TREATMENT O PATIENTS WITH NOCTURNAL HEARTBURN DUE TO GERD]
19-921 30-JUL-93 (3 S)	OCUFLOX (SOLUTION, DROPS)	ALLERGAN IRVINE, CA 92713	OFLOXACIN 0.3% (OPHTHALMIC-QUINOLONE ANTIBACTERIALS)

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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*****ORIGINAL AND SUPPLEMENTAL NDAs***
FOR NEW DRUG PRODUCTS**

20-258
30-JUL-93
(3 P)

IOPIDINE
(SOLUTION, DROPS)

ALCON
FORT WORTH, TX
76134

APRACLONIDINE HYDROCHLORIDE
EQ 0.5% BASE
(ALPHA ADRENERGIC AGONIST)
[SHORT-TERM ADJUNCTIVE
THERAPY
FOR INTRA-OCULAR PRESSURE
REDUCTION]

50-694
30-JUL-93
(5 S)

CEFOTAN
IN PLASTIC CONTAINER
(INJECTABLE)

ZENECA PHARMS
WILMINGTON, DE
19897

CEFOTETAN DISODIUM
EQ 20MG BASE/ML
EQ 40MG BASE/ML
(ANTIBIOTIC, CEPHALOSPORIN)

V* - Designated Orphan Drug

NDA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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APPROVABLE ORIGINAL NDAs

An **approvable letter** indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters **may not be** legally **marketed** until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

20-304 01-JUL-93	TRASYLOL (INJECTABLE)	MILES PHARM WEST HAVEN, CT 06516	APROTININ BOVINE 10,000 UNITS/ML (FIBRINOLYTICS/ ANTIFIBRINOLYTICS)
20-225 15-JUL-93	IMDUR (EXTENDED RELEASE, TABLET)	SCHERING KENILWORTH, NJ 07033	ISOSORBIDE MONONITRATE 30MG 60MG (VASODILATOR)
50-657 26-JUL-93	MINOCYCLINE HCL (CAPSULE, COATED PELLETS)	FAULDING SALISBURY SOUTH AUSTRALIA	MINOCYCLINE HYDROCHLORIDE EQ 50MG BASE EQ 100MG BASE (TETRACYCLINES - SYSTEMIC)
20-322 30-JUL-93	DIFLUCAN (TABLET)	PFIZER CENTRAL RES GROTON, CT 06340	FLUCONAZOLE 150MG (ANTIFUNGAL-VAGINAL) [VAGINAL CANDIDA INFECTIONS]

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
*** ORIGINAL ABBREVIATED NDAS ***			
62-797 12-JUL-93	AMPICILLIN SODIUM (INJECTABLE)	IBI APRILIA, ITALY	AMPICILLIN SODIUM EQ 125MG BASE/VIAL EQ 2GM BASE/VIAL (PENICILLINS)
74-165* 16-JUL-93	CLOTRIMAZOLE (CREAM)	NMC GLENDALE, NY 11385	CLOTRIMAZOLE 1% (FUNGICIDES) (OTC)
63-295* 26-JUL-93	MONOCID (INJECTABLE)	SMITHKLINE BEECHAM PHILADELPHIA, PA 19101	CEFONICID SODIUM EQ 1GM BASE/VIAL (CEPHALOSPORINS)
74-234 26-JUL-93	NORTRIPTYLINE HCL (CAPSULE)	MYLAN MORGANTOWN, WV 26505	NORTRIPTYLINE HYDROCHLORIDE EQ 10MG BASE EQ 25MG BASE EQ 50MG BASE EQ 75MG BASE (ANTIDEPRESSANTS)
62-751 30-JUL-93	C-SOLVE-2 (SWAB)	SYOSSET LABS SYOSSET, NY 11791	ERYTHROMYCIN 2% (ANTIBIOTIC, MACROLIDE)
63-253 30-JUL-93	ERYTHROMYCIN LACTOBIONATE (INJECTABLE)	GENSIA IRVINE, CA 92718	ERYTHROMYCIN LACTOBIONATE EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL (ANTIBIOTIC, MACROLIDE)
63-350 30-JUL-93	AMIKACIN SULFATE (INJECTABLE)	DUPONT MERCK GARDEN CITY, NY 11530	AMIKACIN SULFATE EQ 50MG BASE/ML EQ 250MG BASE/ML (AMINOGLYCOSIDES)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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ORIGINAL ABBREVIATED NDAS

* - First Time Product Available Generically

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
*** ORIGINAL ABBREVIATED NDAS ***			
72-781 30-JUL-93	NIFEDIPINE (CAPSULE)	FLEMINGTON FLEMINGTON, NJ 08822	NIFEDIPINE 10MG (CALCIUM CHANNEL BLOCKERS)
73-254 30-JUL-93	LOPERAMIDE HCL (TABLET)	NOVOPHARM SCARBOROUGH, ONTARIO CANADA	LOPERAMIDE HYDROCHLORIDE 2MG (ANTIDIARRHEAL) (OTC)
81-002 30-JUL-93	MEPERIDINE HCL (INJECTABLE)	ASTRA USA WESTBOROUGH, MA 01581	MEPERIDINE HYDROCHLORIDE 10MG/ML (NARCOTIC ANALGESICS)
81-306 30-JUL-93	ETHOSUXIMIDE (SYRUP)	COPLEY PHARM CANTON, MA 02021	ETHOSUXIMIDE 250MG/5ML (ANTICONSULSANTS)

NDA NUMBER TENTATIVE APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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ORIGINAL ABBREVIATED NDAs WITH TENTATIVE APPROVALS

A *tentative approval* indicates that FDA has given an abbreviated new drug application (ANDA) provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Generic drug products that are the subjects of tentative approvals **may not be** legally **marketed** until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the ANDA receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluation" list published by FDA. Additional information on these ANDAs will become available to the public when the applications receive final approval.

74-174 09-JUL-93	ALPRAZOLAM (TABLET)	LEDERLE PEARL RIVER, NY 10965	ALPRAZOLAM 0.25MG 0.5MG 1MG 2MG (ANXIOLYTIC)
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NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
18-602 01-JUL-93	CARDIZEM (TABLET)	MARION MERRELL DOW KANSAS CITY, MO 64137	DILTIAZEM HYDROCHLORIDE 30MG 60MG 90MG 120MG (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS)
18-998 01-JUL-93	VASOTEC (TABLET)	MERCK WEST POINT, PA 19486	ENALAPRIL MALEATE 2.5MG 5MG 10MG 20MG (LABELING REVISION -- CLINICAL PHARMACOLOGY)
19-386 01-JUL-93	BREVIBLOC (INJECTABLE)	ANAQUEST LIBERTY CORNER, NJ 07938	ESMOLOL HYDROCHLORIDE 10MG/ML 250MG/ML (LABELING REVISION -- PRECAUTIONS)
17-769 06-JUL-93	CALCIMAR (INJECTABLE)	RHONE POULENC RORER COLLEGEVILLE, PA 19426	CALCITONIN, SALMON 200 IU/ML (LABELING REVISION -- PRECAUTIONS)
18-883 07-JUL-93	DELFLX W/DEXTROSE 1.5% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION)	FRESENIUS WALNUT CREEK, CA 94598	CALCIUM CHLORIDE 25.7MG/100ML DEXTROSE 1.5GM/100ML MAGNESIUM CHLORIDE 5.08MG/100ML SODIUM CHLORIDE 538MG/100ML SODIUM LACTATE 448MG/100ML (LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
18-883	DELFLX	FRESENIUS	CALCIUM CHLORIDE

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
07-JUL-93	W/DEXTROSE 1.5% IN PLASTIC CONTAINER (SOLUTION)	WALNUT CREEK, CA 94598	25.7MG/100ML DEXTROSE 1.5GM/100ML MAGNESIUM CHLORIDE 15.2MG/100ML SODIUM CHLORIDE 567MG/100ML SODIUM LACTATE 392MG/100ML (LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
18-883 07-JUL-93	DELFLX W/DEXTROSE 2.5% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION)	FRESENIUS WALNUT CREEK, CA 94598	CALCIUM CHLORIDE 25.7MG/100ML DEXTROSE 2.5GM/100ML MAGNESIUM CHLORIDE 5.08MG/100ML SODIUM CHLORIDE 538MG/100ML SODIUM LACTATE 448MG/100ML (LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
18-883 07-JUL-93	DELFLX W/DEXTROSE 2.5% IN PLASTIC CONTAINER (SOLUTION)	FRESENIUS WALNUT CREEK, CA 94598	CALCIUM CHLORIDE 25.7MG/100ML DEXTROSE 2.5GM/100ML MAGNESIUM CHLORIDE 15.2MG/100ML SODIUM CHLORIDE 567MG/100ML SODIUM LACTATE 392MG/100ML (LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
***** LABELING SUPPLEMENTS TO ORIGINAL NDAs *****			
18-883 07-JUL-93	DELFLEX W/DEXTROSE 4.25% LOW MAGNESIUM IN PLASTIC CONTAINER (SOLUTION)	FRESENIUS WALNUT CREEK, CA 94598	CALCIUM CHLORIDE 25.7MG/100ML DEXTROSE 4.25GM/100ML MAGNESIUM CHLORIDE 5.08MG/100ML SODIUM CHLORIDE 538MG/100ML SODIUM LACTATE 448MG/100ML (LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
18-883 07-JUL-93	DELFLEX W/DEXTROSE 4.25% IN PLASTIC CONTAINER (SOLUTION)	FRESENIUS WALNUT CREEK, CA 94598	CALCIUM CHLORIDE 25.7MG/100ML DEXTROSE 4.25GM/100ML MAGNESIUM CHLORIDE 15.2MG/100ML SODIUM CHLORIDE 567MG/100ML SODIUM LACTATE 392MG/100ML (LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)
17-063 13-JUL-93	ISMOTIC (SOLUTION)	ALCON LABS FORT WORTH, TX 76134	ISOSORBIDE 100GM/220ML (LABELING REVISION -- DESCRIPTION; ADVERSE REACTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAS			
18-956 13-JUL-93	OMNIPAQUE 180 (SOLUTION)	STERLING NEW YORK, NY 10016	IOHEXOL 38.8% (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
18-956 13-JUL-93	OMNIPAQUE 240 (SOLUTION)	STERLING NEW YORK, NY 10016	IOHEXOL 51.8% (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
18-956 13-JUL-93	OMNIPAQUE 300 (SOLUTION)	STERLING NEW YORK, NY 10016	IOHEXOL 64.7% (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
50-368 14-JUL-93	ILOTYCIN (OINTMENT)	LILLY INDIANAPOLIS, IN 46285	ERYTHROMYCIN 5MG/GM (LABELING REVISION -- CLINICAL PHARMACOLOGY)
18-719 16-JUL-93	MODRASTANE (CAPSULE)	STERLING NEW YORK, NY 10016	TRILOSTANE 30MG 60MG (LABELING REVISION -- PRECAUTIONS)
18-473 20-JUL-93	VENTOLIN (AEROSOL, METERED)	GLAXO RES TRIANGLE PK, NC 27709	ALBUTEROL 0.09MG/INH (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
19-489 20-JUL-93	VENTOLIN ROTACAPS (CAPSULE)	GLAXO RES TRIANGLE PK, NC 27709	ALBUTEROL SULFATE EQ 0.2MG BASE (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
17-078 21-JUL-93	DEXEDRINE (CAPSULE, EXTENDED RELEASE)	SMITHKLINE BEECHAM PHILADELPHIA, PA 19101	DEXTROAMPHETAMINE SULFATE 5MG 10MG 15MG (LABELING REVISION -- ADVERSE REACTIONS)
20-013 21-JUL-93	MAXAQUIN (TABLET)	SEARLE SKOKIE, IL 60077	LOMEFLOXACIN HYDROCHLORIDE EQ 400MG BASE (LABELING REVISION -- WARNINGS; PRECAUTIONS; ADVERSE REACTIONS)
18-768 23-JUL-93	VEPESID (INJECTABLE)	BRISTOL SYRACUSE, NY 13221	ETOPOSIDE 20MG/ML (LABELING REVISION -- DESCRIPTION; CONTRAINDICATIONS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
19-557 23-JUL-93	VEPESID (CAPSULE)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	ETOPOSIDE 50MG (LABELING REVISION -- DESCRIPTION; CONTRAINDICATIONS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
20-198 23-JUL-93	ADALAT CC (TABLET, EXTENDED RELEASE)	MILES PHARM WEST HAVEN, CT 06516	NIFEDIPINE 30MG 60MG 90MG (LABELING REVISION -- PATIENT INSTRUCTIONS)
20-262 23-JUL-93	TAXOL (INJECTABLE)	BRISTOL MYERS SQUIBB WALLINGFORD, CT 06492	PACLITAXEL 6MG/ML (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
17-532 27-JUL-93	DIABETA (TABLET)	HOECHST ROUSSEL SOMERVILLE, NJ 08876	GLYBURIDE 1.25MG 2.5MG 5MG (LABELING REVISION -- WARNINGS; DOSAGE AND ADMINISTRATION)
18-202 27-JUL-93	CYTADREN (TABLET)	CIBA PHARM SUMMIT, NJ 07901	AMINOGLUTETHIMIDE 250MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
19-710 27-JUL-93	OPTIRAY 160 (INJECTABLE)	MALLINCKRODT SAINT LOUIS, MO 63134	IOVERSOL 34% (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
19-710 27-JUL-93	OPTIRAY 240 (INJECTABLE)	MALLINCKRODT SAINT LOUIS, MO 63134	IOVERSOL 51% (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
19-710 27-JUL-93	OPTIRAY 320 (INJECTABLE)	MALLINCKRODT SAINT LOUIS, MO 63134	IOVERSOL 68% (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
19-710 27-JUL-93	OPTIRAY 350 (INJECTABLE)	MALLINCKRODT SAINT LOUIS, MO 63134	IOVERSOL 74% (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
17-954 28-JUL-93	BRETYLOL (INJECTABLE)	DUPONT WILMINGTON, DE 19880	BRETYLIUM TOSYLATE 50MG/ML (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
19-501 28-JUL-93	ROGAINE (SOLUTION)	UPJOHN KALAMAZOO, MI 49001	MINOXIDIL 2% (LABELING REVISION -- CLINICAL TRIAL EXPERIENCE-MAL PRECAUTIONS; HOW SUPPLIED; PATIENT INFORMATION; INSTRUCTIONS FOR USE)
19-813 28-JUL-93	DURAGESIC (FILM, EXTENDED RELEASE)	ALZA PALO ALTO, CA 94303	FENTANYL 0.6MG/24HR 1.2MG/24HR 1.8MG/24HR 2.4MG/24HR (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; DOSAGE AND ADMINISTRATION)
50-370 30-JUL-93	ILOTYCIN GLUCEPTATE (INJECTABLE)	DISTA PRODS INDIANAPOLIS, IN 46206	ERYTHROMYCIN GLUCEPTATE EQ 250MG BASE/VIAL EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL (LABELING REVISION -- PRECAUTIONS)
50-588 30-JUL-93	CEFOTAN (INJECTABLE)	STUART PHARMS WILMINGTON, DE 19897	CEFOTETAN DISODIUM EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL EQ 10GM BASE/VIAL (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-637 30-JUL-93	ZEFAZONE (INJECTABLE)	UPJOHN KALAMAZOO, MI 49001	CEFMETAZOLE SODIUM EQ 1GM BASE/VIAL EQ 2GM BASE/VIAL (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
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LICENCE NUMBER LICENCE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
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BIOLOGICAL PRODUCT LICENCES ISSUED

1106 07-23-93	BETASERON (INJECTABLE)	CHIRON EMERYVILLE, CA 94608	INTERFERON BETA-1B (TREATMENT OF MULTIPLE SCLEROSIS) (B)
1166 07-26-93	NONE (INJECTABLE)	NATIONAL HLTH GUARD FORT LAUDERDALE, FL 33309	RED BLOOD CELLS (TRANSFUSION) (A&B)
1166 07-26-93	NONE (INJECTABLE)	NATIONAL HLTH GUARD FORT LAUDERDALE, FL 33309	WHOLE BLOOD (TRANSFUSION) (A&B)

LICENCE NUMBER LICENCE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
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BIOLOGICAL PRODUCT LICENCES ISSUED

(A) Establishment License Issued
(B) Product License Issued

BK910034 07-29-93	QWICK 1 BLOOD AND PLASMA WARMER	MICROWAVE MED SYS LITTLETON, MA 01460	BLOOD AND PLASMA WARMING DEVICE (C)
BK920026 07-30-93	SDP MICROPLATE ASSAY MANAGEMENT	GENETIC SYS SEATTLE, WA 98121	MICROPLATE ASSAY MANAGEMENT (C)

DEVICE NUMBER APPROVABLE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
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BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

P910013 07/09/93	WESLEY-JESSEN HS-16 CLEANING SOLUTION	WESLEY-JESSEN CORPORATION CHICAGO, IL 60610-3496	WESLEY-JESSEN HS-16 CLEANING SOLUTION FOR USE TO CLEAN SO (HYDROPHILIC) CONTACT LENSES BEFORE RINSING AND DISINFECTI
P910065 07/17/93	AIA-PACK PA	TOSOH MEDICS, INC. TOKYO, JAPAN	APPROVAL FOR THE TOSOH AIA P PA

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

N17676/S24 07/02/93	NATURVUE (HEFILCON A) SOFT (HYDROPHILIC) CONTACT LENS, BAUSCH & LOMB (HEFILCON C) VISIBILITY TINTED CONTACT LENSES	BAUSCH & LOMB HEALTHCARE AND OPTICS ROCHESTER, NY 14692-0450	TINTED WITH C.I. REACTIVE BLUE 246 IN ACCORDANCE WITH 21 CFR 73.3106
P790007/S11 07/02/93	HANCOCK MODIFIED ORIFICE AORTIC BIOPROSTHESIS (MODELS 250 AND 150)	MEDTRONIC HEALTH VALVES MINNEAPOLIS, MN 55440	REVISED LABELING
P790032/S03 07/23/93	CLINICAL ASSAYS GAMMADAB [125I], ALPHA FETOPROTEIN RADIOIMMUNOASSAY KIT	BAXTER HEALTHCARE CORPORATION MIAMI, FL 33152-0672	KITS TO BE MANUFACTURED AT FACILITIES LOCATED IN STILLWATER, MN
P810046/S122 07/29/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, STACK PERFUSION IV CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	APPROVAL FOR THE ACS STACK PERFUSION IV CORONARY DILATA CATHETER
P810046/S125 07/07/93	SIMPSON-ROBERT CORONARY DILATATION CATHETER, ACS RX STREAK .014 CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS TEMECULA, CA 92591-4628	ADDITIONAL BALLOON LENGTHS F THE ACS RX STREAK .014 CORONA DILATATION CATHETER
P810046/S126 07/21/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS PINKERTON 18-PRELOAD, AND ACS OMEGA 010-PRELOAD CORONARY DILATATION	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	TO PREPACKAGE AN ACS GUIDEW WITHIN THE GUIDEWIRE LUMEN O ACS PINKERTON AND OMEGA CORONARY DILATATION CATHETE

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTS

P810046/S130 07/23/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS EDGE CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	APPROVAL FOR THE ACS EDGE CORONARY DILATATION CATHETER
P820053/S22 07/28/93	COMFORTCARE GP WETTING AND SOAKING SOLUTION	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	ALTERNATE MANUFACTURING SITE
P820060/S06 07/01/93	ABBOTT AFP-EIA, ABBOTT IMX-AFP	ABBOTT LABORATORIES ABBOTT PARK, IL 60064	MODIFIED MANUFACTURING PROCESS TO PROVIDE AN ADDITIONAL PURIFICATION STEP
P820083/S13 07/01/93	GORE-TEX EXPANDED PTFE SUTURE	W.L. GORE & ASSOCIATES, INC. FLAGSTAFF, AZ 86003-2300	ALTERNATIVE MANUFACTURING FACILITY FOR BOXING OPERATION
P840008/S44 07/19/93	MODEL MFL5000 MOBILE LITHOTRIPTER	DORNIER MEDICAL SYSTEMS KENNESAW, GA 30144	ALTERNATE TRANSPORT DEVICE DESIGN THAT SECURES THE SHOCK WAVE GENERATOR FOR BOTH VERSIONS OF THE MFL5000 MOBILE LITHOTRIPTER
P840040/S37 07/08/93	HEART TRAK CORONARY BALLOON DILATATION CATHETER SYSTEM, 3.4 F SLIDER 40 MM LONG BALLOON DILATATION CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	APPROVAL FOR THE 3.4 F SLIDER 40 MM LONG BALLOON DILATATION CATHETER
P840055/S30 07/12/93	SGP II (TELEFOCON B) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	PERMEABLE TECHNOLOGIES, INC. MORGANVILLE, NJ 07751	APPROVAL OF THE LENSES IN SPHERICAL AND ASPHERICAL SINGLE VISION AND SPHERICAL AND ASPHERICAL MULTIFOCAL CONFIGURATIONS
P850007/S13 07/29/93	SPINAL-STIM	AMERICAN MEDICAL ELECTRONICS, INC. RICHARDSON, TX 75081	MODIFIED LABELING

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTS			
P850021/S22 07/01/93	HYBRID PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, LONG REACH 40 MM PTCA CATHETER	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	APPROVAL FOR THE LONG REACH 40 MM PTCA CATHETER
P850051/S39 07/02/93	ACTIVITRAX PACING SYSTEM, MODEL 8360 MICRO MINIX IMPLANTABLE PULSE GENERATOR	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFIED LABELING
P860019/S52 07/21/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER, SCIMED QUANTUM PTCA DILATATION CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	APPROVAL FOR A NEW MODEL PTCA CATHETER
P860019/S68 07/01/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, NC RALLY	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	APPROVAL FOR A NEW MODEL CATHETER
P860019/S74 07/29/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY (PTCA) CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	APPROVAL FOR A CHANGE IN THE TRADE NAME FOR THE QUANTUM CATHETER
P860058/S01 07/29/93	ENZYMUN-TEST CEA	BOEHRINGER MANNHEIM INDIANAPOLIS, IN 46250-0100	APPROVAL FOR A CHANGE IN KIT CONFIGURATION
P870078/S03 07/02/93	HANCOCK STANDARD PORCINE BIOPROSTHESIS (MODELS 242, 342, 342R, AND 342C)	MEDTRONIC HEART VALVES MINNEAPOLIS, MN 55440	MODIFIED LABELING
P880003/S13 07/07/93	SLEEK PTCA DILATATION CATHETERS WITH 3 AND 4 CM BALLOONS	CORDIS CORPORATION MIAMI, FL 33102-5700	APPROVAL FOR CORDIS SLEEK PT DILATATION CATHETERS WITH 3 A CM BALLOONS

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTS

P880003/S14 07/21/93	CORDIS PTCA DILATATION CATHETERS, PREDATOR PTCA DILATATION CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	APPROVAL FOR THE PREDATOR P DILATATION CATHETER
P880003/S18 07/29/93	CORDIS PTCA DILATATION CATHETERS, CORDIS SLEEK PTCA DILATATION CATHETER	CORDIS CORPORATION MIAMI, FL 33102-5700	MANUFACTURING MODIFICATION
P890047/S01 07/20/93	PROVISC	ALCON LABORATORIES, INC. FORT WORTH, TX 76134	MODIFIED MANUFACTURING PROC
P900023/S01 07/12/93	ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	APPROVAL FOR THE ADDITION OF ALARM MUTE SWITCH
P910064/S02 07/09/93	REALITY FEMALE CONDOM	WISCONSIN PHARMACAL COMPANY CHICAGO, IL 60611	REVISED PATIENT DEVICE LABELI

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL VETRINARY NADAs

140-896 09-JUN-93	OTOMAX (OINTMENT)	DOGS SCHERING PLOUGH KENILWORTH, NJ 07033	GENTAMICIN SULFATE 3MG/GM BETAMETHASONE VALERATE 1MG/GM CLOTRIMAZOLE 10MG/GM
140-892 29-JUN-93	SYNANTHIC BOVINE DEWORMER (PASTE)	CATTLE SYNTEX AN HLTH PALO ALTO, CA 94303	OXFENDAZOLE 18.5%

ORIGINAL ABBREVIATED VETERINARY NADAs

200-038 05-25-93	SULFADIMETHOXINE (LIQUID)	CATTLE AGRI LABS ST JOSEPH, MO 64503	SULFADIMETHOXINE 400MG/ML
200-033 06-11-93	UNIPRIM (POWDER)	HORSES MACLEOD PHARMA FT COLLINS, CO 80525	TRIMETHOPRIM 67MG/GM SULFADIAZINE 333MG/GM
200-113 06-28-93	BLOSOL (LIQUID)	CATTLE, UPJOHN SWINE, KALAMAZOO,MI SHEEP, 49001 GOATS	NEOMYCIN SULFATE 200MG/ML (EQUIVALENT TO 140MG NEOMYCIN PER ML)

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR JULY 1993.

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL VETRINARY NADAs

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL VETRINARY NADAs

**FDA DRUG AND DEVICE
PRODUCT APPROVALS**

**VOLUME 16 (08)
AUGUST 1993**

**Center for Drug Evaluation
and Research**
*George R. Scott (301) 443-3910

**Center for Biologics
Evaluation and Research**
Joseph Wilczek (301) 594-2012

**Center for Devices and
Radiological Health**
Mary Jo Robinson (301) 594-21

Center for Veterinary Medicine
Norman Turner
(301) 594-1623

*To whom general inquiries should be directed.

This report is compiled by the Division of Drug Information Resources, OM, CDER.
It is available by subscription from the National Technical Information Service,
Springfield, VA 22161.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL AND SUPPLEMENTAL NDAs FOR NEW DRUG PRODUCTS			
19-843 09-AUG-93 (5 S)	ISOLYTE S IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	MCGAW IRVINE, CA 92713	DEXTROSE 5GM/100ML MAGNESIUM CHLORIDE 30MG/100ML POTASSIUM CHLORIDE 37MG/100ML SODIUM ACETATE 370MG/100ML SODIUM CHLORIDE 530MG/100ML SODIUM GLUCONATE 500MG/100ML (NUTRITION/ELECTROLYTE REPLENISHER)
20-225 12-AUG-93 (3 S)	IMDUR (TABLET, EXTENDED RELEASE)	SCHERING PLOUGH KENILWORTH, NJ 07033	ISOSORBIDE MONONITRATE 30MG* 60MG (VASODILATORS)
20-007 13-AUG-93 (SUPPL)	ZOFRAN (INJECTABLE)	GLAXO RES TRIANGLE PK, NC 27709	ONDANSETRON HYDROCHLOR EQ 2MG BASE/ML (NEW OR MODIFIED INDICATIO PREVENTION OF POSTOPERAT NAUSEA AND/OR VOMITING)

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL VETRINARY NADAs

* - Not Marketed at This Time

20-091 13-AUG-93 (1 S)	IMAGENT (LIQUID)	ALLIANCE PHARM SAN DIEGO, CA 92121	PERFLUBRON 100% (DIAGNOSTIC) [USE WITH MR IMAGING TO ENHANCE DELINEATION OF THE BOWEL]
19-596 17-AUG-93 (SUPPL)	MAGNEVIST (INJECTABLE)	BERLEX LABS WAYNE, NJ 07470	GADOPENTETATE DIMEGLUMIN 469.01MG/ML (NEW OR MODIFIED INDICATION) USE WITH MRI IN ADULTS TO PROVIDE CONTRAST ENHANCEMENT AND FACILITATE VISUALIZATION OF LESIONS IN THE BODY [EXCLUDING THE HEART]
20-136 23-AUG-93 (1 S)	DEMADEX (TABLET)	BOEHRINGER MANNHEIM ROCKVILLE, MD 20850	TORSEMIDE 5MG 10MG 20MG 100MG (DIURETICS AND RENAL TUBULE INHIBITORS)
20-137 23-AUG-93 (3 S)	DEMADEX (INJECTABLE)	BOEHRINGER MANNHEIM ROCKVILLE, MD 20850	TORSEMIDE 10MG/ML (DIURETICS AND RENAL TUBULE INHIBITORS)
09-218 24-AUG-93 (SUPPL)	COUMADIN (TABLET)	DUPONT WILMINGTON, DE 19880	WARFARIN SODIUM 4MG (NEW STRENGTH)

NDA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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APPROVABLE ORIGINAL NDAs

An *approvable letter* indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters *may not be* legally *marketed* until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

****THERE ARE NO APPROVABLE ORIGINAL NDAs FOR THE MONTH OF AUGUST 1993.****

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL ABBREVIATED NDAs			
87-771 06-AUG-93	CETAPRED (OINTMENT)	ALCON LABS FORT WORTH, TX 76134	PREDNISOLONE ACETATE 0.25% SULFACETAMIDE SODIUM 10% (CORTICOSTEROID/ANTI-INFECTIVE)
63-239 13-AUG-93	ROCEPHIN (INJECTABLE)	ROCHE LABS NUTLEY, NJ 07110	CEFTRIAZONE SODIUM EQ 250MG BASE/VIAL * EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL (CEPHALOSPORINS)
81-309 30-AUG-93	MEPERIDINE HCL (INJECTABLE)	INTL MEDICATION SOUTH EL MONTE, CA 91733	MEPERIDINE HYDROCHLORIDE 10MG/ML (NARCOTIC ANALGESICS)
72-640* 31-AUG-93	CLOTRIMAZOLE (CREAM)	TARO PHARMS DOWNSVIEW, ONTARIO CANADA	CLOTRIMAZOLE 1% (FUNGICIDES) (RX/OTC)
73-098 31-AUG-93	PEG-LYTE (POWDER FOR RECONSTITUTION)	INVAMED FAIRFIELD, NJ 07004	POLYETHYLENE GLYCOL 3350 236GM/BOT POTASSIUM CHLORIDE 2.97GM/BOT SODIUM BICARBONATE 6.74GM/BOT SODIUM CHLORIDE 5.86GM/BOT SODIUM SULFATE, ANHYDROUS 22.74GM/BOT (LAXATIVES)
74-106* 31-AUG-93	NAPROXEN SODIUM (TABLET)	HAMILTON HUMACAO, PR 00791	NAPROXEN SODIUM 275MG 550MG (NSAID)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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ORIGINAL ABBREVIATED NDAS

* - First Time Product Available Generically

NDA NUMBER TENTATIVE APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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ORIGINAL ABBREVIATED NDAs WITH TENTATIVE APPROVALS

A *tentative approval* indicates that FDA has given an abbreviated new drug application (ANDA) provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Generic drug products that are the subjects of tentative approvals **may not be** legally **marketed** until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the ANDA receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluation" list published by FDA. Additional information on these ANDAs will become available to the public when the applications receive final approval.

74-105 30-AUG-93	NAPROXEN (TABLET)	LEDERLE PEARL RIVER, NY 10965	NAPROXEN 250MG 375MG 500MG (NSAID)
74-121 31-AUG-93	NAPROXEN (TABLET)	MYLAN MORGANTOWN, WV 26504	NAPROXEN 250MG 375MG 500MG (NSAID)

NDA NUMBER TENTATIVE APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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ORIGINAL ABBREVIATED NDAs WITH TENTATIVE APPROVALS

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
06-525 04-AUG-93	GANTRISIN (TABLET)	ROCHE NUTLEY, NJ 07110	SULFISOXAZOLE 500MG (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS)
09-182 04-AUG-93	GANTRISIN (SUSPENSION)	ROCHE NUTLEY, NJ 07110	SULFISOXAZOLE ACETYL EQ 500MG BASE/5ML (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS)
09-182 04-AUG-93	GANTRISIN (SYRUP)	ROCHE NUTLEY, NJ 07110	SULFISOXAZOLE ACETYL EQ 500MG BASE/5ML (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS)
09-218 06-AUG-93	COUMADIN (TABLET)	DUPONT WILMINGTON, DE 19880	WARFARIN SODIUM 1MG 2MG 2.5MG 5MG 7.5MG 10MG (LABELING REVISION -- CLINICAL PHARMACOLOGY)
06-536 09-AUG-93	URECHOLINE (TABLET)	MSD WEST POINT, PA 19486	BETHANECHOL CHLORIDE 5MG 10MG 25MG 50MG (LABELING REVISION -- ADVERSE REACTIONS; HOW SUPPLIED)
06-536 09-AUG-93	URECHOLINE (INJECTABLE)	MSD WEST POINT, PA 19486	BETHANECHOL CHLORIDE 5MG/ML (LABELING REVISION -- ADVERSE REACTIONS; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
18-596 09-AUG-93	INTAL (SOLUTION)	FISONS BEDFORD, MA 01730	CROMOLYN SODIUM 10MG/ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; HOW SUPPLIED)
12-708* 12-AUG-93	DIUTENSIN-R (TABLET)	WALLACE LABS CRANBURY, NJ 08512	METHYCHLOTHIAZIDE 2.5MG RESERPINE 0.1MG (LABELING REVISION -- LABELING FORMAT REVISION PROGRAM)
20-007 13-AUG-93	ZOFRAN (INJECTABLE)	GLAXO RES TRIANGLE PK, NC 27709	ONDANSETRON HYDROCHLORIDE EQ 2MG BASE/ML (LABELING REVISION -- CLINICAL TRIALS; INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
19-596 17-AUG-93	MAGNEVIST (INJECTABLE)	BERLEX LABS WAYNE, NJ 07470	GADOPENTETATE DIMEGLUMINE 469.01MG/ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS)
06-460 18-AUG-93	PROTAMINE SULFATE (INJECTABLE)	LILLY INDIANAPOLIS, IN 46285	PROTAMINE SULFATE 10MG/ML (LABELING REVISION -- PRECAUTIONS; OVERDOSAGE; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
18-936 18-AUG-93	PROZAC (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	FLUOXETINE HYDROCHLORIDE EQ 10MG BASE EQ 20MG BASE (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
* - Permitted 20-101 18-AUG-93	PROZAC (SOLUTION)	LILLY INDIANAPOLIS, IN 46285	FLUOXETINE HYDROCHLORIDE EQ 20MG BASE/5ML (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
09-218 24-AUG-93	COUMADIN (TABLET)	DUPONT WILMINGTON, DE 19880	WARFARIN SODIUM 1MG 2MG 2.5MG 4MG 5MG 7.5MG 10MG (LABELING REVISION -- DESCRIPTION, HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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*****LABELING SUPPLEMENTS TO ORIGINAL NDAs*****

19-655 24-AUG-93	RETROVIR (CAPSULE)	BURROUGHS WELLCOME RES TRIANGLE PK, NC 27709	ZIDOVUDINE 100MG (LABELING REVISION -- BOXED WARNINGS; DESCRIPTION CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
19-910 24-AUG-93	RETROVIR (SYRUP)	BURROUGHS WELLCOME RES TRIANGLE PK, NC 27709	ZIDOVUDINE 50MG/5ML (LABELING REVISION -- BOXED WARNINGS; DESCRIPTION CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
11-664 25-AUG-93	DECADRON (TABLET)	MSD WEST POINT, PA 19486	DEXAMETHASONE 0.25MG 0.5MG 0.75MG 1.5MG 4MG 6MG (LABELING REVISION -- WARNINGS; PRECAUTIONS; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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*****LABELING SUPPLEMENTS TO ORIGINAL NDAs*****

17-029 25-AUG-93	HEPARIN SODIUM (INJECTABLE)	FUJISAWA MELROSE PARK, IL 60160	HEPARIN SODIUM 1,000 UNITS/ML 5,000 UNITS/ML 10,000 UNITS/ML 20,000 UNITS/ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
17-029 25-AUG-93	HEPARIN LOCK FLUSH (INJECTABLE)	FUJISAWA MELROSE PARK, IL 60160	HEPARIN SODIUM 10 UNITS/ML 100 UNITS/ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
17-651 25-AUG-93	HEPARIN SODIUM (INJECTABLE)	FUJISAWA MELROSE PARK, IL 60160	HEPARIN SODIUM 5,000 UNITS/ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
17-651 25-AUG-93	HEPFLUSH-10 (INJECTABLE)	FUJISAWA MELROSE PARK, IL 60160	HEPARIN LOCK FLUSH SOLUTION 10 UNITS/ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
07-110 26-AUG-93	CORTONE (INJECTABLE)	MSD WEST POINT, PA 19486	CORTISONE ACETATE 50MG/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
10-562 26-AUG-93	HYDELTRA-TBA (INJECTABLE)	MSD WEST POINT, PA 19486	PREDNISOLONE TEBUTATE 20MG/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
11-583 26-AUG-93	HYDELTRASOL (INJECTABLE)	MSD WEST POINT, PA 19486	PREDNISOLONE SODIUM PHOSPHATE EQ 20MG PHOSPHATE/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
12-052 26-AUG-93	HYDROCORTONE (INJECTABLE)	MSD WEST POINT, PA 19486	HYDROCORTISONE SODIUM PHOSPHATE EQ 50MG BASE/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
12-071 26-AUG-93	DECADRON (INJECTABLE)	MSD WEST POINT, PA 19486	DEXAMETHASONE SODIUM PHOSPHATE EQ 4MG PHOSPHATE/ML EQ 24MG PHOSPHATE/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
17-979 26-AUG-93	HEPARIN SODIUM (INJECTABLE)	FUJISAWA MELROSE PARK, IL 60160	HEPARIN SODIUM 1,000 UNITS/ML 10,000 UNITS/ML (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
07-750 27-AUG-93	CORTONE (TABLET)	MSD WEST POINT, PA 19486	CORTISONE ACETATE 25MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
08-506 27-AUG-93	HYDROCORTONE (TABLET)	MSD WEST POINT, PA 19486	HYDROCORTISONE 10MG 20MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
08-228 27-AUG-93	HYDROCORTONE (INJECTABLE)	MSD WEST POINT, PA 19486	HYDROCORTISONE ACETATE 25MG/ML 50MG/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
12-376 27-AUG-93	DECADRON (ELIXIR)	MSD WEST POINT, PA 19486	DEXAMETHASONE 0.5MG/5ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
13-334 27-AUG-93	DECADRON W/XYLOCAINE (INJECTABLE)	MSD WEST POINT, PA 19486	DEXAMETHASONE SODIUM PHOSPHATE EQ 4MG PHOSPHATE/ML LIDOCAINE HYDROCHLORIDE 10MG/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
16-675 27-AUG-93	DECADRON-LA (INJECTABLE)	MERCK WEST POINT, PA 19486	DEXAMETHASONE ACETATE EQ 8MG BASE/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)

LICENCE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
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BIOLOGICAL PRODUCT LICENCES ISSUED

NO BIOLOGICAL PRODUCT LICENSES ISSUED FOR THE MONTH OF AUGUST 1993.

DEVICE NUMBER APPROVABLE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
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BIOLOGICAL PRODUCT DEVICE APPROVALS

BK920025 08/05/93	FETAL CELLS SCREENING KIT	BAXTER DIAGS MIAMI, FL 33172	DADE FETAL-CYTE SCREENING KIT (C)
BK920031 08/20/92	LEUKOCYTE TYPING TRAY	MEDICAL MARKETING CONSULTANTS BETHESDA, MD 20814	sHLA-STAT B27 ELISA FOR HLA-B27 TYPING (C)

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

P910073 08/26/93	0060 SERIES ENDOTAK LEAD SYSTEM	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	APPROVAL OF THE 0060 SERIES ENDOTAK LEAD SYSTEM
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APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

P790024/S23 08/11/93	LC-65 DAILY CONTACT LENS CLEANER WITHOUT THIMEROSAL	ALLERGAN OPTICAL IRVINE, CA 92713-9534	ADDITIONAL CONTAINER SIZE FOR LENS PLUS DAILY CLEANER FORMULATION AND TRADE NAME CHANGE TO LC-65 DAILY CONTACT LENS CLEANER
P810046/S139 08/09/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ALTERNATE STERILIZATION METHOD (E-BEAM RADIATION) FOR ACS PTCA CATHETERS	ADVANCED CARDIOVASCULAR SYSTEMS TEMECULA, CA 92591-4628	ADDITION OF AN ALTERNATE STERILIZATION METHOD
P810046/S141 08/24/93	SIMPSON-ROBERT BALLOON DILATATION CATHETER, ACS RX FLOWTRACK 40 CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	ADDITION OF A WARNING TO THE INSTRUCTIONS FOR USE
P820003/S65 08/04/93	VERSATRAX PACING SYSTEM, MEDTRONIC MODEL 5346 TEMPORARY PULSE GENERATOR	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR MEDTRONIC MODEL 5346 TEMPORARY PULSE GENERATOR
P820003/S67 08/10/93	VERSATRAX PACING SYSTEM, MEDTRONIC MODEL 5423 ELECTROCARDIOGRAM CABLE	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR THE MEDTRONIC MODEL 5423 ELECTROCARDIOGRAM CABLE

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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*****MEDICAL DEVICE - PMA SUPPLEMENTS*****

P820049/S53 08/11/93	MODELS PC-37NB, PC-63CNB, AND PC-64CNB ULTRAVIOLET- ABSORBING POSTERIOR CHAMBER INTRAOCULAR LENSES	ALLERGAN MEDICAL OPTICS IRVINE, CA 92718	APPROVAL FOR MODELS PC-37NB PC-63CNB, AND PC-64CNB ULTRAVIOLET-ABSORBING POSTE CHAMBER INTRAOCULAR LENSES
P830026/S58 08/04/93	COSMOS PACING SYSTEM, COSMOS II MODELS 284-05 AND 283-03 PULSE GENERATORS	INTERMEDICS, INC. ANGLETON, TX 77515	MODIFIED MANUFACTURING
P840008/S46 08/04/93	DORNIER MFL5000 LITHOTRIPTER	DORNIER MEDICAL SYSTEMS KENNESAW, GA 30144	MODIFIED LABELING
P840040/S39 08/17/93	MANSFIELD CORONARY BALLOON DILATATION CATHETER SYSTEM, SYNERGY CONVERTIBLE RAPID EXCHANGE PTCA CATHETER	BOSTON SCIENTIFIC CORPORATION WATERTOWN, MA 02172	MANUFACTURING MODIFICATION
P850022/S08 08/06/93	ORTHOPAK BONE GROWTH STIMULATOR	BIOELECTRON, INC. HACKENSAK, NJ 07601	APPROVAL TO DISTRIBUTE BONE GROWTH STIMULATING SYSTEM V NEW ELECTRODE GEL
P860007/S12 08/04/93	INTERTACH PACING SYSTEM, INTERTACH II PULSE GENERATORS MODELS 262-16 AND 262-16R	INTERMEDICS, INC. ANGLETON, TX 77515	MODIFIED MANUFACTURING

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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*****MEDICAL DEVICE - PMA SUPPLEMENTS*****

P870023/S03 08/24/93	DE.STAT 3 CLEANING/DISINFECTING STORAGE SOLUTION, ULTRA 3 CLEANING. DISINFECTING. STORAGE SOLUTION	SHERMAN PHARMACEUTICALS, INC. MANDEVILLE, LA 70470-1377	MANUFACTURING MODIFICATION
P870036/S21 08/27/93	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC 14K LONG CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	APPROVAL OF A NEW MODEL CATHETER WITH A 30MM BALLOON LENGTH AND ONE RADIOPAQUE MARKER BAND UNDER THE BALLOON
P870036/S23 08/06/93	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC SPIRIT CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	NEW MODEL CATHETER TO BE MARKETED UNDER THE TRADE NAME MEDTRONIC SPIRIT CORONARY BALLOON DILATATION CATHETER
P870036/S24 08/09/93	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC 14K CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	MODIFIED SPECIFICATIONS FOR THE GUIDEWIRE LUMEN TUBING EXTRUSION
P880003/S15 08/20/93	CORDIS PTCA DILATATION CATHETERS, PREDATOR PTCA DILATATION CATHETER (WITH 3 AND 4 CM) LONG BALLOONS	CORDIS CORPORATION MIAMI, FL 33102-5700	APPROVAL FOR 3 AND 4 CM LONG BALLOONS FOR THE PREDATOR PTCA DILATATION CATHETER

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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*****MEDICAL DEVICE - PMA SUPPLEMENTS*****

P880003/S19 08/02/93	CORDIS PTCA DILATATION CATHETERS, CORDIS OLYMPIX AND SLEUTH XT DILATATION CATHETERS	CORDIS CORPORATION MIAMI, FL 33102-5700	MANUFACTURING MODIFICATION
P880013/S02 08/11/93	HFV INFANT STAR VENTILATOR	INFRASONICS, INC. SAN DIEGO, CA 92121	NEW MANUFACTURING FACILITY
P880027/S26 08/12/93	SCHNEIDER MICROSOFTTRAC PTCA CATHETER	SCHNEIDER (USA) INC. PLYMOUTH, MN 55442	ALTERNATIVE PACKAGING AND LABELING
P880035/S06 08/11/93	VISTA OPTICS, VISTACRYL 18 (KOLFOCON A) AND VISTA OPTICS, VISTACRYL 32 (KOLFOCON B) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	VISTA OPTICS LIMITED UNITED KINGDOM 14396-86	ELEVEN ADDITIONAL RIGID GAS PERMEABLE CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTING SITES
P880090/S07 08/11/93	ANTERIOR CHAMBER INTRAOCULAR LENSES: PRIVATE DISTRIBUTION REQUEST	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	APPROVAL FOR OPTICAL RADIATION CORPORATION TO DISTRIBUTE MODELS 121UV AND S121UV AS ORC MODELS UV15L AND UV15S ULTRAVIOLET-ABSORBING ANTERIOR CHAMBER IOLS
P880090/S08 08/11/93	ANTERIOR CHAMBER INTRAOCULAR LENSES: PRIVATE DISTRIBUTION REQUEST	STORZ OPHTHALMICS, INC. CLEARWATER, FL 34619	APPROVAL FOR WORLD OPTICS, I TO DISTRIBUTE MODELS 121UV AND S121UV AS WORLD OPTICS MODELS W221UV AND WS221UV ULTRAVIOLET-ABSORBING ANTER CHAMBER IOLS

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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*****MEDICAL DEVICE - PMA SUPPLEMENTS*****

P890003/S23 08/10/93	SYNERGYST PACING SYSTEM, MEDTRONIC MODEL 5424 ELECTROCARDIOGRAM CABLE	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	APPROVAL FOR THE MEDTRONIC MODEL 5424 ELECTROCARDIOGRAM CABLE
P890029/S02 08/02/93	CIBA 2000 SPHERICAL (ATLAFILCON A) SOFT (HYDROPHILIC) LENS, CIBA 2000 (ATLAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS	CIBA VISION CORPORATION DULUTH, GA 30136-1518	APPROVAL FOR THE TINTED VERSION OF THE ATLAFILCON A CONTACT LENSES
P890039/S11 08/26/93	MAESTRO SAVVI MODEL 305 PACING SYSTEM, MAESTRO SAVVI MODEL 325 PULSE GENERATOR	CARDIAC CONTROL SYSTEMS, INC. PALM COAST, FL 32137	APPROVAL FOR THE MAESTRO SAVVI MODEL 325 PULSE GENERATOR
P900023/S04 08/20/93	ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	CHANGE TO THE POWER SUPPLY PRINTED CIRCUIT BOARD IN THE ABIOMED BVS 5000 CONSOLE
P900032/S06 08/12/93	DYMER 200+ EXCIMER LASER SYSTEM	ADVANCED INTERVENTIONAL IRVINE, CA 92718	APPROVAL FOR THE MODEL PC40 LASER CATHETER
P900039/S02 08/05/93	COLLAGRAFT BONE GRAFT MATRIX	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	MODIFIED SPECIFICATIONS FOR A COMPONENT OF THE COLLAGRAF BONE GRAFT MATRIX
P900048/S02 08/23/93	ELASTIMIDE SILICONE POSTERIOR CHAMBER INTRAOCULAR LENSES, CHIROFLEX SILICONE POSTERIOR CHAMBER INTRAOCULAR LENSES	SOFLENSCO, INC. IRVINE, CA 92718-1903	REVISED LABELING

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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*****MEDICAL DEVICE - PMA SUPPLEMENTS*****

P910030/S01 08/30/93	GIANTURCO-ROUBIN FLEX-STENT CORONARY STENT	COOK, INC. BLOOMINGTON, IN 47402	MANUFACTURING MODIFICATION
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NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL VETRINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR AUGUST 1993.

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ABBREVIATED VETERINARY NADAs FOR AUGUST 1993.

SUPPLEMENTAL VETERINARY NADAs

12-123 30-JUN-93	GALLIMYCIN (INJECTABLE)	CATTLE SANOFI AN HLTH OVERLAND PK, KS 66210	ERYTHROMYCIN 200MG/ML
8-622 09-JUL-93	TERRAMYCIN (POWDER)	BEES, PFIZER CALVES, NEW YORK, NY CATTLE, 10017 CHICKENS, SHEEP, SWINE, TURKEYS	OXYTETRACYCLINE HYDROCHLORIDE 1GM/1.32GM 1GM/2.73GM 1GM/4.43GM 1GM/18.14GM

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL VETRINARY NADAs

38-200 09-JUL-93	OXY WS MEDAMYCIN (POWDER)	CHICKENS,FERMENTA AN TURKEYS HLTH KANSAS CITY, MO 64153	OXYTETRACYCLINE HYDROCHLORIDE 1GM/4.2GM
111-607 16-JUL-93	DRONCIT (SOLUTION)	CATS, MILES DOGS AGRICULTURE DIV AN HLTH PRODS SHAWNEE MISSION, KS 66201	PRAZIQUANTEL 5.68%
111-798 16-JUL-93	DRONCIT (TABLET)	DOGS MILES AGRICULTURE DIV AN HLTH PRODS SHAWNEE MISSION, KS 66201	PRAZIQUANTEL 34MG
96-298 17-AUG-93	BOVATEC (LIQUID)	CATTLE HOFFMAN LA ROCHE NUTLEY, NJ 07110	LASALOCID SODIUM 90.8GM/LB

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL VETRINARY NADAs

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL VETRINARY NADAs

**FDA DRUG AND DEVICE
PRODUCT APPROVALS**

**VOLUME 16 (09)
SEPTEMBER 1993**

**Center for Drug Evaluation
and Research**
*George R. Scott (301) 443-3910

**Center for Biologics
Evaluation and Research**
Joseph Wilczek (301) 594-2012

**Center for Devices and
Radiological Health**
Mary Jo Robinson (301) 594-21

Center for Veterinary Medicine
Norman Turner
(301) 594-1623

*To whom general inquiries should be directed.

This report is compiled by the Division of Drug Information Resources, OM, CDER.
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U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL AND SUPPLEMENTAL NDAs FOR NEW DRUG PRODUCTS			
20-070 09-SEP-93 (1 P)	COGNEX (CAPSULE)	PARKE DAVIS ANN ARBOR, MI 48105	TACRINE HYDROCHLORIDE EQ 10MG BASE EQ 20MG BASE EQ 30MG BASE EQ 40MG BASE (REVERSIBLE CHOLINESTERAS INHIBITOR) [DEMENTIA OF THE ALZHEIMER TYPE]
20-264 10-SEP-93 (3 S, V*)	MEGACE (SUSPENSION)	BRISTOL MYERS SQUIBB EVANSVILLE, IN 47721	MEGESTROL ACETATE 40MG/ML (PROGESTERONE DERIVATIVE [TREATMENT OF ANOREXIA, CACHEXIA, OR UNEXPLAINED WEIGHT LOSS IN PATIENTS WITH AIDS])
19-649 17-SEP-93 (1 P)	FLUMADINE (TABLET)	FOREST LABS NEW YORK, NY 10155	RIMANTADINE HYDROCHLORID 100MG (ANTIVIRAL - ANTI-INFLUENZA)
19-650 17-SEP-93 (3 P)	FLUMADINE (SYRUP)	FOREST LABS NEW YORK, NY 10155	RIMANTADINE HYDROCHLORID 10MG/ML (ANTIVIRAL - ANTI-INFLUENZA)

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
ORIGINAL VETRINARY NADAs			
V* - Designated Orphan Drug 19-508 21-SEP-93 (SUPPL)	AXID (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	NIZATIDINE 150MG 300MG (NEW INDICATION -- TREATMENT OF ACTIVE BENIG GASTRIC ULCER UP TO 8 WEEK
20-213 22-SEP-93 (3 S)	MIOCHOL-E (POWDER FOR RECONSTITUTION)	IOLAB CLAREMONT, CA 91711	ACETYLCHOLINE CHLORIDE 20MG/VIAL (PARASYMPATHOMIMETIC) [MIOSIS OF THE IRIS]
18-343 23-SEP-93 (SUPPL)	CAPOTEN (TABLET)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	CAPTOPRIL 12.5MG 25MG 50MG 100MG (NEW INDICATION -- TREATMENT OF LEFT VENTRIC DYSFUNCTION FOLLOWING MYOCARDIAL INFARCTION)
20-191 23-SEP-93 (1 S, V*)	ALOMIDE (SOLUTION/DROPS)	ALCON FORT WORTH, TX 76115	LODOXAMIDE TROMETHAMINE EQ 0.1% BASE (MAST CELL STABILIZER) [VERNAL KERATOCONJUNCTIV VERNAL CONJUNCTIVITIS, VERNAL KERATITIS]
19-816 24-SEP-93 (3 S)	ORUVAIL (CAPSULE, EXTENDED RELEASE)	WYETH AYERST RADNOR, PA 19087	KETOPROFEN 200MG (NSAID) [RHEUMATOID ARTHRITIS, OSTEOARTHRITIS]
20-051 24-SEP-93 (SUPPL)	GLYNASE (TABLET)	UPJOHN KALAMAZOO, MI 49001	GLYBURIDE 4.5MG 6MG (NEW STRENGTHS)

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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*****ORIGINAL AND SUPPLEMENTAL NDAs***
FOR NEW DRUG PRODUCTS**

V* - Designated Orphan Drug

20-201** 27-SEP-93 (5 S)	DOBUTAMINE IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	ABBOTT LABS ABBOTT PARK, IL 60064	DOBUTAMINE HYDROCHLORID EQ 50MG BASE/100ML EQ 100MG BASE/100ML EQ 200MG BASE/100ML (SYMPATHOMIMETIC/BETA-1 ADRENERGIC AGONIST)
20-255** 27-SEP-93 (5 S)	DOBUTAMINE HCL IN DEXTROSE 5% IN PLASTIC CONTAINER (INJECTABLE)	BAXTER ROUND LAKE, IL 60073	DOBUTAMINE HYDROCHLORID EQ 50MG BASE/100ML EQ 100MG BASE/100ML EQ 200MG BASE/100ML EQ 400MG BASE/100ML (SYMPATHOMIMETIC/BETA-1 ADRENERGIC AGONIST)
20-269** 27-SEP-93 (5 S)	DOBUTAMINE IN DEXTROSE 5% (INJECTABLE)	ABBOTT LABS ABBOTT PARK, IL 60064	DOBUTAMINE HYDROCHLORID EQ 50MG BASE/100ML EQ 100MG BASE/100ML EQ 200MG BASE/100ML (SYMPATHOMIMETIC/BETA-1 ADRENERGIC AGONIST)
19-057 29-SEP-93 (SUPPL)	HYTRIN (TABLET)	ABBOTT LABS ABBOTT PARK, IL 60064	TERAZOSIN HYDROCHLORIDE EQ 1MG BASE EQ 2MG BASE EQ 5MG BASE EQ 10MG BASE (NEW CLAIM FOR ALREADY MARKETED DRUG PRODUCT -- TREATMENT OF SYMPTOMATIC BENIGN PROSTATIC HYPERPLA
20-122 29-SEP-93 (SUPPL)	NIPENT (INJECTABLE)	PARKE DAVIS ANN ARBOR, MI 48105	PENTOSTATIN 10MG/VIAL (NEW INDICATION -- SINGLE AGENT TREATMENT FO UNTREATED HAIRY CELL LEUK

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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*****ORIGINAL AND SUPPLEMENTAL NDAs***
FOR NEW DRUG PRODUCTS**

** - Effectiveness of the approval is delayed until October 19, 1993

20-223 29-SEP-93 (6 S)	HYTRIN (TABLET)	ABBOTT LABS ABBOTT PARK, IL 60064	TERAZOSIN HYDROCHLORIDE EQ 1MG BASE EQ 2MG BASE EQ 5MG BASE EQ 10MG BASE (ALPHA-1 ADRENORECEPTOR BLOCKER) [NEW CLAIM FOR ALREADY MARKETED DRUG PRODUCT -- TREATMENT OF SYMPTOMATIC BENIGN PROSTATIC HYPERPLA
20-228 29-SEP-93 (3 P)	ATROVENT (SOLUTION)	BOEHRINGER INGELHEIM RIDGEFIELD, CT 06877	IPRATROPIUM BROMIDE 0.02% (BRONCHODILATOR)

NDA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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APPROVABLE ORIGINAL NDAs

An **approvable letter** indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters **may not be** legally **marketed** until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

20-095 09-SEP-93	ZANTAC 150 (CAPSULE)	GLAXO RES TRIANGLE PK, NC 27709	RANITIDINE HYDROCHLORIDE EQ 150MG BASE (HISTAMINE H2-RECEPTOR ANTAGONIST)
20-095 09-SEP-93	ZANTAC 300 (CAPSULE)	GLAXO RES TRIANGLE PK, NC 27709	RANITIDINE HYDROCHLORIDE 300MG (HISTAMINE H2-RECEPTOR ANTAGONIST)
20-251 14-SEP-93	ZANTAC (GRANULE, EFFERVESCENT)	GLAXO RES TRIANGLE PK, NC 27709	RANITIDINE HYDROCHLORIDE EQ 150MG BASE/PACKET (HISTAMINE H2-RECEPTOR ANTAGONIST)
20-251 14-SEP-93	ZANTAC (TABLET, EFFERVESCENT)	GLAXO RES TRIANGLE PK, NC 27709	RANITIDINE HYDROCHLORIDE EQ 150MG BASE (HISTAMINE H2-RECEPTOR ANTAGONIST)
20-249 15-SEP-93	PEPCID IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER (INJECTABLE)	MERCK WEST POINT, PA 19486	FAMOTIDINE 0.4MG/ML (HISTAMINE H2-RECEPTOR ANTAGONIST)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL ABBREVIATED NDAS			
74-260 03-SEP-93	CARBIDOPA AND LEVODOPA (TABLET)	PUREPAC ELIZABETH, NJ 07207	CARBIDOPA 10MG LEVODOPA 100MG (ANTI-PARKINSON DRUGS)
74-260 03-SEP-93	CARBIDOPA AND LEVODOPA (TABLET)	PUREPAC ELIZABETH, NJ 07207	CARBIDOPA 25MG LEVODOPA 100MG (ANTI-PARKINSON DRUGS)
74-260 03-SEP-93	CARBIDOPA AND LEVODOPA (TABLET)	PUREPAC ELIZABETH, NJ 07207	CARBIDOPA 25MG LEVODOPA 250MG (ANTI-PARKINSON DRUGS)
73-449 23-SEP-93	TRIAMTERENE AND HYDROCHLOROTHIAZIDE (TABLET)	WATSON LABS CORONA, CA 91720	HYDROCHLOROTHIAZIDE 25MG TRIAMTERENE 37.5MG (DIURETICS AND RENAL TUBULE INHIBITORS)
81-213 23-SEP-93	ESTROPIPATE (TABLET)	WATSON LABS CORONA, CA 91720	ESTROPIPATE 0.75MG (ESTROGENS)
81-214 23-SEP-93	ESTROPIPATE (TABLET)	WATSON LABS CORONA, CA 91720	ESTROPIPATE 1.5MG (ESTROGENS)
81-215 23-SEP-93	ESTROPIPATE (TABLET)	WATSON LABS CORONA, CA 91720	ESTROPIPATE 3MG (ESTROGENS)
81-216 23-SEP-93	ESTROPIPATE (TABLET)	WATSON LABS CORONA, CA 91720	ESTROPIPATE 6MG (ESTROGENS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL ABBREVIATED NDAS			
73-485 27-SEP-93	VERAPAMIL HCL (INJECTABLE)	MARSAM CHERRY HILL, NJ 08034	VERAPAMIL HYDROCHLORIDE 2.5MG/ML (CALCIUM CHANNEL BLOCKERS)
74-002 27-SEP-93	TOLMETIN SODIUM (TABLET)	GENEVA BROOMFIELD, CO 80038	TOLMETIN SODIUM EQ 600MG BASE (NSAID)
74-270* 27-SEP-93	GEMFIBROZIL (TABLET)	LEDERLE PEARL RIVER, NY 10965	GEMFIBROZIL 600MG (LIPID ALTERING AGENTS)
64-045 28-SEP-93	AMIKACIN SULFATE (INJECTABLE)	GENSIA IRVINE, CA 92718	AMIKACIN SULFATE EQ 50MG BASE/ML EQ 250MG BASE/ML (AMINOGLYCOSIDES)
73-364 28-SEP-93	HALOPERIDOL (CONCENTRATE)	SILARX SPRING VALLEY, NY 10977	HALOPERIDOL LACTATE EQ 2MG BASE/ML (ANTIPSYCHOTICS)
73-381 28-SEP-93	CARBIDOPA AND LEVODOPA (TABLET)	WATSON LABS CORONA, CA 91720	CARBIDOPA 10MG LEVODOPA 100MG (ANTI-PARKINSON DRUGS)
73-382 28-SEP-93	CARBIDOPA AND LEVODOPA (TABLET)	WATSON LABS CORONA, CA 91720	CARBIDOPA 25MG LEVODOPA 100MG (ANTI-PARKINSON DRUGS)
73-383 28-SEP-93	CARBIDOPA AND LEVODOPA (TABLET)	WATSON LABS CORONA, CA 91720	CARBIDOPA 25MG LEVODOPA 250MG (ANTI-PARKINSON DRUGS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
ORIGINAL ABBREVIATED NDAS			
81-277 28-SEP-93	LEUCOVORIN CALCIUM (INJECTABLE)	GENSIA IRVINE, CA 92718	LEUCOVORIN CALCIUM EQ 100MG BASE/VIAL (FOLIC ACID ANTAGONIST ANTIDO
81-278 28-SEP-93	LEUCOVORIN CALCIUM (INJECTABLE)	GENSIA IRVINE, CA 92718	LEUCOVORIN CALCIUM EQ 50MG BASE/VIAL (FOLIC ACID ANTAGONIST ANTIDO

* - First Time Product Available Generically

NDA NUMBER TENTATIVE APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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ORIGINAL ABBREVIATED NDAs WITH TENTATIVE APPROVALS

A *tentative approval* indicates that FDA has given an abbreviated new drug application (ANDA) provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Generic drug products that are the subjects of tentative approvals *may not be* legally *marketed* until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the ANDA receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluation" list published by FDA. Additional information on these ANDAs will become available to the public when the applications receive final approval.

74-046 28-SEP-93	ALPRAZOLAM (TABLET)	ALPHAPHARM PTY LTD BRISBANE, AUSTRALIA	ALPRAZOLAM 0.25MG 0.5MG 1MG (ANXIOLYTIC)
74-257 28-SEP-93	NAPROXEN SODIUM (TABLET)	ROXANE COLUMBUS, OH 43216	NAPROXEN SODIUM 275MG 550MG (NSAID)
74-263 28-SEP-93	NAPROXEN (TABLET)	PUREPAC PHARM ELIZABETH, NJ 07207	NAPROXEN 250MG 375MG 500MG (NSAID)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
07-842 17-AUG-93	FLAXEDIL (INJECTABLE)	DAVIS AND GECK PEARL RIVER, NY 10965	GALLAMINE TRIETHIODIDE 20MG/ML (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
06-325 02-SEP-93	TUBOCURARINE CHLORIDE (INJECTABLE)	LILLY INDIANAPOLIS, IN 46285	TUBOCURARINE CHLORIDE 3MG/ML (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
09-766 07-SEP-93	METICORTEN (TABLET)	SCHERING KENILWORTH, NJ 07033	PREDNISONE 1MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
11-161 07-SEP-93	ARISTOCORT (TABLET)	LEDERLE LABS PEARL RIVER, NY 10965	TRIAMCINOLONE 1MG 2MG 4MG 8MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
11-283 07-SEP-93	KENACORT (TABLET)	SQUIBB NEW BRUNSWICK, NJ 08903	TRIAMCINOLONE DIACETATE 4MG 8MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
11-685 07-SEP-93	ARISTOCORT (INJECTABLE)	LEDERLE LABS PEARL RIVER, NY 10965	TRIAMCINOLONE DIACETATE 25MG/ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
12-515 07-SEP-93	KENACORT (SYRUP)	SQUIBB NEW BRUNSWICK, NJ 08903	TRIAMCINOLONE DIACETATE EQ 4MG BASE/5ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
12-657 07-SEP-93	CELESTONE (TABLET)	SCHERING KENILWORTH, NJ 07033	BETAMETHASONE 0.6MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
12-665 07-SEP-93	VELBAN (INJECTABLE)	LILLY INDIANAPOLIS, IN 46285	VINBLASTINE SULFATE 10MG/VIAL (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
12-802 07-SEP-93	ARISTOCORT (INJECTABLE)	LEDERLE LABS PEARL RIVER, NY 10965	TRIAMCINOLONE DIACETATE 40MG/ML (LABELING REVISION -- WARNING; PRECAUTIONS)
14-215 07-SEP-93	CELESTONE (SYRUP)	SCHERING KENILWORTH, NJ 07033	BETAMETHASONE 0.6MG/5ML (LABELING REVISION -- WARNING; PRECAUTIONS)
14-602 07-SEP-93	CELESTONE SOLUSPAN (INJECTABLE)	SCHERING KENILWORTH, NJ 07033	BETAMETHASONE ACETATE 3MG/ML BETAMETHASONE SODIUM PHOSPHATE EQ 3MG BASE/ML (LABELING REVISION -- WARNING; PRECAUTIONS)
16-466 07-SEP-93	ARISTOSPAN (INJECTABLE)	LEDERLE LABS PEARL RIVER, NY 10965	TRIAMCINOLONE HEXACETONIDE 5MG/ML (LABELING REVISION -- WARNING; PRECAUTIONS)
17-561 07-SEP-93	CELESTONE (INJECTABLE)	SCHERING KENILWORTH, NJ 07033	BETAMETHASONE SODIUM PHOSF EQ 3MG BASE/ML (LABELING REVISION -- WARNING; PRECAUTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
18-949 07-SEP-93	SELDANE (TABLET)	MERRELL DOW CINCINNATI, OH 45215	TERFENADINE 60MG (LABELING REVISION -- BOXED WARNING; DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; PATIENT PACKAGE INSERT)
19-243 07-SEP-93	PROVENTIL (SOLUTION)	SCHERING KENILWORTH, NJ 07033	ALBUTEROL SULFATE EQ 0.083% BASE EQ 0.5% BASE (LABELING REVISION -- HOW SUPPLIED)
19-664 07-SEP-93	SELDANE-D (TABLET, EXTENDED RELEASE)	MERRELL DOW CINCINNATI, OH 45215	PSEUDOEPHEDRINE HYDROCHLO 120MG TERFENADINE 60MG (LABELING REVISION -- BOXED WARNING; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; PATIENT PACKAGE INSERT)
50-542 13-SEP-93	AMOXIL (TABLET, CHEWABLE)	SMITHKLINE BEECHAM PHILADELPHIA, PA 19101	AMOXICILLIN 125MG 250MG (LABELING REVISION -- WARNINGS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
***** LABELING SUPPLEMENTS TO ORIGINAL NDAS *****			
17-892 14-SEP-93	HALCION (TABLET)	UPJOHN KALAMAZOO, MI 49001	TRIAZOLAM 0.125MG 0.25MG (LABELING REVISION -- OVERDOSAGE; HOW SUPPLIED)
18-276 14-SEP-93	XANAX (TABLET)	UPJOHN KALAMAZOO, MI 49001	ALPRAZOLAM 0.25MG 0.5MG 1MG 2MG (LABELING REVISION -- OVERDOSAGE; HOW SUPPLIED)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAS			
19-658 17-SEP-93	CLARITIN (TABLET)	SCHERING KENILWORTH, NJ 07033	LORATADINE 10MG (LABELING REVISION -- ADVERSE REACTIONS)
19-508 21-SEP-93	AXID (CAPSULE)	LILLY INDIANAPOLIS, IN 46285	NIZATIDINE 150MG 300MG (LABELING REVISION -- INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)
19-478 22-SEP-93	ADALAT (CAPSULE)	MILES PHARM WEST HAVEN, CT 06516	NIFEDIPINE 10MG 20MG (LABELING REVISION -- WARNINGS; PRECAUTIONS)
19-834 22-SEP-93	PLENDIL (TABLET, EXTENDED RELEASE)	MERCK WEST POINT, PA 19486	FELODIPINE 5MG 10MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)
50-138 22-SEP-93	BICILLIN C-R (INJECTABLE)	WYETH AYERST PHILADELPHIA, PA 19101	PENICILLIN G BENZATHINE 300,000 UNITS/ML PENICILLIN G PROCAINE 300,000 UNITS/ML (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
50-138 22-SEP-93	BICILLIN C-R 900/300 (INJECTABLE)	WYETH AYERST PHILADELPHIA, PA 19101	PENICILLIN G BENZATHINE 900,000 UNITS/2ML PENICILLIN G PROCAINE 300,000 UNITS/2ML (LABELING REVISION -- DOSAGE AND ADMINISTRATION)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
*** LABELING SUPPLEMENTS TO ORIGINAL NDAs ***			
50-141 22-SEP-93	BICILLIN L-A (INJECTABLE)	WYETH AYERST PHILADELPHIA, PA 19101	PENICILLIN G BENZATHINE 300,000 UNITS/ML 600,000 UNITS/ML (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
18-343 23-SEP-93	CAPOTEN (TABLET)	BRISTOL MYERS SQUIBB PRINCETON, NJ 08543	CAPTOPRIL 12.5MG 25MG 37.5MG 50MG 100MG (LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS; DOSAGE AND ADMINISTRATION)
18-731 23-SEP-93	BUSPAR (TABLET)	BRISTOL SYRACUSE, NY 13221	BUSPIRONE HYDROCHLORIDE 5MG 10MG (LABELING REVISION -- PRECAUTIONS)
19-558 23-SEP-93	PRINIVIL (TABLET)	MERCK WEST POINT, PA 19486	LISINOPRIL 5MG 10MG 20MG 40MG (LABELING REVISION -- ADVERSE REACTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
19-777 23-SEP-93	ZESTRIL (TABLET)	ZENECA PHARMS WILMINGTON, DE 19897	LISINOPRIL 5MG 10MG 20MG 40MG (LABELING REVISION -- CLINICAL PHARMACOLOGY; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; HOW SUPPLIED)
19-778 23-SEP-93	PRINZIDE 12.5 (TABLET)	MERCK WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL 20MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)
19-778 23-SEP-93	PRINZIDE 25 (TABLET)	MERCK WEST POINT, PA 19486	HYDROCHLOROTHIAZIDE 25MG LISINOPRIL 20MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)
19-888 23-SEP-93	ZESTORETIC 20/12.5 (TABLET)	ZENECA PHARMS WILMINGTON, DE 19897	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL 20MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
19-888 23-SEP-93	ZESTORETIC 20/25 (TABLET)	ZENECA PHARMS WILMINGTON, DE 19897	HYDROCHLOROTHIAZIDE 25MG LISINOPRIL 20MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE)
19-960 23-SEP-93	MANOPLAX (TABLET)	BOOTS SHREVEPORT, LA 71136	FLOSEQUINAN 50MG 75MG 100MG (LABELING REVISION -- WARNINGS; DOSAGE AND ADMINISTRATION)
20-051 24-SEP-93	GLYNASE (TABLET)	UPJOHN KALAMAZOO, MI 49001	GLYBURIDE 4.5MG 6MG (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; HOW SUPPLIED)
20-210 27-SEP-93	PROPULSID (TABLET)	JANSSEN PISCATAWAY, NJ 08855	CISAPRIDE MONOHYDRATE EQ 10MG BASE (LABELING REVISION -- PRECAUTIONS; HOW SUPPLIED)
19-545 28-SEP-93	DIDRONEL (INJECTABLE)	MGI MINNEAPOLIS, MN 55343	ETIDRONATE DISODIUM 50MG/ML (LABELING REVISION -- PRECAUTIONS)
19-961 28-SEP-93	GANITE (INJECTABLE)	FUJISAWA MELROSE PARK, IL 60160	GALLIUM NITRATE 25MG/ML (LABELING REVISION -- ADVERSE REACTIONS)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
LABELING SUPPLEMENTS TO ORIGINAL NDAs			
50-344 28-SEP-93	STATROL (OINTMENT)	ALCON LABS FORT WORTH, TX 76134	NEOMYCIN SULFATE EQ 3.5MG BASE/GM POLYMYXIN B SULFATE 10,000 UNITS/GM (LABELING REVISION -- DESCRIPTION; PRECAUTIONS)
50-456 28-SEP-93	STATROL (SOLUTION/DROPS)	ALCON LABS FORT WORTH, TX 76134	NEOMYCIN SULFATE EQ 3.5MG BASE/ML POLYMYXIN B SULFATE 16,250 UNITS/ML (LABELING REVISION -- DESCRIPTION; PRECAUTIONS)
19-057 29-SEP-93	HYTRIN (TABLET)	ABBOTT LABS ABBOTT PARK, IL 60064	TERAZOSIN HYDROCHLORIDE EQ 1MG BASE EQ 2MG BASE EQ 5MG BASE EQ 10MG BASE (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; DOSAGE AND ADMINISTRATION)
20-122 29-SEP-93	NIPENT (INJECTABLE)	PARKE DAVIS ANN ARBOR, MI 48105	PENTOSTATIN 10MG/VIAL (LABELING REVISION -- CLINICAL STUDIES; INDICATIONS AND USAGE; ADVERSE EVENTS; DOSAGE AND ADMINISTRATION)

NDA NUMBER APPROVAL DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
*** LABELING SUPPLEMENTS TO ORIGINAL NDAs ***			
19-653 30-SEP-93	ORTHO CYCLEN-21 (TABLET)	JOHNSON RW RARITAN, NJ 08869	ETHINYL ESTRADIOL 0.035MG NORGESTIMATE 0.25MG (LABELING REVISION -- CLINICAL PHARMACOLOGY)
19-653 30-SEP-93	ORTHO CYCLEN-28 (TABLET)	JOHNSON RW RARITAN, NJ 08869	ETHINYL ESTRADIOL 0.035MG NORGESTIMATE 0.25MG (LABELING REVISION -- CLINICAL PHARMACOLOGY)

LICENCE NUMBER LICENCE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
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BIOLOGICAL PRODUCT LICENCES ISSUED

1167 15-SEP-93	NONE (INJECTABLE)	NIH WARREN GRANT MAGNUSON CLINICAL CTR BETHESDA, MD 20892	PLASMA (TRANSFUSION) (A&B)
1167 15-SEP-93	NONE (INJECTABLE)	NIH WARREN GRANT MAGNUSON CLINICAL CTR BETHESDA, MD 20892	RED BLOOD CELLS (TRANSFUSION) (A&B)
1167 15-SEP-93	NONE (INJECTABLE)	NIH WARREN GRANT MAGNUSON CLINICAL CTR BETHESDA, MD 20892	WHOLE BLOOD (TRANSFUSION) (A&B)

LICENCE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
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BIOLOGICAL PRODUCT LICENCES ISSUED

- (A) Establishment License Issued
- (B) Product License Issued

DEVICE NUMBER APPROVABLE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
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BIOLOGICAL PRODUCT DEVICE APPROVALS

BK920039 02-SEP-93	PLASMA COLLECTION SYSTEM PCS 2	HAEMONETICS BRAintree, MA 02184	AUTOMATED BLOOD CELL SEPARATION (C)
BK930010 09-SEP-93	HLA-B27 SCREENING SYSTEM	BECKTON DICKINSON IMMUNOCYTOMETRY SYS SAN JOSE, CA 95131	HLA TYPING SYSTEM (C)
BK930001 20-SEP-93	PLASMA SAMPLE VIAL	MILES BERKELEY, CA 94701	EMPTY CONTAINERS FOR THE COLLECTION AND PROCESSING OF BLOOD AND BLOOD COMPONENTS (C)
BK920033 21-SEP-93	pHIX	IMMUCOR NORCROSS, GA 30091	POTENTIATING MEDIA FOR IN-VITRO DIAGNOSTIC USE (C)
BK920013 29-SEP-93	MTS DILUENT 2	MICRO TYPING SYS POMPANO BEACH, FL 33069	POTENTIATING MEDIA FOR IN-VITRO DIAGNOSTIC USE (C)
BK920014 29-SEP-93	MTS CENTRIFUGE	MICRO TYPING SYS POMPANO BEACH, FL 33069	BLOOD BANK CENTRIFUGE FOR IN-VITRO DIAGNOSTIC USE (C)
BK920016 29-SEP-93	MTS BUFFERED GEL CARD	MICRO TYPING SYS POMPANO BEACH, FL 33069	BLOOD BANK CENTRIFUGE FOR IN-VITRO DIAGNOSTIC USE (C)
BK920030 29-SEP-93	MTS DILUENT 1	MICRO TYPING SYS POMPANO BEACH, FL 33069	STABILIZED ENZYME SOLUTION (C)

DEVICE NUMBER APPROVABLE DATE	TRADE NAME	MANUFACTURER	PROPER NAME (DESCRIPTION)
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BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

P870076 09/29/93	FALOPE-RING BAND AND APPLICATOR SYSTEMS	CABOT MEDICAL CORPORATION LANGHORNE, PA 19047	APPROVAL FOR THE FALOPE-RING BAND AND APPLICATOR SYSTEMS
P890059 09/30/93	PD 1343 DISINFECTING TABLET WITH UNISOL SALINE	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL FOR THE PD 1343 DISINFECTING TABLET WITH UNISOL SALINE
P900030 09/30/93	CONTIGEN BARD COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	APPROVAL FOR THE CONTIGEN BARD COLLAGEN IMPLANT
P900060 09/29/93	CARBOMEDICS PROSTHETIC HEART VALVE	CARBOMEDICS, INC. AUSTIN, TX 78752-1793	APPROVAL FOR THE CARBOMEDICS PROSTHETIC HEART VALVE

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

N17600/S11 09/29/93	AVITENE MICROFIBRILLAR COLLAGEN HEMOSTAT (MCH), SYRINGEAVITENE	MEDCHEM PRODUCTS, INC. WOBURN, MA 01801	MANUFACTURING MODIFICATION
P800022/S39 09/30/93	ZYDERM COLLAGEN IMPLANT AND ZYPLAST COLLAGEN IMPLANT	COLLAGEN CORPORATION PALO ALTO, CA 94303-3308	CHANGE IN THE QUALITY CONTROL TEST METHOD FOR DETERMINING LIDOCAINE CONCENTRATIONS IN FINAL PRODUCT
P810002/S26 09/23/93	ST. JUDE MEDICAL PYROLYTIC CARBON HEART VALVE, HEMODYNAMIC PLUS SERIES	ST. JUDE MEDICAL, INC. ST. PAUL, MN 55117	REVISED LABELING
P810046/S124 09/30/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, 1.5 MM BALLOON ACS SLALOM CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS TEMECULA, CA 92591-4628	APPROVAL FOR THE ACS SLALOM CORONARY DILATATION CATHETER WITH 1.5 MM BALLOON
P810046/S127 09/14/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, RX ELIPSE .014 DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	APPROVAL FOR THE RX ELIPSE .014 DILATATION CATHETER
P810046/S142 09/02/93	SIMPSON-ROBERT CORONARY BALLOON DILATATION CATHETER, ACS CORONARY DILATATION CATHETERS LISTED IN THE SUBMISSION	ADVANCED CARDIOVASCULAR SYSTEMS TEMECULA, CA 92591-4628	MANUFACTURING MODIFICATION

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTS

P820059/S19 09/30/93	CUSTOMEYES-38 (POLYMACON) HYDROPHILIC CONTACT LENSES, NATURAL TOUCH (POLYMACON) CONTACT LENSES, CLEAR AND OPAQUE TINTED	SOLA BARNES HIND SUNNYVALE, CA 94086-5200	APPROVAL FOR ONE ALTERNATE MANUFACTURING SITE
P820065/S80 09/07/93	THE BOSTON LENS II (ITAFICON A) AND THE BOSTON LENS IV (ITAFICON B) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ONE ADDITIONAL FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P820065/S81 09/07/93	THE BOSTON LENS II (ITAFICON A) AND THE BOSTON LENS IV (ITAFICON B) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ONE ADDITIONAL FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P830045/S45 09/02/93	AFP MODEL 203 PULSE GENERATOR WITH MODEL 370 PROGRAMMER, MODEL 3070 AND MODEL 4553 TEMPORARY CARDIAC PACERS	SIEMENS PACESETTER, INC. SYLMAR, CA 91392-9221	REVISED LABELING
P850049/S03 09/23/93	COOK BIRD'S NEST VENA CAVA FILTER, GIANTURCO-ROEHM BIRD'S NEST VENA CAVA FILTER WITH PUSH-BUTTON HANDLE RELEASE	COOK INCORPORATED BLOOMINGTON, IN 47402	APPROVAL FOR THE PUSH-BUTTON HANDLE RELEASE MECHANISM

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTS			
P860019/S69 09/03/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER LONG RALLY	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	APPROVAL FOR A NEW MODEL CATHETER
P860019/S73 09/13/93	SCIMED CORONARY BALLOON DILATATION CATHETER, ACE 1CM TIP AND FLEXIBLE TIP PTCA CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55369-7503	APPROVAL FOR TWO NEW MODEL CATHETERS
P860022/S43 09/07/93	THE BOSTON EQUALENS (ITAFLUOROFICON A) AND THE BOSTON RXD (ITABISFLUOROFICON A) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ONE ADDITIONAL FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P860022/S44 09/07/93	THE BOSTON EQUALENS (ITAFLUOROFICON A) AND THE BOSTON RXD (ITABISFLUOROFICON A) CONTACT LENSES	POLYMER TECHNOLOGY CORPORATION WILMINGTON, MA 01887	ONE ADDITIONAL FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P870026/S05 09/28/93	RESOLVE/GP DAILY CLEANER	ALLERGAN OPTICAL IRVINE, CA 92713-9534	MANUFACTURING MODIFICATION
P870029/S07 09/29/93	STAY-WET 3 LUBRICATING AND WETTING SOLUTION, ULTRA 3 WETTING, LUBRICATING, REWETTING DROPS	SHERMAN PHARMACEUTICALS, INC. MANDEVILLE, LA 70470-1377	APPROVAL TO MODIFY THE PREVIOUSLY APPROVED STAY-WET LUBRICATING AND WETTING SOLUTION
P870077/S01 09/24/93	CARPENTIER EDWARDS DURAFLEX BIOPROSTHESIS	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	APPROVAL TO STOP COLLECTING YEARLY ECHO-DOPPLER DATA IN POSTAPPROVAL STUDY

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTS			
P880001/S39 09/15/93	FLUOREX 700 (FLUSILFOCON A), FLUOREX 500 (FLUSILFOCON B), AND FLUOREX 300 (FLUSILFOCON C) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	G.T. LABORATORIES CHICAGO, IL 60602	THREE ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P880003/S16 09/23/93	OLYMPIX, SLEUTH XT, SLEEK AND PREDATOR PTCA DILATATION CATHETERS	CORDIS CORPORATION MIAMI, FL 33102-5700	MANUFACTURING MODIFICATIONS
P880027/S27 09/23/93	SCHNEIDER MICROSOFTAC PTCA CATHETER, AND FREEHAND PTCA CATHETER MODELS: FH20-020, FH20-025, FH20-030, FH20-035, AND FH20-040	SCHNEIDER (USA) INC. PLYMOUTH, MN 55442	ALTERNATIVE DESIGN TO THE CURRENTLY MARKETED MONGOO PTCA CATHETER TO BE MARKETED UNDER THE TRADE NAME FREEHAND PTCA CATHETER
P890034/S01 09/10/93	MODEL APT 1010 ULTRAHIGH FREQUENCY VENTILATOR	INFRASONICS, INC. ROCKY HILL, CT 06067-3440	SOFTWARE MODIFICATION
P890046/S20 09/20/93	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OPTICAL POLYMER RESEARCH, INC. GAINESVILLE, FL 32609	APPROVAL FOR ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTS			
P890046/S21 09/20/93	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OPTICAL POLYMER RESEARCH, INC. GAINESVILLE, FL 32609	APPROVAL FOR ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P890046/S22 09/20/93	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OPTICAL POLYMER RESEARCH, INC. GAINESVILLE, FL 32609	APPROVAL FOR ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P890046/S23 09/30/93	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OPTICAL POLYMER RESEARCH, INC. GAINESVILLE, FL 32609	APPROVAL FOR ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P890058/S10 09/02/93	NOVALENS (ROSIFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OCUTEC CORPORATION MORRISVILLE, NC 27560	APPROVAL FOR PRINCETON POLY LABS AS A SUB-CONTRACT MANUFACTURING FACILITY FOR THE MANUFACTURE OF BUTTONS USED IN MFG
P890072/S09 09/07/93	ALBERTA LENS 'S' (SULFOCON A) RIGID GAS PERMEABLE CONTACT LENS FOR DAILY WEAR (CLEAR AND TINTED) WITH AN ULTRAVIOLET LIGHT ABSORBER	PROGRESSIVE OPTICAL RESEARCH, LTD. ALBERTA, CANADA	THREE ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTING SITES
P910001/S02 09/23/93	SPECTRANETICS CVX-300 EXCIMER LASER SYSTEM MODEL 4	SPECTRANETICS CORPORATION COLORADO SPRINGS, CO 80907-5159	APPROVAL FOR THE CVX-300 EXCIMER LASER SYSTEM, MODEL 4

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTS

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL VETRINARY NADAs

141-014 13-AUG-93	SUPER-OV (POWDER)	COWS AUSA INTL TYLER, TX 75703	FOLLICLE STIMULATING HORMON 75 UNITS/VIAL
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ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ABBREVIATED VETERINARY NADAs FOR SEPTEMBER 1993.

SUPPLEMENTAL VETERINARY NADAs

065-252 05-AUG-93	STREP SOL (SOLUTION)	CALVES, VETERINARY CHICKENS, SVCS SWINE MEDESTO, CA 95354	STREPTOMYCIN SULFATE 250MG/ML
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NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL VETRINARY NADAs

NADA NUMBER
APPROVABLE DATE

TRADE NAME
(DOSAGE FORM)

APPLICANT

ACTIVE INGREDIENT(S)
STRENGTH(S)

ORIGINAL VETRINARY NADAs

NADA NUMBER APPROVABLE DATE	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL VETRINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

**Center for Drug Evaluation
and Research**
*George R. Scott (301) 443-3910

**Center for Devices and
Radiological Health**
Mary Jo Robinson (301) 594-2186

**Center for Biologics
Evaluation and Research**
Joseph Wilczek (301) 594-2012

Center for Veterinary Medicine
Norman Turner
(301) 594-1623

*To whom general inquiries should be directed.

This report is compiled by the Division of Drug Information Resources, OM, CDER.
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**Volume 16 (10)
October 1993**

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT	ACTIVE INGREDIENT(S) STRENGTH(S) CLASSIFICATION(S)
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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

20-195 04-OCT-93 (5 S)	FENTANYL (TROCHE/LOZENGE) 84103	ANESTA SALT LAKE CITY, UT	FENTANYL CITRATE EQ 0.2MG BASE EQ 0.3MG BASE EQ 0.4MG BASE (NARCOTIC ANALGESIC)
19-762 12-OCT-93 (3 S)	TESTODERM (FILM, EXTENDED RELEASE)	ALZA PALO ALTO, CA 94303	TESTOSTERONE 4MG/24HR 6MG/24HR (ANDROGEN)
50-684 22-OCT-93 (1, 4 S)	ZOSYN (INJECTABLE) 10965	LEDERLE LABS PEARL RIVER, NY	PIPERACILLIN SODIUM EQ 2GM BASE/VIAL (ANTIBIOTIC, PENICILLIN) TAZOBACTAM SODIUM EQ 250MG BASE/VIAL

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

(BETA LACTAMASE INHIBITOR)

50-684	ZOSYN	LEDERLE LABS	PIPERACILLIN SODIUM
22-OCT-93	(INJECTABLE)	PEARL RIVER, NY	EQ 3GM BASE/VIAL
(1, 4 S)	10965	(ANTIBIOTIC, PENICILLIN)	
		TAZOBACTAM SODIUM	
		EQ 375MG BASE/VIAL	
		(BETA LACTAMASE INHIBITOR)	

50-684	ZOSYN	LEDERLE LABS	PIPERACILLIN SODIUM
22-OCT-93	(INJECTABLE)	PEARL RIVER, NY	EQ 4GM BASE/VIAL
(1, 4 S)	10965	(ANTIBIOTIC, PENICILLIN)	
		TAZOBACTAM SODIUM	
		EQ 500MG BASE/VIAL	
		(BETA LACTAMASE INHIBITOR)	

50-684	ZOSYN	LEDERLE LABS	PIPERACILLIN SODIUM
22-OCT-93	(INJECTABLE)	PEARL RIVER, NY	EQ 36GM BASE/VIAL
(1, 4 S)	10965	(ANTIBIOTIC, PENICILLIN)	
		TAZOBACTAM SODIUM	
		EQ 4.5GM BASE/VIAL	
		(BETA LACTAMASE INHIBITOR)	

19-627	DIPRIVAN	ZENECA	PROPOFOL
26-OCT-93	(INJECTABLE)	WILMINGTON, DE	10MG/ML
(SUPPL)	19897	(NEW INDICATION --	
		PEDIATRIC ANESTHESIA IN	
		CHILDREN 3 YEARS AND OLDER)	

19-885	ACCUPRIL	PARKE DAVIS	QUINAPRIL HYDROCHLORIDE
29-OCT-93	(TABLET)	ANN ARBOR, MI	EQ 5MG BASE
(SUPPL)	48106	EQ 10MG BASE	
		EQ 20MG BASE	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

EQ 40MG BASE
(NEW INDICATION --
ADJUNCTIVE THERAPY IN THE
MANAGEMENT OF HEART FAILURE)

20-279	DERMATOP	HOECHST ROUSSEL	PREDNICARBATE
29-OCT-93	(CREAM)	SOMERVILLE, NJ	0.1%
(3 S)	08876	(CORTICOSTEROID)	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

20-126 15-OCT-93	ZONALON (CREAM) 60069	GENDERM LINCOLNSHIRE, IL (ANTIPRURITIC)	DOXEPIN HYDROCHLORIDE 5%
20-296 20-OCT-93	MEGACE (TABLET) 47721	BRISTOL MYERS SQUIBB EVANSVILLE, IN (PROGESTERONE DERIVATIVE)	MEGESTROL ACETATE 250MG
19-183 25-OCT-93	CARAFATE (SUSPENSION) 64134	MARION MERRELL DOW KANSAS CITY, MO (ANTIULCER)	SUCRALFATE 500MG/5ML

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

63-321 15-OCT-93	VANCOLED (POWDER FOR RECONSTITUTION)	LEDERLE CAROLINA, PR 00630 (ANTIBIOTIC, GLYCOPEPTIDE)	VANCOMYCIN HYDROCHLORIDE EQ 250MG BASE/5ML EQ 500MG BASE/6ML
74-046* 19-OCT-93	ALPRAZOLAM (TABLET)	ALPHAPHARM BRISBANE, AUSTRALIA 0.5MG 1MG (ANXIOLYTIC)	ALPRAZOLAM 0.25MG
74-174* 19-OCT-93	ALPRAZOLAM (TABLET) 10965	LEDERLE PEARL RIVER, NY 0.5MG 1MG 2MG (ANXIOLYTIC)	ALPRAZOLAM 0.25MG
74-199* 19-OCT-93	ALPRAZOLAM (TABLET) 43216	ROXANE COLUMBUS, OH 0.5MG 1MG (ANXIOLYTIC)	ALPRAZOLAM 0.25MG
74-206* 19-OCT-93	DOBUTAMINE HCL (INJECTABLE) 92718	GENSIA IRVINE, CA (SYMPATHOMIMETIC/ BETA-1 ADRENERGIC AGONIST)	DOBUTAMINE HYDROCHLORIDE EQ 12.5MG BASE/ML
64-032 31-OCT-93	TAZICEF (INJECTABLE) 19101	SMITHKLINE BEECHAM PHILADELPHIA, PA 2GM/VIAL (ANTIBIOTIC, CEPHEM)	CEFTAZIDIME 1GM/VIAL

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

64-033	CEFAZOLIN SODIUM	SMITHKLINE BEECHAM	CEFAZOLIN SODIUM
31-OCT-93	(INJECTABLE)	PHILADELPHIA, PA	EQ 1GM BASE/VIAL
	19101	(ANTIBIOTIC, CEPHEM)	

* - First Time Product Available Generically

73-458	CLEMASTINE FUMARATE	GENEVA	CLEMASTINE FUMARATE
31-OCT-93	(TABLET)	BROOMFIELD, CO	1.34MG
	80020	(ANTIHISTAMINE)	

73-459	CLEMASTINE FUMARATE	GENEVA	CLEMASTINE FUMARATE
31-OCT-93	(TABLET)	BROOMFIELD, CO	2.68MG
	80020	(ANTIHISTAMINE)	

73-661	PINDOLOL	NOVOPHARM	PINDOLOL
31-OCT-93	(TABLET)	SCARBOROUGH, ONTARIO	5MG
	CANADA	10MG	
		(BETA ADRENERGIC BLOCKER)	

74-075	CLEMASTINE FUMARATE	BARRE	CLEMASTINE FUMARATE
31-OCT-93	(SYRUP)	BALTIMORE, MD	EQ 0.5MG BASE/5ML
	21207	(ANTIHISTAMINE)	

74-172*	NADOLOL	MYLAN	NADOLOL
31-OCT-93	(TABLET)	MORGANTOWN, WV	20MG
	26505	40MG	
		80MG	
		(BETA ADRENERGIC BLOCKER)	

74-203	ATENOLOL AND	MYLAN	ATENOLOL
31-OCT-93	CHLORTHALIDONE	MORGANTOWN, WV	50MG
	(TABLET)	26505	CHLORTHALIDONE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

			25MG (ANTIHYPERTENSIVE)
74-203	ATENOLOL AND	MYLAN	ATENOLOL
31-OCT-93	CHLORTHALIDONE	MORGANTOWN, WV	100MG
	(TABLET) 26505	CHLORTHALIDONE	
			25MG (ANTIHYPERTENSIVE)
74-256	GEMFIBROZIL	LEMMON	GEMFIBROZIL
31-OCT-93	(TABLET)	SELLERSVILLE, PA	600MG
	18960	(LIPID ALTERING AGENTS)	

* - First Time Product Available Generically

74-312*	ALPRAZOLAM	ROXANE	ALPRAZOLAM
31-OCT-93	(CONCENTRATE)	COLUMBUS, OH	1MG/ML
	43216	(ANXIOLYTIC)	
74-314*	ALPRAZOLAM	ROXANE	ALPRAZOLAM
31-OCT-93	(SOLUTION)	COLUMBUS, OH	0.5MG/5ML
	43216	(ANXIOLYTIC)	
74-342	ALPRAZOLAM	PUREPAC PHARM	ALPRAZOLAM
31-OCT-93	(TABLET)	ELIZABETH, NJ	0.25MG
	07207	0.5MG	
		1MG	
		2MG	
		(ANXIOLYTIC)	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

* - First Time Product Available Generically

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
TENTATIVE	(DOSAGE FORM)		STRENGTH(S)
APPROVAL DATE			CLASSIFICATION(S)

ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

74-246	CIMETIDINE	MYLAN	CIMETIDINE
22-OCT-93	(TABLET)	MORGANTOWN, WV	200MG
	26504	300MG	
		400MG	
		800MG	
		(HISTAMINE H2-RECEPTOR	
		ANTAGONIST)	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

17-769 24-SEP-93	CALCIMAR (INJECTABLE) 19034	RHONE POULENC RORER FT WASHINGTON, PA (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS)	CALCITONIN, SALMON 200IU/ML
19-190 04-OCT-93	TRIPHASIL-28 (TABLET) 19101	WYETH AYERST PHILADELPHIA, PA LEVONORGESTREL 0.05MG,0.075MG,0.125MG (LABELING REVISION -- DESCRIPTION; INDICATIONS AND USAGE; PRECAUTIONS; PATIENT PACKAGE INSERT)	ETHINYL ESTRADIOL 0.03MG,0.04MG,0.03MG
50-012 05-OCT-93	GARAMYCIN (INJECTABLE) 07033	SCHERING KENILWORTH, NJ (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS)	GENTAMICIN SULFATE EQ 40MG BASE/ML
50-437 05-OCT-93	GARAMYCIN (INJECTABLE) 07033	SCHERING KENILWORTH, NJ (LABELING REVISION -- WARNINGS; ADVERSE REACTIONS)	GENTAMICIN SULFATE EQ 10MG BASE/ML
20-062 06-OCT-93	CARDIZEM CD (CAPSULE, EXTENDED RELEASE)	CARDERM THALWIL, SWITZERLAND 180MG 240MG 300MG (LABELING REVISION -- DOSAGE AND ADMINISTRATION)	DILTIAZEM HYDROCHLORIDE 120MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-585	ROCEPHIN	ROCHE	CEFTRIAXONE SODIUM
07-OCT-93	(INJECTABLE)	NUTLEY, NJ	EQ 250MG BASE/VIAL
	07110	EQ 500MG BASE/VIAL	
		EQ 1GM BASE/VIAL	
		EQ 2GM BASE/VIAL	
		EQ 10GM BASE/VIAL	
		(LABELING REVISION --	
		ADVERSE REACTIONS)	
50-624	ROCEPHIN W/ DEXTROSE	ROCHE	CEFTRIAXONE SODIUM
07-OCT-93	IN PLASTIC CONTAINER	NUTLEY, NJ	EQ 20MG BASE/ML
	(INJECTABLE)	07110	EQ 40MG BASE/ML
		(LABELING REVISION --	
		ADVERSE REACTIONS)	
50-675	VANTIN	UPJOHN	CEFPODOXIME PROXETIL
12-OCT-93	(GRANULE,	KALAMAZOO, MI	EQ 50MG BASE/5ML
	FOR RECONSTITUTION)	49001	EQ 100MG BASE/5ML
		(LABELING REVISION --	
		CLINICAL PHARMACOLOGY;	
		DOSAGE AND ADMINISTRATION)	
50-605	CEFTIN	GLAXO	CEFUROXIME AXETIL
18-OCT-93	(TABLET)	RES TRIANGLE PK, NC	EQ 125MG BASE
	27709	EQ 250MG BASE	
		EQ 500MG BASE	
		(LABELING REVISION --	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

CLINICAL PHARMACOLOGY;
DOSAGE AND ADMINISTRATION)

50-624	ROCEPHIN W/ DEXTROSE	ROCHE	CEFTRIAXONE SODIUM
20-OCT-93	IN PLASTIC CONTAINER	NUTLEY, NJ	EQ 20MG BASE/ML
	(INJECTABLE)	07110	EQ 40MG BASE/ML
			(LABELING REVISION -- DOSAGE AND ADMINISTRATION)

50-675	VANTIN	UPJOHN	CEFPODOXIME PROXETIL
20-OCT-93	(GRANULE, FOR RECONSTITUTION)	KALAMAZOO, MI	EQ 50MG BASE/5ML
		49001	EQ 100MG BASE/5ML
			(LABELING REVISION -- INDICATIONS AND USAGE)

18-225	BUMEX	ROCHE	BUMETANIDE
21-OCT-93	(TABLET)	NUTLEY, NJ	0.5MG
	07110	1MG	
		2MG	
			(LABELING REVISION -- PRECAUTIONS)

18-226	BUMEX	ROCHE	BUMETANIDE
21-OCT-93	(INJECTABLE)	NUTLEY, NJ	0.25MG/ML
	07110		(LABELING REVISION -- PRECAUTIONS)

18-998	VASOTEC	MERCK	ENALAPRIL MALEATE
21-OCT-93	(TABLET)	WEST POINT, PA	2.5MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19486 5MG
 10MG
 20MG
 (LABELING REVISION --
 ADVERSE REACTIONS)

19-221 21-OCT-93	VASERETIC (TABLET) 19486	MERCK WEST POINT, PA	ENALAPRIL MALEATE 10MG HYDROCHLOROTHIAZIDE 25MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)
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19-309 21-OCT-93	VASOTEC (INJECTABLE) 19486	MERCK WEST POINT, PA	ENALAPRILAT 1.25MG/ML (LABELING REVISION -- ADVERSE REACTIONS)
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19-851 21-OCT-93	LOTENSIN (TABLET) 07901	CIBA PHARM SUMMIT, NJ	BENAZEPRIL HYDROCHLORIDE EQ 5MG BASE EQ 10MG BASE EQ 20MG BASE EQ 40MG BASE (LABELING REVISION -- WARNINGS; PRECAUTIONS)
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20-033 21-OCT-93	LOTENSIN HCT (TABLET) 07901	CIBA PHARM SUMMIT, NJ	BENAZEPRIL HYDROCHLORIDE 5MG HYDROCHLOROTHIAZIDE 6.25MG (LABELING REVISION --
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

WARNINGS; PRECAUTIONS)

20-033	LOTENSIN HCT	CIBA PHARM	BENAZEPRIL HYDROCHLORIDE
21-OCT-93	(TABLET)	SUMMIT, NJ	10MG
	07901		HYDROCHLOROTHIAZIDE

12.5MG
(LABELING REVISION --
WARNINGS; PRECAUTIONS)

20-033	LOTENSIN HCT	CIBA PHARM	BENAZEPRIL HYDROCHLORIDE
21-OCT-93	(TABLET)	SUMMIT, NJ	20MG
	07901		HYDROCHLOROTHIAZIDE

12.5MG
(LABELING REVISION --
WARNINGS; PRECAUTIONS)

20-033	LOTENSIN HCT	CIBA PHARM	BENAZEPRIL HYDROCHLORIDE
21-OCT-93	(TABLET)	SUMMIT, NJ	20MG
	07901		HYDROCHLOROTHIAZIDE

25MG
(LABELING REVISION --

WARNINGS;

PRECAUTIONS)

20-209	OXISTAT	GLAXO	OXICONAZOLE NITRATE
21-OCT-93	(LOTION)	RES TRIANGLE PK, NC	EQ 1% BASE
	27709		(LABELING REVISION -- CLINICAL PHARMACOLOGY)

18-080	DEXTROSE 10%	ABBOTT LABS	DEXTROSE
25-OCT-93	IN PLASTIC CONTAINER	ABBOTT PARK, IL	10GM/100ML
	(INJECTABLE)	60064	(LABELING REVISION -- DESCRIPTION; PRECAUTIONS; HOW SUPPLIED)

18-090	SODIUM CHLORIDE 0.45%	ABBOTT LABS	SODIUM CHLORIDE
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

25-OCT-93	IN PLASTIC CONTAINER (INJECTABLE)	ABBOTT PARK, IL 60064	450MG/100ML (LABELING REVISION -- DESCRIPTION; PRECAUTIONS; HOW SUPPLIED)
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18-887 25-OCT-93	INTAL (AEROSOL, METERED) 01730	FISONS BEDFORD, MA	CROMOLYN SODIUM 0.8MG/INH (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; CONTRAINDICATIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
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19-813 25-OCT-93	DURAGESIC (FILM, EXTENDED RELEASE)	ALZA PALO ALTO, CA 94303	FENTANYL 0.6MG/24HR 1.2MG/24HR 1.8MG/24HR 2.4MG/24HR (LABELING REVISION -- DOSAGE AND ADMINISTRATION)
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19-627 26-OCT-93	DIPRIVAN (INJECTABLE) 19897	ZENECA LTD WILMINGTON, DE	PROPOFOL 10MG/ML (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS; ADVERSE REACTIONS)
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-663 28-OCT-93	CHYMODIACTIN (INJECTABLE) 60069	BOOTS PHARMS LINCOLNSHIRE, IL (LABELING REVISION -- BOXED WARNINGS; DESCRIPTION; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)	CHYMOPAPAIN 4,000 UNITS/VIAL
19-885 29-OCT-93	ACCUPRIL (TABLET) 48106	PARKE DAVIS ANN ARBOR, MI EQ 10MG BASE EQ 20MG BASE EQ 40MG BASE (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)	QUINAPRIL HYDROCHLORIDE EQ 5MG BASE
50-010 29-OCT-93	ILOSONE (SUSPENSION) 46285	LILLY INDIANAPOLIS, IN (LABELING REVISION -- CONTRAINDICATIONS; PRECAUTIONS)	ERYTHROMYCIN ESTOLATE 125MG/5ML
50-365 29-OCT-93	ILOSONE (TABLET) 46285	LILLY INDIANAPOLIS, IN (LABELING REVISION -- CONTRAINDICATIONS; PRECAUTIONS)	ERYTHROMYCIN ESTOLATE 500MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-426	ILOSONE	LILLY	ERYTHROMYCIN ESTOLATE
29-OCT-93	(CAPSULE)	INDIANAPOLIS, IN	250MG
	46285	(LABELING REVISION --	
		CONTRAINDICATIONS;	
		PRECAUTIONS)	

LICENSE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
LICENSE DATE	(DOSAGE FORM)		(DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

THERE ARE NO BIOLOGICAL PRODUCT LICENSES ISSUED FOR THE MONTH OF OCTOBER 1993.

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE		(DESCRIPTION)	

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK920037	PEG (PLUS)	ORGANON TEKNIKA	POLYETHYLENE GLYCOL ENHANCEMENT
21-OCT-93	27704	DURHAM, NC	ADDITIVE FOR ADDITIVE ANTIBODY
			DETECTION TEST
		(C)	

BK930014	GTI REDUCED WASH	GENETIC TESTING INST	ELUTION KIT FOR RAPID ELUTION
28-OCT-93	ELUTION KIT	BROOKVILLE, WI	OF ANTIBODIES FROM RBC
	53045	(C)	

BK930025	KELSEA CLAMP	ICU MED	NEEDLE PROTECTOR
28-OCT-93	NEEDLE COVER	IRVINE, CA	(C)
	AND GUIDE	92718	

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE		(DESCRIPTION)	

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

APPLICATION NO. TRADE NAME	APPLICANT	DESCRIPTION AND
APPROVAL DATE		INDICATION OF DEVICE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

THERE ARE NO PREMARKET APPROVAL APPLICATIONS FOR THE MONTH OF OCTOBER 1993.

APPLICATION NO. TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

N12159/S12	SURGICEL/SURGICEL	JOHNSON AND JOHNSON	APPROVAL TO MARKET
10/13/93	NU-KNIT	MEDICAL, INC.	A 1 INCH X 3.5 INCH
	ABSORBABLE HEMOSTAT	ARLINGTON, VA	SIZE SURGICEL NU-KNIT
	76004-3130	ABSORBABLE HEMOSTAT	

N18033/S24	HYDRO-MARC	VISTAKON, INC.	REVISED LABELING
10/27/93	(ETAFILCON A)	JACKSONVILLE, FL	
	HYDROPHILIC	32247-0157	
	CONTACT LENS,		
	ACUVUE (ETAFILCON A)		
	HYDROPHILIC		
	CONTACT LENS		

P810046/S140	SIMPSON-ROBERT	ADVANCED	APPROVAL FOR THE RX
10/21/93	CORONARY BALLOON	CARDIOVASCULAR SYSTEMS	ELLIPSE .014
	DILATATION CATHETER	SANTA CLARA, CA	DILATATION CATHETER
	95052-8167		

P810046/S145	SIMPSON-ROBERT	ADVANCED	ADDITION OF A WARNING
10/13/93	CORONARY BALLOON	CARDIOVASCULAR SYSTEMS	TO THE INSTRUCTIONS
	DILATATION CATHETER,	SANTA CLARA, CA	FOR USE AND TO THE
	ACS SPECTRUM	95052-8167	PACKAGE LABELS FOR
	CORONARY		THE ACS SPECTRUM
	DILATATION CATHETER		CORONARY DILATATION
		CATHETER	

P820083/S14	GORE-TEX EPTFE	W.L. GORE & ASSOCIATES, INC.	APPROVAL FOR AN
10/15/93	SUTURE	FLAGSTAFF, AZ	ALTERNATIVE
	86003-2300	STERILIZATION	

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
FACILITY AND STERILIZATION PROCESS			
P840004/S07 10/14/93	SATURN II (SYNERGICON A) CONTACT LENSES, SOFTPERM (SYNERGICON A) CONTACT LENSES	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	REVISED LABELING
P840040/S38 10/21/93	BSC/MANSFIELD PTCA CATHETER WATERTOWN, MA 02172-2414	BOSTON SCIENTIFIC CORPORATION	MANUFACTURING MODIFICATIONS
P850021/S24 10/25/93	HYBRID PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETERS, THE SLINKY AND REACH .14 PTCA CATHETERS	BAXTER HEALTHCARE CORPORATION SANTA ANA, CA 92711-1150	MANUFACTURING MODIFICATIONS
P880013/S03 10/26/93	HFV INFANT STAR VENTILATOR 92121	INFRASONICS, INC. SAN DIEGO, CA	PACKAGE COLOR CHANGE
P890068/S01 10/22/93	ULTRAVIOLET- ABSORBING	CHIRON INTRAOPTICS, INC. IRVINE, CA	APPROVAL FOR ULTRAVIOLET-ABSORBING

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

POSTERIOR CHAMBER INTRAOCULAR LENSES	92718-1903	POSTERIOR CHAMBER INTRAOCULAR LENSES APPROVED UNDER DGS INC.'S PMAS P880072 AND P880072/S7, WHICH DGS LICENSED TO CII
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P900032/S15 10/25/93	DYMER 200+ EXCIMER LASER SYSTEM IRVINE, CA 92718	ADVANCED INTERVENTIONAL SYSTEMS	MANUFACTURING MODIFICATIONS
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NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

THERE ARE NO ORIGINAL VETERINARY NADAs FOR THE MONTH OF OCTOBER 1993.

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR THE MONTH OF OCTOBER 1993.

SUPPLEMENTAL VETERINARY NADAs

140-856 08-30-93	PG 600 (POWDER FOR RECONSTITUTION)	SWINE	INTERVET MILLSBORO, DE 19966	CHORIONIC GONADOTROPIN 200 IU/VIAL SERUM GONADOTROPIN 400 IU/VIAL
115-581 09-20-93	RUMENSIN (BLOCKS)	CATTLE 72119	MOORMAN MANUFACTURING NORTH LITTLE ROCK, AR	MONENSIN 300GM/TON
44-581 09-21-93	FLAVOMYCIN (POWDER)	CATTLE SOMERVILLE, NJ 08876	HOECHST ROUSSEL AGRI VET 4GM/LB 10GM/LB	BAMBERMYCINS 2GM/LB

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

Center for Drug Evaluation and Research
 *George R. Scott (301) 443-3910

Center for Devices and Radiological Health
 Mary Jo Robinson (301) 594-2186

Center for Biologics Evaluation and Research
 Joseph Wilczek (301) 594-2012

Center for Veterinary Medicine
 Norman Turner (301) 594-1623

*To whom general inquiries should be directed.

This report is compiled by the Division of Drug Information Resources, OM, CDER. It is available by subscription from the National Technical Information Service, Springfield, VA 22161.

Volume 16 (11) November 1993

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
 FOR NEW DRUG PRODUCTS

18-998 04-NOV-93 (SUPPL)	VASOTEC (TABLET)	MERCK WEST POINT, PA 19486	ENALAPRIL MALEATE 2.5MG 5MG 10MG 20MG (NEW INDICATION -- ASYMPTOMATIC LEFT VENTRICULAR DYSFUNCTION)
20-330 04-NOV-93 (3 S)	TIMOPTIC-XE (SOLUTION/DROPS)	MERCK WEST POINT, PA 19486	TIMOLOL MALEATE EQ 0.25% BASE EQ 0.5% BASE (BETA ADRENERGIC BLOCKER)
19-516	MS CONTIN	PURDUE FREDERICK	MORPHINE SULFATE

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT CLASSIFICATION(S)	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

08-NOV-93 (SUPPL)	(TABLET, EXTENDED RELEASE)	NORWALK, CT 06850	200MG (NEW STRENGTH)
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20-219 10-NOV-93 (1 P)	LIVOSTIN (SUSPENSION/DROPS) 91711	IOLAB CLAREMONT, CA (ANTIHISTAMINE)	LEVOCABASTINE HYDROCHLORIDE EQ 0.05% BASE
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20-168 17-NOV-93 (5 S)	NUTROPIN (INJECTABLE) 94080	GENENTECH SAN FRANCISCO, CA 10MG/VIAL (HUMAN GROWTH HORMONE)	SOMATROPIN, BIOSYNTHETIC 5MG/VIAL
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19-778 18-NOV-93 (SUPPL)	PRINZIDE 10-12.5 (TABLET) 19486	MERCK WEST POINT, PA LISINOPRIL 10MG (NEW DOSAGE REGIMEN -- DOSING REGIMEN OF 10MG LISINOPRIL AND 12.5MG HYDROCHLOROTHIAZIDE) [NEW STRENGTH]	HYDROCHLOROTHIAZIDE 12.5MG
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19-778 18-NOV-93 (SUPPL)	PRINZIDE 20-12.5 (TABLET) 19486	MERCK WEST POINT, PA LISINOPRIL 20MG (NEW DOSAGE REGIMEN -- DOSING REGIMEN OF 10MG LISINOPRIL AND 12.5MG HYDROCHLOROTHIAZIDE)	HYDROCHLOROTHIAZIDE 12.5MG
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19-778 18-NOV-93 (SUPPL)	PRINZIDE 20-25 (TABLET) 19486	MERCK WEST POINT, PA LISINOPRIL 20MG (NEW DOSAGE REGIMEN -- DOSING REGIMEN OF 10MG	HYDROCHLOROTHIAZIDE 25MG
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NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT CLASSIFICATION(S)	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

LISINOPRIL AND 12.5MG
HYDROCHLOROTHIAZIDE)

19-888 18-NOV-93 (SUPPL)	ZESTORETIC 10-12.5 (TABLET)	ZENECA WILMINGTON, DE 19897	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL 10MG (NEW DOSAGE REGIMEN -- DOSING REGIMEN OF 10MG LISINOPRIL AND 12.5MG HYDROCHLOROTHIAZIDE) [NEW STRENGTH]
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19-888 18-NOV-93 (SUPPL)	ZESTORETIC 20-12.5 (TABLET)	ZENECA WILMINGTON, DE 19897	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL 20MG (NEW DOSAGE REGIMEN -- DOSING REGIMEN OF 10MG LISINOPRIL AND 12.5MG HYDROCHLOROTHIAZIDE)
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19-888 18-NOV-93 (SUPPL)	ZESTORETIC 20-25 (TABLET)	ZENECA WILMINGTON, DE 19897	HYDROCHLOROTHIAZIDE 25MG LISINOPRIL 20MG (NEW DOSAGE REGIMEN -- DOSING REGIMEN OF 10MG LISINOPRIL AND 12.5MG HYDROCHLOROTHIAZIDE)
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

19-353 22-NOV-93 (SUPPL)	ALFENTA (INJECTABLE) 08854	JANSSEN PISCATAWAY, NJ (NEW INDICATION -- ANALGESIC COMPONENT FOR MONITORED ANESTHESIA CARE)	ALFENTANIL HYDROCHLORIDE EQ 0.5MG BASE/ML
20-142 24-NOV-93 (3 S)	CATAFLAM (TABLET) 07901	GEIGY SUMMIT, NJ 50MG (NONSTEROIDAL ANTI-INFLAMMATORY)	DICLOFENAC POTASSIUM 25MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE (DOSAGE FORM)		CLASSIFICATION(S)	STRENGTH(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

20-187 02-NOV-93	PROZAC (CAPSULE) 46285	LILLY INDIANAPOLIS, IN	FLUOXETINE HYDROCHLORIDE EQ 10MG BASE EQ 20MG BASE (ANTIDEPRESSANT) [OBSESSIVE COMPULSIVE DISORDER]
20-187 02-NOV-93	PROZAC (SOLUTION) 46285	LILLY INDIANAPOLIS, IN	FLUOXETINE HYDROCHLORIDE EQ 20MG BASE/5ML (ANTIDEPRESSANT) [OBSESSIVE COMPULSIVE DISORDER]
20-151 08-NOV-93	EFFEXOR (TABLET) 19101	WYETH AYERST PHILADELPHIA, PA	VENLAFAXINE HYDROCHLORIDE EQ 12.5MG BASE EQ 25MG BASE EQ 37.5MG BASE EQ 50MG BASE EQ 75MG BASE EQ 100MG BASE (ANTIDEPRESSANT)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

73-507*	MICONAZOLE NITRATE (SUPPOSITORY) 07080	ABLE SOUTH PLAINFIELD, NJ (ANTIFUNGAL) (OTC)	MICONAZOLE NITRATE 100MG
73-508*	MICONAZOLE NITRATE (SUPPOSITORY) 07080	ABLE SOUTH PLAINFIELD, NJ (ANTIFUNGAL)	MICONAZOLE NITRATE 200MG
40-058*	PROCHLORPERAZINE (SUPPOSITORY) 07080	G AND W SOUTH PLAINFIELD, NJ (ANTIEMETIC, ANTIPSYCHOTIC)	PROCHLORPERAZINE 25MG
64-052	TOBRAMYCIN (SOLUTION/DROPS) 33637	BAUSCH AND LOMB TAMPA, FL (ANTIBIOTIC, AMINOGLYCOSIDE)	TOBRAMYCIN 0.3%
74-086	DOBUTAMINE HCL (INJECTABLE) 60064	ABBOTT ABBOTT PARK, IL (SYMPATHOMIMETIC/ BETA-1 ADRENERGIC AGONIST)	DOBUTAMINE HYDROCHLORIDE EQ 12.5MG BASE/ML
73-528	LOPERAMIDE HCL (TABLET) 07080	ABLE SOUTH PLAINFIELD, NJ (ANTIDIARRHEAL) (OTC)	LOPERAMIDE HYDROCHLORIDE 2MG
74-079*	DILTIAZEM HCL (CAPSULE, EXTENDED RELEASE)	PROGRAPHARM SELLERSVILLE, PA 18960 120MG (CALCIUM ION INFLUX INHIBITOR)	DILTIAZEM HYDROCHLORIDE 60MG 90MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		CLASSIFICATION(S)	

ORIGINAL ABBREVIATED NDAs

74-114	DOBUTAMINE HCL	STERIS	DOBUTAMINE HYDROCHLORIDE
30-NOV-93	(INJECTABLE)	PHOENIX, AZ	EQ 12.5MG BASE/ML
	85043	(SYMPATHOMIMETIC/ BETA-1 ADRENERGIC AGONIST)	

* First Time Product Available Generically

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
TENTATIVE	(DOSAGE FORM)		STRENGTH(S)
APPROVAL DATE			CLASSIFICATION(S)

ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

74-142 30-NOV-93	NAPROXEN SODIUM (TABLET) CANADA	NOVOPHARM LTD SCARBOROUGH, ONTARIO 550MG (NONSTEROIDAL ANTI-INFLAMMATORY)	NAPROXEN SODIUM 275MG
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

09-458 06-OCT-93	CORTISONE ACETATE (TABLET) 19124	RICHLYN LABS PHILADELPHIA, PA (LABELING REVISION -- WARNINGS; PRECAUTIONS)	CORTISONE ACETATE 25MG
17-351 15-OCT-93	CORTIFOAM (AEROSOL) 07302	REED AND CARNRICK JERSEY CITY, NJ (LABELING REVISION -- WARNINGS; PRECAUTIONS)	HYDROCORTISONE ACETATE 10%
08-453 29-OCT-93	ANECTINE (INJECTABLE) 27709	BURROUGHS WELLCOME RES TRIANGLE PK, NC 500MG/VIAL 1GM/VIAL (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION)	SUCCINYLMCHOLINE CHLORIDE 20MG/ML
07-073 02-NOV-93	AZULFIDINE (TABLET) 08855	KABI PISCATAWAY, NJ (LABELING REVISION -- ADVERSE REACTIONS)	SULFASALAZINE 500MG
11-960 02-NOV-93	ARISTOCORT (SYRUP) 10965	LEDERLE PEARL RIVER, NY (LABELING REVISION -- DESCRIPTION; ADVERSE REACTIONS)	TRIAMCINOLONE DIACETATE 2MG/5ML

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-591	LARIAM	ROCHE	MEFLOQUINE HYDROCHLORIDE
02-NOV-93	(TABLET)	NUTLEY, NJ	250MG
	07110		(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)

50-674	VANTIN	UPJOHN	CEFPODOXIME PROXETIL
02-NOV-93	(TABLET)	KALAMAZOO, MI	EQ 100MG BASE
	49001		EQ 200MG BASE (LABELING REVISION -- PRECAUTIONS)

50-675	VANTIN	UPJOHN	CEFPODOXIME PROXETIL
02-NOV-93	(GRANULE, FOR RECONSTITUTION)	KALAMAZOO, MI	EQ 50MG BASE/5ML
		49001	EQ 100MG BASE/5ML (LABELING REVISION -- PRECAUTIONS)

07-073	AZULFIDINE EN-TABS	KABI	SULFASALAZINE
03-NOV-93	(TABLET, DELAYED RELEASE)	PISCATAWAY, NJ	500MG
		08855	(LABELING REVISION -- ADVERSE REACTIONS)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

20-145*	NITRO-DUR	SCHERING	NITROGLYCERIN
03-NOV-93	(FILM, EXTENDED RELEASE)	KENILWORTH, NJ 07033	2.4MG/24HR 4.8MG/24HR
		7.2MG/24HR 9.6MG/24HR 14.4MG/24HR	
		(LABELING REVISION -- INDICATIONS AND USAGE; PRECAUTIONS)	

* - Permitted

18-343	CAPOTEN	BRISTOL MYERS SQUIBB	CAPTOPRIL
04-NOV-93	(TABLET)	PRINCETON, NJ	12.5MG
	08543	25MG 50MG 100MG	
		(LABELING REVISION -- WARNINGS)	

18-998	VASOTEC	MERCK	ENALAPRIL MALEATE
04-NOV-93	(TABLET)	WEST POINT, PA	2.5MG
	19486	5MG 10MG 20MG	
		(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; DOSAGE AND ADMINISTRATION)	

50-587	PRIMAXIN	MSD	CILASTATIN SODIUM
04-NOV-93	(INJECTABLE)	WEST POINT, PA	EQ 250MG BASE/VIAL

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19486			IMIPENEM 250MG/VIAL (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; COMPATIBILITY AND STABILITY)
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50-587	PRIMAXIN	MSD	CILASTATIN SODIUM
04-NOV-93	(INJECTABLE)	WEST POINT, PA	EQ 500MG BASE/VIAL
	19486		IMIPENEM 500MG/VIAL (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; COMPATIBILITY AND STABILITY)

50-630	PRIMAXIN	MSD	CILASTATIN SODIUM
04-NOV-93	(INJECTABLE)	WEST POINT, PA	EQ 500MG BASE/VIAL
	19486		IMIPENEM 500MG/VIAL (LABELING REVISION -- CLINICAL PHARMACOLOGY; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION; PREPARATION FOR ADMINISTRATION)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

50-630	PRIMAXIN	MSD	CILASTATIN SODIUM
04-NOV-93	(INJECTABLE)	WEST POINT, PA	EQ 750MG BASE/VIAL
	19486	IMIPENEM	
		750MG/VIAL	
		(LABELING REVISION --	
		CLINICAL PHARMACOLOGY;	
		WARNINGS; PRECAUTIONS;	
		ADVERSE REACTIONS;	
		DOSAGE AND ADMINISTRATION;	
		PREPARATION	
		FOR ADMINISTRATION)	

50-608	UNASYN	PFIZER	AMPICILLIN SODIUM
05-NOV-93	(INJECTABLE)	NEW YORK, NY	EQ 1GM BASE/VIAL
	10017	SULBACTAM SODIUM	
		EQ 500MG BASE/VIAL	
		(LABELING REVISION --	

REACTIONS)

ADVERSE

50-608	UNASYN	PFIZER	AMPICILLIN SODIUM
05-NOV-93	(INJECTABLE)	NEW YORK, NY	EQ 2GM BASE/VIAL
	10017	SULBACTAM SODIUM	
		EQ 1GM BASE/VIAL	
		(LABELING REVISION --	

REACTIONS)

ADVERSE

19-516	MS CONTIN	PURDUE FREDERICK	MORPHINE SULFATE
08-NOV-93	(TABLET,	NORWALK, CT	15MG
	EXTENDED RELEASE)	06850	30MG
		60MG	
		100MG	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

200MG
(LABELING REVISION --
DESCRIPTION; PRECAUTIONS;
DOSAGE AND ADMINISTRATION;
HOW SUPPLIED)

50-634	FORTAZ	GLAXO	CEFTAZIDIME SODIUM
08-NOV-93	IN PLASTIC CONTAINER (INJECTABLE)	RES TRIANGLE PK, NC 27709	EQ 20MG BASE/ML EQ 40MG BASE/ML
(LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)			

11-694	DIMETANE-DC	ROBINS	BROMPHENIRAMINE MALEATE
09-NOV-93	(SYRUP) 23220	RICHMOND, VA	2MG/5ML CODEINE PHOSPHATE 10MG/5ML PHENYLPROPANOLAMINE HYDROCHLORIDE 12.5MG/5ML
(LABELING REVISION -- DOSAGE AND ADMINISTRATION)			

20-083	SPORANOX	JANSSEN	ITRACONAZOLE
09-NOV-93	(CAPSULE) 08855	PISCATAWAY, NJ	100MG
(LABELING REVISION -- ADVERSE REACTIONS)			

19-640	HUMATROPE	LILLY	SOMATROPIN, BIOSYNTHETIC
18-NOV-93	(INJECTABLE) 46285	INDIANAPOLIS, IN	5MG/VIAL
(LABELING REVISION -- DESCRIPTION)			

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-778	PRINZIDE 10-12.5	MERCK	HYDROCHLOROTHIAZIDE
18-NOV-93	(TABLET)	WEST POINT, PA	12.5MG
	19486	LISINOPRIL	
		10MG	
		(LABELING REVISION --	
		DESCRIPTION;	
		CLINICAL PHARMACOLOGY;	
		DOSAGE AND ADMINISTRATION;	
		HOW SUPPLIED)	

19-778	PRINZIDE 20-12.5	MERCK	HYDROCHLOROTHIAZIDE
18-NOV-93	(TABLET)	WEST POINT, PA	12.5MG
	19486	LISINOPRIL	
		20MG	
		(LABELING REVISION --	
		DESCRIPTION;	
		CLINICAL PHARMACOLOGY;	
		DOSAGE AND ADMINISTRATION;	
		HOW SUPPLIED)	

19-778	PRINZIDE 20-25	MERCK	HYDROCHLOROTHIAZIDE
18-NOV-93	(TABLET)	WEST POINT, PA	25MG
	19486	LISINOPRIL	
		20MG	
		(LABELING REVISION --	
		DESCRIPTION;	
		CLINICAL PHARMACOLOGY;	
		DOSAGE AND ADMINISTRATION;	
		HOW SUPPLIED)	

19-888	ZESTORETIC 10-12.5	ZENECA	HYDROCHLOROTHIAZIDE
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

18-NOV-93	(TABLET) 19897	WILMINGTON, DE LISINOPRIL 10MG (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)	12.5MG
19-888 18-NOV-93	ZESTORETIC 20-12.5 (TABLET) 19897	ZENECA WILMINGTON, DE LISINOPRIL 20MG (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)	HYDROCHLOROTHIAZIDE 12.5MG
19-888 18-NOV-93	ZESTORETIC 20-25 (TABLET) 19897	ZENECA WILMINGTON, DE LISINOPRIL 20MG (LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)	HYDROCHLOROTHIAZIDE 25MG
18-153 19-NOV-93	BECLOVENT (AEROSOL, METERED) 27709	GLAXO RES TRIANGLE PK, NC (LABELING REVISION --	BECLOMETHASONE DIPROPIONATE 0.042MG/INH

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

WARNINGS; PRECAUTIONS)

18-584	BECONASE	GLAXO	BECLOMETHASONE DIPROPIONATE
19-NOV-93	(AEROSOL, METERED)	RES TRIANGLE PK, NC	0.042MG/INH
	27709	(LABELING REVISION --	WARNINGS; PRECAUTIONS)

19-389	BECONASE AQ	GLAXO	BECLOMETHASONE
19-NOV-93	(SPRAY, METERED)	RES TRIANGLE PK, NC	DIPROPIONATE MONOHYDRATE
	27709	EQ 0.042MG DIPROP/INH	(LABELING REVISION --
		WARNINGS; PRECAUTIONS)	

50-587	PRIMAXIN	MSD	CILASTATIN SODIUM
19-NOV-93	(INJECTABLE)	WEST POINT, PA	EQ 250MG BASE/VIAL
	19486	IMIPENEM	250MG/VIAL
		(LABELING REVISION --	COMPATIBILITY AND STABILITY)

50-587	PRIMAXIN	MSD	CILASTATIN SODIUM
19-NOV-93	(INJECTABLE)	WEST POINT, PA	EQ 500MG BASE/VIAL
	19486	IMIPENEM	500MG/VIAL
		(LABELING REVISION --	COMPATIBILITY AND STABILITY)

19-009	MAXAIR	3M	PIRBUTEROL ACETATE
22-NOV-93	(AEROSOL, METERED)	SAINT PAUL, MN	EQ 0.2MG BASE/INH
	55144	(LABELING REVISION --	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

DESCRIPTION;
 CLINICAL PHARMACOLOGY;
 HOW SUPPLIED)

19-157 22-NOV-93	PEDIAPRED (SOLUTION) 14603	FISONS ROCHESTER, NY	PREDNISOLONE SODIUM PHOSPHATE EQ 5MG BASE/5ML (LABELING REVISION -- WARNINGS; PRECAUTIONS)
19-353 22-NOV-93	ALFENTA (INJECTABLE) 08854	JANSSEN PISCATAWAY, NJ	ALFENTANIL HYDROCHLORIDE EQ 0.5MG BASE/ML (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
19-618 22-NOV-93	ROWASA (ENEMA) 30062	SOLVAY MARIETTA, GA	MESALAMINE 4GM/60ML (LABELING REVISION -- PRECLINICAL TOXICOLOGY; PRECAUTIONS)
19-643 22-NOV-93	MEVACOR (TABLET) 19486	MERCK WEST POINT, PA	LOVASTATIN 20MG 40MG (LABELING REVISION --

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

CLINICAL PHARMACOLOGY;
PRECAUTIONS)

19-583	RELAFEN	SMITHKLINE BEECHAM	NABUMETONE
23-NOV-93	(TABLET)	KING OF PRUSSIA, PA	500MG
	19406	750MG	
		(LABELING REVISION -- CLINICAL PHARMACOLOGY; INDIVIDUALIZATION OF DOSING; WARNINGS; ADVERSE REACTIONS)	

19-643	MEVACOR	MERCK	LOVASTATIN
23-NOV-93	(TABLET)	WEST POINT, PA	10MG
	19486	20MG	
		40MG	
		(LABELING REVISION -- CLINICAL PHARMACOLOGY)	

19-643	MEVACOR	MERCK	LOVASTATIN
24-NOV-93	(TABLET)	WEST POINT, PA	10MG
	19486	20MG	
		40MG	
		(LABELING REVISION -- CLINICAL PHARMACOLOGY)	

19-111	TUSSIONEX	FISONS	CHLORPHENIRAMINE POLISTIREX
26-NOV-93	(SUSPENSION, EXTENDED RELEASE)	BEDFORD, MA	EQ 8MG MALEATE/5ML
		01730	HYDROCODONE POLISTIREX

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

EQ 10MG BITARTRATE/5ML
(LABELING REVISION --
WARNINGS; PRECAUTIONS;
ADVERSE REACTIONS;
OVERDOSAGE;
DOSAGE AND ADMINISTRATION)

19-621	VENTOLIN	GLAXO	ALBUTEROL SULFATE
26-NOV-93	(SYRUP)	RES TRIANGLE PK, NC	EQ 2MG BASE/5ML
	27709		(LABELING REVISION -- DESCRIPTION; PRECAUTIONS; OVERDOSAGE)

06-146	BENADRYL	PARKE DAVIS	DIPHENHYDRAMINE
29-NOV-93	(INJECTABLE)	MORRIS PLAINS, NJ	HYDROCHLORIDE
	07950	10MG/ML	
		50MG/ML	
			(LABELING REVISION -- HOW SUPPLIED)

LICENSE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
LICENSE DATE	(DOSAGE FORM)	(DESCRIPTION)	

BIOLOGICAL PRODUCT LICENSES ISSUED

1062	NONE	BIOSCOT	BLOOD GROUPING REAGENT
08-NOV-93	(IN VITRO TEST)	LIVINGSTON, UK	(MONOCLONAL)
		(FOR FURTHER MANUFACTURING USE)	
		(B)	

228	NONE	SW FLORIDA BLOOD BANK	SOURCE LEUKOCYTES
16-NOV-93	(INJECTABLE)	TAMPA, FL	(B)
	33601		

457	NONE	PALM BEACH BLOOD BANK	SOURCE LEUKOCYTES
16-NOV-93	(INJECTABLE)	WEST PALM BEACH, FL	(B)
	33407		

1168	NONE	PLANK STREET LAB	SOURCE PLASMA
23-NOV-93	(INJECTABLE)	FORT SMITH, AR	(A&B)
	72903		

LICENSE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
LICENSE DATE	(DOSAGE FORM)		(DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

- (A) Establishment License Issued
- (B) Product License Issued

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE	(DESCRIPTION)		

BIOLOGICAL PRODUCT DEVICE APPROVALS

BK930007 16-NOV-93	EXTENDED STORAGE PLATELET COLLECTION SET	HAEMONETICS BRAINTREE, MA 02184	EMPTY CONTAINERS FOR THE COLLECTION AND PROCESSING OF BLOOD COMPONENTS
		(C)	

BK930008 16-NOV-93	FRESH FROZEN PLASMA COLLECTION SET (LATHAM BOWL)	HAEMONETICS BRAINTREE, MA 02184	EMPTY CONTAINERS FOR THE COLLECTION AND PROCESSING OF BLOOD COMPONENTS
		(C)	

BK930009 16-NOV-93	FRESH FROZEN PLASMA COLLECTION SET (BLOW MOLDED BOWL)	HAEMONETICS BRAINTREE, MA 02184	EMPTY CONTAINERS FOR THE COLLECTION AND PROCESSING OF BLOOD COMPONENTS
		(C)	

BK930016 16-NOV-93	VITROL I REAGENTS (CMV) 94583	BLACKHAWK BIOSYS SAN RAMON, CA (C)	QUALITY CONTROL KITS FOR BLOOD BANKING REAGENTS
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BK930021 16-NOV-93	SAMPLINK 07632	MIGADAS SYLVAN CLIFFS, NY	BLOOD SAMPLING DEVICE (C)
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BK930026 16-NOV-93	GAMMA RQC KIT HOUSTON, TX 77092	GAMMA BIOLOGS (C)	QUALITY CONTROL KITS FOR BLOOD BANKING REAGENTS
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DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE		(DESCRIPTION)	

BIOLOGICAL PRODUCT DEVICE APPROVALS

(C) Substantially Equivalent

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND
APPROVAL DATE			INDICATION OF DEVICE

MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

P920036	S-38 SOFT	NISSEL LIMITED	APPROVAL FOR THE S-38
11/26/93	(POLYMACON)	HERTFORDSHIRE, UK	SOFT (POLYMACON)
	CONTACT LENS		CONTACT LENS

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

N17679/S27 11/23/93	VANTAGE (TETRAFILCON A) SOFT AND VANTAGE TORIC (TETRAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS (CLEAR AND TINTED)	COOPERVISION, INC. SCOTTSVILLE, NY 14546 MATERIAL	ALTERNATE DESIGN CONFIGURATION FOR THE TETRAFILCON A
N18033/S26 11/04/93	ACUVUE (ETAFILCON A) CONTACT LENS AND SUREVUE (ETAFILCON A) CONTACT LENS	VISTAKON JACKSONVILLE, FL 32247	MODIFIED MANUFACTURING PROCESS
P780007/S39 11/23/93	HYDRON (POLYMACON) HYDROPHILIC CONTACT LENS, HYDRON BIOMEDICS HYDROPHILIC CONTACT LENSES	OCULAR SCIENCES AMERICAN HYDRON SO. SAN FRANCISCO, CA 94080	REVISED LABELING
P790027/S56 11/17/93	POSTERIOR CHAMBER INTRAOCULAR LENSES (IOLS) WITH HAPTIC	IOLAB CORPORATION CLAREMONT, CA 91711	APPROVAL FOR ANY PMA-APPROVED INTRAOCULAR LENS DESIGN WITH

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
	DIAMETERS OF 5.0MM		SYMMETRICAL HAPTICS IN OPTIC DIAMETERS DOWN TO 5.0MM
P800022/S40 11/01/93	ZYPLAST AND ZYDERM COLLAGEN IMPLANT 94230	COLLAGEN CORPORATION PALO ALTO, CA	APPROVAL FOR A 24 MONTH EXPIRATION DATE
P800022/S41 11/01/93	ZYPLAST AND ZYDERM COLLAGEN IMPLANT 94230	COLLAGEN CORPORATION PALO ALTO, CA	APPROVAL FOR SCALE-UP OF EQUIPMENT USED
P800022/S44 11/01/93	ZYPLAST AND ZYDERM COLLAGEN IMPLANT 94230	COLLAGEN CORPORATION PALO ALTO, CA	APPROVAL FOR A LARGE SCALE COLLAGEN HOMOGENIZATION SYSTEM
P810006/S16 11/01/93	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE 94025	VITAPHORE CORPORATION MENLO PARK, CA	ALTERNATIVE PACKAGING CONFIGURATIONS IN SINGLE OR DOUBLE TYVEK POUCHES
P810046/S146 11/08/93	ACS RX ELIPSE .014 CORONARY DILATATION CATHETER 95052-8167	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA	ADDITION OF A QUALITY CONTROL TEST TO THE MANUFACTURING PROCESS
P820059/S20 11/23/93	POLYMACON CONTACT LENSES 94086-5200	SOLA BARNES HIND SUNNYVALE, CA	APPROVAL FOR AN EXPIRATION DATING OF FIVE YEARS
P820086/S11 11/23/93	CIBASOFT, CIBASOFT STD, CIBATHIN, TORISOFT, AND DULUTH, GA 30136-1518	CIBA VISION CORPORATION	MODIFICATION OF THE LENSES BY INCORPORATING "LISTED" COLOR

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

BI-SOFT (TEFILCON) SOFT (HYDROPHILIC) CONTACT LENS WITH CIBATINT		ADDITIVES USING THE CIBATINT PROCESS
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P840066/S31 11/04/93	SOFT MATE CONSEPT-2 NEUTRALIZING AND RINSING SOLUTION	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	REVISED STABILITY SPECIFICATION FOR THE PRESERVATIVE FOR THE SOLUTION
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P850002/S08 11/17/93	UNILENS SOFT ASPHERIC CONTACT LENS, SIMULVUE SOFT BIFOCAL, AND ALGES (HEFILCON A) SOFT (HYDROPHILIC) BIFOCAL CONTACT LENS	UNILENS CORP. U.S.A. LARGO, FL 34647-1511	REVISED LABELING
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P850002/S09 11/17/93	UNILENS SOFT ASPHERIC CONTACT LENS, SIMULVUE SOFT BIFOCAL, AND ALGES (HEFILCON A) SOFT (HYDROPHILIC) BIFOCAL CONTACT	UNILENS CORP. U.S.A. LARGO, FL 34647-1511	REVISED LABELING
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APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

LENS

P850035/S10 11/15/93	SPF IMPLANTABLE SPINAL FUSION STIMULATOR	ELECTRO-BIOLOGY, INC. PARSIPPANY, NJ 07054-1079	APPROVAL FOR THE SPF IMPLANTABLE SPINAL FUSION STIMULATOR
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P860005/S02 11/17/93	INTERPORE PRO OSTEON IMPLANT 500 CORALLINE HYDROXYAPATITE	INTERPORE INTERNATIONAL IRVINE, CA 92718-2402	MANUFACTURING DEVICE IN NEW SIZES AND CONFIGURATIONS
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P860019/S71 11/08/93	SCIMED PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, SCIMED STRIKER PTCA CATHETER	SCIMED LIFE SYSTEMS, INC. MAPLE GROVE, MN 55311-3648	APPROVAL FOR A NEW MODEL CATHETER
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P870024/S36 11/23/93	FLUOROPERM (PAFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS, FLUOROPERM 151 (PAFLUFOCON D) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	PARAGON VISION SCIENCES PHOENIX, AZ 85022	MODIFIED VERSION OF LENS MATERIAL
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APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
APPROVAL DATE			
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P870036/S26 11/04/93	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC RAIDER CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	ALTERNATIVE MODIFIED VERSION OF MEDTRONIC 14K PTCA CATHETER
P870036/S27 11/05/93	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC PANTHER CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	APPROVAL FOR A MODIFIED, UPDATED VERSION OF THE MEDTRONIC 14K PTCA CATHETER
P870045/S29 11/17/93	REQUEST FOR AN ALTERNATE MANUFACTURING PROCEDURE	CHIRON INTRAOPTICS, INC. IRVINE, CA 92718-1903	APPROVAL FOR AN ALTERNATE HAPTIC STAKING PROCESS
P880001/S40 11/23/93	FLUOREX 700 (FLUSILFOCON A),	G.T. LABORATORIES CHICAGO, IL	APPROVAL FOR THREE ADDITIONAL CONTACT

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

FLUOREX 500 (FLUSILFOCON B), AND FLUOREX 300 (FLUSILFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	60601		LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
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P890003/S21 11/08/93	SYNERGYST PACING SYSTEM, ELITE II PULSE GENERATOR MODELS 7084, 7085 AND 7086; MODEL 9857E SOFTWARE AND MODEL 9748 MEMORYMOD	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MANUFACTURING MODIFICATION
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P890046/S24 11/04/93	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OPTICAL POLYMER RESEARCH, INC. GAINESVILLE, FL 32609	ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
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P900023/S05 11/23/93	ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	APPROVAL TO INCREASE THE STERILIZATION LOAD SIZE FOR THE BVS 5000 BLOOD PUMP SET FROM 20 TO 30 UNITS
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P900023/S06 11/23/93	BVS 5000 BI-VENTRICULAR	ABIOMED, INC. DANVERS, MA	APPROVAL TO REPLACE THE CURRENT
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APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
	SUPPORT SYSTEM	01923	DIFFERENTIAL PRESSURE TRANSDUCER WITH ANOTHER MODEL DUE TO UNAVAILABILITY IN THE NEAR FUTURE
P900032/S20 11/23/93	DYMER 200+ EXCIMER LASER SYSTEM IRVINE, CA 92718	ADVANCED INTERVENTIONAL SYSTEMS CATHETER	APPROVAL FOR THE MODEL PC4016 LASER
P910029/S02 11/23/93	BLANCHARD SOFT (POLYMACON) CONTACT LENS, ESSTECH PC ASPHERIC (POLYMACON) SOFT (HYDROPHILIC) CONTACT LENS	LES LABORATORIES BLANCHARD QUEBEC, CANADA	APPROVAL FOR BENZ RESEARCH AND DEVELOPMENT, SARASOTA, FL AS AN ALTERNATE SUPPLIER OF POLYMACON LENS BLANKS
N17679/S27 11/23/93	VANTAGE (TETRAFILCON A) SOFT AND VANTAGE TORIC (TETRAFILCON A) SOFT (HYDROPHILIC) CONTACT LENS (CLEAR AND TINTED)	COOPERVISION, INC. SCOTTSVILLE, NY 14546 MATERIAL	ALTERNATE DESIGN CONFIGURATION FOR THE TETRAFILCON A
N18033/S26 11/04/93	ACUVUE (ETAFILCON A) CONTACT LENS AND SUREVUE	VISTAKON JACKSONVILLE, FL 32247	MODIFIED MANUFACTURING PROCESS

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

(ETAFILCON A)
CONTACT LENS

P780007/S39	HYDRON (POLYMACON) HYDROPHILIC CONTACT LENS, HYDRON BIOMEDICS HYDROPHILIC CONTACT LENSES	OCULAR SCIENCES AMERICAN HYDRON SO. SAN FRANCISCO, CA 94080	REVISED LABELING
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P790027/S56	POSTERIOR CHAMBER INTRAOCULAR LENSES (IOLS) WITH HAPTIC DIAMETERS OF 5.0MM	IOLAB CORPORATION CLAREMONT, CA 91711	APPROVAL FOR ANY PMA-APPROVED INTRAOCULAR LENS DESIGN WITH SYMMETRICAL HAPTICS IN OPTIC DIAMETERS DOWN TO 5.0MM
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P800022/S40	ZYPLAST AND ZYDERM COLLAGEN IMPLANT	94230 COLLAGEN CORPORATION PALO ALTO, CA	APPROVAL FOR A 24 MONTH EXPIRATION DATE
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P800022/S41	ZYPLAST AND ZYDERM COLLAGEN IMPLANT	94230 COLLAGEN CORPORATION PALO ALTO, CA	APPROVAL FOR SCALE-UP OF EQUIPMENT USED
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P800022/S44	ZYPLAST AND ZYDERM COLLAGEN IMPLANT	94230 COLLAGEN CORPORATION PALO ALTO, CA	APPROVAL FOR A LARGE SCALE COLLAGEN HOMOGENIZATION SYSTEM
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APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
P810006/S16 11/01/93	COLLASTAT ABSORBABLE COLLAGEN HEMOSTATIC SPONGE	VITAPHORE CORPORATION MENLO PARK, CA 94025	ALTERNATIVE PACKAGING CONFIGURATIONS IN SINGLE OR DOUBLE TYVEK POUCHES
P810046/S146 11/08/93	ACS RX ELIPSE .014 CORONARY DILATATION CATHETER	ADVANCED CARDIOVASCULAR SYSTEMS SANTA CLARA, CA 95052-8167	ADDITION OF A QUALITY CONTROL TEST TO THE MANUFACTURING PROCESS
P820059/S20 11/23/93	POLYMACON CONTACT LENSES 94086-5200	SOLA BARNES HIND SUNNYVALE, CA FIVE YEARS	APPROVAL FOR AN EXPIRATION DATING OF
P820086/S11 11/23/93	CIBASOFT, CIBASOFT STD, CIBATHIN, TORISOFT, AND BI-SOFT (TEFILCON) SOFT (HYDROPHILIC) CONTACT LENS WITH CIBATINT	CIBA VISION CORPORATION DULUTH, GA 30136-1518	MODIFICATION OF THE LENSES BY INCORPORATING "LISTED" COLOR ADDITIVES USING THE CIBATINT PROCESS
P840066/S31 11/04/93	SOFT MATE CONSEPT-2 NEUTRALIZING	PILKINGTON BARNES HIND SUNNYVALE, CA 94086-5200	REVISED STABILITY SPECIFICATION FOR THE PRESERVATIVE FOR THE

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

AND RINSING SOLUTION
SOLUTION

P850002/S08 11/17/93	UNILENS SOFT ASPHERIC CONTACT LENS, SIMULVUE 34647-1511 SOFT BIFOCAL, AND ALGES (HEFILCON A) SOFT (HYDROPHILIC) BIFOCAL CONTACT LENS	UNILENS CORP. U.S.A. LARGO, FL	REVISED LABELING
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P850002/S09 11/17/93	UNILENS SOFT ASPHERIC CONTACT LENS, SIMULVUE 34647-1511 SOFT BIFOCAL, AND ALGES (HEFILCON A) SOFT (HYDROPHILIC) BIFOCAL CONTACT LENS	UNILENS CORP. U.S.A. LARGO, FL	REVISED LABELING
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P850035/S10 11/15/93	SPF IMPLANTABLE SPINAL FUSION STIMULATOR 07054-1079	ELECTRO-BIOLOGY, INC. PARSIPPANY, NJ	APPROVAL FOR THE SPF IMPLANTABLE SPINAL FUSION STIMULATOR
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P860005/S02 11/17/93	INTERPORE PRO OSTEON IMPLANT 500 CORALLINE HYDROXYAPATITE 92718-2402	INTERPORE INTERNATIONAL IRVINE, CA	MANUFACTURING DEVICE IN NEW SIZES AND CONFIGURATIONS
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P860019/S71	SCIMED	SCIMED LIFE SYSTEMS,	APPROVAL FOR A NEW
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APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
MEDICAL DEVICE - PMA SUPPLEMENTALS			
11/08/93	PERCUTANEOUS TRANSLUMINAL CORONARY ANGIOPLASTY CATHETER, SCIMED STRIKER PTCA CATHETER	INC. MAPLE GROVE, MN 55311-3648	MODEL CATHETER
P870024/S36 11/23/93	FLUOROPERM (PAFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS, FLUOROPERM 151 (PAFLUFOCON D) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	PARAGON VISION SCIENCES PHOENIX, AZ 85022	MODIFIED VERSION OF LENS MATERIAL
P870036/S26 11/04/93	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC RAIDER CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	ALTERNATIVE MODIFIED VERSION OF MEDTRONIC 14K PTCA CATHETER

APPLICATION NO. TRADE NAME APPROVAL DATE	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

P870036/S27 11/05/93	VERSAFLEX BUCHBINDER OMNIFLEX PTCA CATHETER SYSTEM, MEDTRONIC PANTHER CORONARY BALLOON DILATATION CATHETER	MEDTRONIC INTERVENTIONAL SAN DIEGO, CA 92121-2256	APPROVAL FOR A MODIFIED, UPDATED VERSION OF THE MEDTRONIC 14K PTCA CATHETER
P870045/S29 11/17/93	REQUEST FOR AN ALTERNATE MANUFACTURING PROCEDURE	CHIRON INTRAOPTICS, INC. IRVINE, CA 92718-1903	APPROVAL FOR AN ALTERNATE HAPTIC STAKING PROCESS
P880001/S40 11/23/93	FLUOREX 700 (FLUSILFOCON A), FLUOREX 500 (FLUSILFOCON B), AND FLUOREX 300 (FLUSILFOCON C) RIGID GAS PERMEABLE CONTACT LENSES (CLEAR AND TINTED)	G.T. LABORATORIES CHICAGO, IL 60601	APPROVAL FOR THREE ADDITIONAL CONTACT LENS FINISHING LABORATORIES TO BECOME ALTERNATE MANUFACTURING AND DISTRIBUTION SITES
P890003/S21 11/08/93	SYNERGYST PACING SYSTEM, ELITE II PULSE GENERATOR MODELS 7084, 7085 AND 7086; MODEL 9857E SOFTWARE AND MODEL 9748 MEMORYMOD	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MANUFACTURING MODIFICATION

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

P890046/S24 11/04/93	0-> PERM F60 (OXYFLUFOCON A) RIGID GAS PERMEABLE CONTACT LENS (CLEAR AND TINTED)	OPTICAL POLYMER RESEARCH, INC. GAINESVILLE, FL 32609	ONE ADDITIONAL CONTACT LENS FINISHING LABORATORY TO BECOME AN ALTERNATE MANUFACTURING AND DISTRIBUTION SITE
P900023/S05 11/23/93	ABIOMED BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	APPROVAL TO INCREASE THE STERILIZATION LOAD SIZE FOR THE BVS 5000 BLOOD PUMP SET FROM 20 TO 30 UNITS
P900023/S06 11/23/93	BVS 5000 BI-VENTRICULAR SUPPORT SYSTEM	ABIOMED, INC. DANVERS, MA 01923	APPROVAL TO REPLACE THE CURRENT DIFFERENTIAL PRESSURE TRANSDUCER WITH ANOTHER MODEL DUE TO UNAVAILABILITY IN THE NEAR FUTURE
P900032/S20 11/23/93	DYMER 200+ EXCIMER LASER SYSTEM 92718	ADVANCED INTERVENTIONAL SYSTEMS IRVINE, CA	APPROVAL FOR THE MODEL PC4016 LASER CATHETER
P910029/S02 11/23/93	BLANCHARD SOFT (POLYMACON) CONTACT LENS, ESSTECH PC ASPHERIC (POLYMACON) SOFT	LES LABORATORIES BLANCHARD QUEBEC, CANADA SARASOTA, FL AS AN ALTERNATE SUPPLIER OF	APPROVAL FOR BENZ RESEARCH AND DEVELOPMENT, POLYMACON LENS BLANKS

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND
APPROVAL DATE			INDICATION OF DEVICE

MEDICAL DEVICE - PMA SUPPLEMENTALS

(HYDROPHILIC)
CONTACT LENS

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

141-036 09-10-93	PIRSUE (GEL)	CATTLE KALAMAZOO, MI 49001	UPJOHN 5MG/ML	PIRLIMYCIN HYDROCHLORIDE
140-974 09-23-93	IVOMEC (PREMIX)	SWINE RAHWAY, NJ 07065	MERCK	IVERMECTIN 0.6% W/W
141-008 09-29-93	DRONTAL (TABLET)	CATS KITTENS 66201	MILES SHANNEE MISSION, KS PYRANTEL PAMOATE 72.6MG	PRAZIQUANTEL 18.2MG
140-872 11-05-93	POSILAC (SUSPENSION)	COWS 63167	MONSANTO ST LOUIS, MO BOVINE SOMATOTROPIN 500MG/VIAL	RECOMBINANT DNA DERIVED METHIONYL

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR NOVEMBER 1993.

SUPPLEMENTAL VETERINARY NADAs

140-989	PARASITE-S	SHRIMP	WESTERN CHEMICAL	FORMALIN
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NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

09-30-93	(SOLUTION)		FERNDALE, WA	37%
	98248			
65-256	CHLORTET SOLUBLE-O	CHICKENS	FEED SPECIALTIES	CHLORTETRACYCLINE
10-15-93	(POWDER)	SWINE	DES MOINES, IA	HYDROCHLORIDE
	TURKEYS	50313	25.6GM/PACKET	
			102.4GM/PACKET	

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

FDA DRUG AND DEVICE PRODUCT APPROVALS

Center for Drug Evaluation and Research
 *George R. Scott (301) 443-3910

Center for Devices and Radiological Health
 Mary Jo Robinson (301) 594-2186

Center for Biologics Evaluation and Research
 Joseph Wilczek (301) 594-2012

Center for Veterinary Medicine
 Norman Turner
 (301) 594-1623

*To whom general inquiries should be directed.

This report is compiled by the Division of Drug Information Resources, OM, CDER. It is available by subscription from the National Technical Information Service, Springfield, VA 22161.

Volume 16 (12) December 1993

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, PUBLIC HEALTH SERVICE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
 FOR NEW DRUG PRODUCTS

18-150	THALLOUS	MALLINCKRODT	THALLOUS CHLORIDE, TL-201
16-DEC-93	CHLORIDE TL 201	SAINT LOUIS, MO	1MCI/ML
(SUPPL)	(INJECTABLE)	63134	(NEW DOSAGE REGIMEN -- INCREASE IN PATIENT DOSE WHEN USE OF SINGLE PHOTON EMISSION TOMOGRAPHY (SPECT) IS INTENDED)

19-183	CARAFATE	MARION MERRELL DOW	SUCRALFATE
16-DEC-93	(SUSPENSION)	KANSAS CITY, MO	1GM/10ML
(3 S)	64134	(ANTIULCER)	

20-326	NEUTREXIN	US BIOSCIENCE	TRIMETREXATE GLUCURONATE
17-DEC-93	(INJECTABLE)	WEST CONSHOCKEN, PA	EQ 25MG BASE/VIAL
(1P, AA*,	19428	(FOLATE ANTAGONIST)	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

V**, E***)

[PNEUMOCYSTIS CARINII
PNEUMONIA]

AA* - Priority Classification AIDS Drug
V** - Designated Orphan Drug
E*** - Drug for Severely Debilitating/Life Threatening Illness

19-867	ISOLYTE E	MCGAW	CALCIUM CHLORIDE
20-DEC-93	IN DEXTROSE 5%	IRVINE, CA	35MG/100ML
(5 S)	IN PLASTIC CONTAINER	92713	DEXTROSE
	(INJECTABLE)		5GM/100ML
			MAGNESIUM CHLORIDE
			30MG/100ML
			POTASSIUM CHLORIDE
			74MG/100ML
			SODIUM ACETATE
			640MG/100ML
			SODIUM CHLORIDE
			500MG/100ML
			SODIUM CITRATE
			74MG/100ML
			(FLUID AND

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

ELECTROLYTE REPLENISHER)

20-090	DIFLUCAN	PFIZER	FLUCONAZOLE
23-DEC-93	(POWDER,	NEW YORK, NY	50MG/5ML
(3 S)	FOR RECONSTITUTION)	10017	200MG/5ML
		(ANTIFUNGAL)	

50-662	BIAXIN	ABBOTT	CLARITHROMYCIN
23-DEC-93	(TABLET)	ABBOTT PARK, IL	250MG
(SUPPL)		60064	500MG
		(NEW INDICATION --	
		TREATMENT OF DISSEMINATED	
		MYCOBACTERIAL INFECTIONS	
		DUE TO MYCOBACTERIUM	
		AVIUM AND MYCOBACTERIUM	
		INTRACELLULARE)	

50-697	BIAXIN	ABBOTT	CLARITHROMYCIN
23-DEC-93	(TABLET)	ABBOTT PARK, IL	250MG
(6 S, AA*, E***)		60064	500MG
		(ANTIBIOTIC, MACROLIDE)	
		[TREATMENT OF DISSEMINATED	
		MYCOBACTERIAL INFECTIONS	
		DUE TO MYCOBACTERIUM	
		AVIUM AND MYCOBACTERIUM	
		INTRACELLULARE]	

AA* - Priority Classification AIDS Drug

E*** - Drug for Severely Debilitating/Life Threatening Illness

50-698	BIAXIN	ABBOTT	CLARITHROMYCIN
23-DEC-93	(GRANULE,	ABBOTT PARK, IL	125MG/5ML
(3 S)	FOR RECONSTITUTION)	60064	250MG/5ML
		(ANTIBIOTIC, MACROLIDE)	
		[TREATMENT OF DISSEMINATED	
		MYCOBACTERIAL INFECTIONS	
		DUE TO MYCOBACTERIUM AVIUM	
		AND MYCOBACTERIUM	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

INTRACELLULARE]

20-151	EFFEXOR	WYETH AYERST	VENLAFAXINE HYDROCHLORIDE
28-DEC-93	(TABLET)	PHILADELPHIA, PA	EQ 12.5MG BASE*
(1 S)	19101	EQ 25MG BASE	
		EQ 37.5MG BASE	
		EQ 50MG BASE	
		EQ 75MG BASE	
		EQ 100MG BASE	
		(ANTIDEPRESSANT)	

18-467	HEPATOLITE	DUPONT	TECHNETIUM TC-99M
29-DEC-93	(INJECTABLE)	WILMINGTON, DE	DISOFENIN KIT
(SUPPL)	19880	N/A	
		(NEW INDICATION --	
		DIAGNOSIS AND EVALUATION OF	
		ACUTE CHOLECYSTITIS WHEN	
		PERFORMED WITH MORPHINE	
		SULFATE AUGMENTATION)	

* - Not Marketed at This Time

20-176	KABIVITE PED F+W KIT	KABI	ASCORBIC ACID
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NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT CLASSIFICATION(S)	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

29-DEC-93 (3 P)	(INJECTABLE) 27520	CLAYTON, NC BIOTIN 0.02MG/VIAL CYANOCOBALAMIN 0.001MG/VIAL FOLIC ACID 0.14MG/VIAL NIACINAMIDE 17MG/VIAL PANTOTHENIC ACID 5MG/VIAL PYRIDOXINE 1MG/VIAL RIBOFLAVIN 1.4MG/VIAL THIAMINE 1.2MG/VIAL [WATER SOLUBLE VIAL] ERGOCALCIFEROL 400IU/10ML PHYTONADIONE 0.2MG/10ML VITAMIN A PALMITATE EQ 2,300 UNITS BASE/10ML VITAMIN E 7IU/10ML [FAT SOLUBLE VIAL] (PEDIATRIC MULTIVITAMIN)	80MG/VIAL
20-239 29-DEC-93 (1 S)	KYTRIL (INJECTABLE) 19406	SMITHKLINE BEECHAM KING OF PRUSSIA, PA (ANTIEMETIC)	GRANISETRON HYDROCHLORIDE EQ 3MG BASE/ML
20-272 29-DEC-93 (1 P)	RISPERDAL (TABLET) 08560	JANSSEN TITUSVILLE, NJ 2MG	RISPERIDONE 1MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)		CLASSIFICATION(S)	

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

3MG
4MG
5MG*
(ANTIPSYCHOTIC)

* - Not Marketed At This Time

20-273	DOVONEX	BRISTOL MYERS SQUIBB	CALCIPOTRIENE
29-DEC-93	(OINTMENT)	BUFFALO, NY	0.005%
(1 S)	14213	(ANTIPSORIATIC)	

20-304	TRASYLOL	MILES PHARM	APROTININ
29-DEC-93	(INJECTABLE)	WEST HAVEN, CT	10,000 KIU/ML ***
(1P, V**)	06516	(FIBRINOLYTICS/ ANTIFIBRINOLYTICS)	
		[PROPHYLACTIC USE TO REDUCE PERIOPERATIVE BLOOD LOSS/ NEED FOR TRANSFUSION IN SELECT CORONARY PATIENTS]	

19-942	INTRALIPID	KABI	SOYBEAN OIL
30-DEC-93	(INJECTABLE)	CLAYTON, NC	30%
(5 S)	27520	(CALORIE AND ESSENTIAL FATTY ACID REPLENISHER)	

19-949	DIFLUCAN	PFIZER	FLUCONAZOLE
30-DEC-93	(TABLET)	GROTON, CT	50MG
(SUPPL)	06340	100MG	
		200MG	
		(NEW INDICATION -- TO DECREASE THE INCIDENCE OF CANDIDIASIS IN PATIENTS UNDERGOING BONE MARROW TRANSPLANTATION WHO RECEIVE CYTOTOXIC CHEMOTHERAPY AND/OR RADIATION THERAPY)	

19-950	DIFLUCAN	PFIZER	FLUCONAZOLE
30-DEC-93	(INJECTABLE)	NEW YORK, NY	2MG/ML

NDA NUMBER APPROVAL DATE (CLASSIFICATION)	TRADE NAME (DOSAGE FORM)	APPLICANT CLASSIFICATION(S)	ACTIVE INGREDIENT(S) STRENGTH(S)
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ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

(SUPPL)	10017	(NEW INDICATION -- TO DECREASE THE INCIDENCE OF CANDIDIASIS IN PATIENTS UNDERGOING BONE MARROW TRANSPLANTATION WHO RECEIVE CYTOTOXIC CHEMOTHERAPY AND/OR RADIATION THERAPY)	
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V** - Designated Orphan Drug

*** - Kallikrein Inhibitor Units

20-184 30-DEC-93 (1 S)	ACEON (TABLET) 19477	JOHNSON RW SPRING HOUSE, PA 4MG 8MG	PERINDOPRIL ERBUMINE 2MG
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(ANGIOTENSIN CONVERTING
ENZYME INHIBITOR)

20-235 30-DEC-93 (1 P)	NEURONTIN (CAPSULE) 48105	PARKE DAVIS ANN ARBOR, MI 300MG 400MG	GABAPENTIN 100MG
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(ANTICONVULSANT)

19-304 31-DEC-93 (1 S)	LIPIDIL (CAPSULE)	FOURNIER CHENOVE, FRANCE (LIPID REGULATING AGENT)	FENOFIBRATE 100MG
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20-261 31-DEC-93 (1 S)	LESCOL (CAPSULE) 07936	SANDOZ EAST HANOVER, NJ EQ 40MG BASE (CHOLESTEROL LOWERING AGENT)	FLUVASTATIN SODIUM EQ 20MG BASE
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
(CLASSIFICATION)			CLASSIFICATION(S)

ORIGINAL AND SUPPLEMENTAL NDAs
FOR NEW DRUG PRODUCTS

ERRATA

20-195	FENTANYL	ANESTA	FENTANYL CITRATE
04-OCT-93	(TROCHE/LOZENGE)	SALT LAKE CITY, UT	EQ 0.2MG BASE
(3 P)*	84103	EQ 0.3MG BASE	
		EQ 0.4MG BASE	
		(NARCOTIC ANALGESIC)	

* - Revised Classification code

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

APPROVABLE ORIGINAL NDAs

An approvable letter indicates that FDA is prepared to approve the application upon the satisfaction of conditions specified in the approvable letter.

Drug products which are the subject of approvable letters may not be legally marketed until the firm has satisfied the identified deficiencies, as well as any other requirements that may be imposed by FDA, and has been notified in writing that the application has been approved. Further information on approvable NDAs is not subject to Freedom of Information (FOI) release until applications are approved.

20-059 13-DEC-93	ADENOSCAN (INJECTABLE) 27709	MEDCO RES TRIANGLE PK, NC (NUCLEOSIDE) [ADJUNCT TO THALLIUM-201 MYOCARDIAL PERFUSION SCINTIGRAPHY IN PATIENTS UNABLE TO EXERCISE ADEQUATELY]	ADENOSINE 3MG/ML
20-239 13-DEC-93	KYTRIL (INJECTABLE) 19406	SMITHKLINE BEECHAM KING OF PRUSSIA, PA (ANTIEMETIC)	GRANISETRON HYDROCHLORIDE EQ 3MG BASE/ML
20-334 14-DEC-93	METRONIDAZOLE (CAPSULE) 60077	SEARLE SKOKIE, IL (ANTIPROTOZOAL)	METRONIDAZOLE 375MG
20-337 16-DEC-93	TEMOVATE (GEL) 27709	GLAXO RES TRIANGLE PK, NC (CORTICOSTEROID)	CLOBETASOL PROPIONATE 0.05%
19-754	CONCENTRATED	ABBOTT	DEXTROSE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE (DOSAGE FORM)		CLASSIFICATION(S)	STRENGTH(S)

APPROVABLE ORIGINAL NDAs

17-DEC-93	DEXTROSE AND SODIUM CHLORIDE IN PLASTIC CONTAINER (SOLUTION)	ABBOTT PARK, IL 60064	0.2GM/100ML SODIUM CHLORIDE 0.9GM/100ML (RED BLOOD CELL PROCESSOR)
19-755 17-DEC-93	CONCENTRATED LACTATED RINGERS IN PLASTIC CONTAINER (SOLUTION)	ABBOTT ABBOTT PARK, IL 60064	CALCIUM CHLORIDE 0.02GM/100ML POTASSIUM CHLORIDE 0.03GM/100ML SODIUM CHLORIDE 0.6GM/100ML SODIUM LACTATE 0.31GM/100ML (FLUID AND ELECTROLYTE REPLENISHER)
19-756 17-DEC-93	CONCENTRATED SODIUM CHLORIDE IN PLASTIC CONTAINER (SOLUTION)	ABBOTT ABBOTT PARK, IL 60064	SODIUM CHLORIDE 0.9GM/100ML (FLUID AND ELECTROLYTE REPLENISHER)
20-184 17-DEC-93	ACEON (TABLET) 19477	JOHNSON RW SPRING HOUSE, PA 4MG	PERINDOPRIL ERBUMINE 2MG 8MG (ANGIOTENSIN CONVERTING ENZYME INHIBITOR) [HYPERTENSION]

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE (DOSAGE FORM)		CLASSIFICATION(S)	STRENGTH(S)

APPROVABLE ORIGINAL NDAs

20-233 17-DEC-93	RHINOCORT (AEROSOL, METERED) 08540	BESSELAAR PRINCETON, NJ (GLUCOCORTICOSTEROID) [MANAGEMENT OF SYMPTOMS OF RHINITIS]	BUDESONIDE 0.032MG/INH
20-235 21-DEC-93	NEURONTIN (CAPSULE) 48105	PARKE DAVIS ANN ARBOR, MI 300MG 400MG (ANTICONVULSANT)	GABAPENTIN 100MG
20-340 22-DEC-93	TEMOVATE (CREAM) 27709	GLAXO RES TRIANGLE PK, NC (CORTICOSTEROID)	CLOBETASOL PROPIONATE 0.05%
50-673 22-DEC-93	CECLOR CD (TABLET) 46285	LILLY INDIANAPOLIS, IN (ANTIBIOTIC, CEPHEM)	CEFACLOR EQ 375MG BASE
20-237 28-DEC-93	SALAGEN (TABLET) 55343	MGI MINNEAPOLIS, MN 10MG (CHOLINERGIC AGONIST) [TREATMENT OF SYMPTOMS OF XEROSTOMIA DUE TO SALIVARY GLAND HYPOFUNCTION RESULTING FROM RADIOTHERAPY FOR CANCER OF THE HEAD	PILOCARPINE HYDROCHLORIDE 5MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVABLE DATE (DOSAGE FORM)		CLASSIFICATION(S)	STRENGTH(S)

APPROVABLE ORIGINAL NDAs

AND NECK]

19-671	TRIAMCINOLONE	WHITBY	TRIAMCINOLONE ACETONIDE
30-DEC-93	ACETONIDE (CREAM)	RICHMOND, VA	0.05%
	23261	(CORTICOSTEROID)	

20-336	DYNACIRC CR	SANDOZ	ISRADIPINE
30-DEC-93	(TABLET, EXTENDED RELEASE)	EAST HANOVER, NJ	5MG
		07936	10MG
		(CALCIUM ION INFLUX INHIBITOR)	
		[HYPERTENSION]	

20-343	PRIMACOR	STERLING WINTHROP	MILRINONE LACTATE
30-DEC-93	IN DEXTROSE 5%	COLLEGEVILLE, PA	EQ 0.1MG BASE/ML
	IN PLASTIC CONTAINER (INJECTABLE)	19426	EQ 0.15MG BASE/ML
		EQ 0.2MG BASE/ML	
		(INOTROPIC/VASODILATOR)	
		[CONGESTIVE HEART FAILURE]	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

73-592*	LEVORA 0.15/30-21 (TABLET)	SYNTEX PALO ALTO, CA	ETHINYL ESTRADIOL 0.03MG
13-DEC-93	94304	LEVONORGESTREL 0.15MG	(HORMONAL CONTRACEPTIVE)
73-594*	LEVORA 0.15/30-28 (TABLET)	SYNTEX PALO ALTO, CA	ETHINYL ESTRADIOL 0.03MG
13-DEC-93	94304	LEVONORGESTREL 0.15MG	(HORMONAL CONTRACEPTIVE)
40-059	FLUOCINOLONE ACETONIDE (SOLUTION)	BAUSCH AND LOMB TAMPA, FL	FLUOCINOLONE ACETONIDE 0.01%
20-DEC-93	33637	(CORTICOSTEROID)	
73-653*	METOPROLOL TARTRATE (TABLET)	MUTUAL PHARM PHILADELPHIA, PA	METOPROLOL TARTRATE 50MG
21-DEC-93	19124	(BETA ADRENERGIC BLOCKER)	
73-654*	METOPROLOL TARTRATE (TABLET)	MUTUAL PHARM PHILADELPHIA, PA	METOPROLOL TARTRATE 100MG
21-DEC-93	19124	(BETA ADRENERGIC BLOCKER)	
73-666*	METOPROLOL TARTRATE (TABLET)	MYLAN MORGANTOWN, WV	METOPROLOL TARTRATE 50MG
21-DEC-93	26504	100MG	(BETA ADRENERGIC BLOCKER)
74-032*	METOPROLOL TARTRATE (INJECTABLE)	STERIS PHOENIX, AZ	METOPROLOL TARTRATE 1MG/ML
21-DEC-93	85043	(BETA ADRENERGIC BLOCKER)	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

74-105	NAPROXEN	LEDERLE	NAPROXEN
21-DEC-93	(TABLET)	PEARL RIVER, NY	250MG
	10965	375MG	
		500MG	
		(NONSTEROIDAL	
		ANTI-INFLAMMATORY)	

* - First Time Product Available Generically

74-121	NAPROXEN	MYLAN	NAPROXEN
21-DEC-93	(TABLET)	MORGANTOWN, WV	250MG
	26504	375MG	
		500MG	
		(NONSTEROIDAL	
		ANTI-INFLAMMATORY)	

74-129	NAPROXEN	NOVOPHARM	NAPROXEN
21-DEC-93	(TABLET)	SCARBOROUGH, ONTARIO	250MG
	CANADA	375MG	
		500MG	
		(NONSTEROIDAL	
		ANTI-INFLAMMATORY)	

74-133*	METOPROLOL TARTRATE	STERLING WINTHROP	METOPROLOL TARTRATE
21-DEC-93	(INJECTABLE)	NEW YORK, NY	1MG/ML
	10016	(BETA ADRENERGIC BLOCKER)	

74-140	NAPROXEN	GENEVA	NAPROXEN
21-DEC-93	(TABLET)	BROOMFIELD, CO	250MG
	80038	375MG	
		500MG	
		(NONSTEROIDAL	
		ANTI-INFLAMMATORY)	

74-142	NAPROXEN SODIUM	NOVOPHARM	NAPROXEN SODIUM
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

21-DEC-93	(TABLET) CANADA	SCARBOROUGH, ONTARIO	EQ 250MG BASE EQ 500MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)
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74-162 21-DEC-93	NAPROXEN SODIUM (TABLET) 80038	GENEVA BROOMFIELD, CO	NAPROXEN SODIUM EQ 250MG BASE EQ 500MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)
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* - First Time Product Available Generically

74-195 21-DEC-93	NAPROXEN SODIUM (TABLET) 06810	DANBURY DANBURY, CT	NAPROXEN SODIUM EQ 250MG BASE EQ 500MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)
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74-198 21-DEC-93	NAPROXEN SODIUM (TABLET) 18960	LEMMON SELLERSVILLE, PA	NAPROXEN SODIUM EQ 250MG BASE EQ 500MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)
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74-201 21-DEC-93	NAPROXEN (TABLET) 18960	LEMMON SELLERSVILLE, PA	NAPROXEN 250MG 375MG 500MG (NONSTEROIDAL ANTI-INFLAMMATORY)
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)	CLASSIFICATION(S)	STRENGTH(S)

ORIGINAL ABBREVIATED NDAs

74-207 21-DEC-93	NAPROXEN (TABLET) 02021	COPLEY CANTON, MA 375MG 500MG (NONSTEROIDAL ANTI-INFLAMMATORY)	NAPROXEN 250MG
74-257 21-DEC-93	NAPROXEN SODIUM (TABLET) 43216	ROXANE COLUMBUS, OH EQ 500MG BASE (NONSTEROIDAL ANTI-INFLAMMATORY)	NAPROXEN SODIUM EQ 250MG BASE
74-263 21-DEC-93	NAPROXEN (TABLET) 07207	PUREPAC ELIZABETH, NJ 375MG 500MG (NONSTEROIDAL ANTI-INFLAMMATORY)	NAPROXEN 250MG
81-066 29-DEC-93	FOLIC ACID (INJECTABLE) 44146	LOCH PHARMS BEDFORD, OH (VITAMIN)	FOLIC ACID 5MG/ML
81-298 29-DEC-93	CHLORZOXAZONE (TABLET) 08823	OHM FRANKLIN PARK, NJ (SKELETAL MUSCLE RELAXANT)	CHLORZOXAZONE 250MG
81-299 29-DEC-93	CHLORZOXAZONE (TABLET) 08823	OHM FRANKLIN PARK, NJ (SKELETAL MUSCLE RELAXANT)	CHLORZOXAZONE 500MG

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENT(S)
TENTATIVE	(DOSAGE FORM)		STRENGTH(S)
APPROVAL DATE			CLASSIFICATION(S)

ORIGINAL ABBREVIATED AND 505(b)(2) NDAs WITH TENTATIVE APPROVALS

A tentative approval indicates that FDA has given an abbreviated new drug application (ANDA) or 505(b)(2) application provisional approval under the terms of the Drug Price Competition and Patent Term Restoration Act. Such drug products that are the subjects of tentative approvals may not be legally marketed until the market exclusivity and/or patent term of the listed reference drug product has expired. Final approval is also contingent upon conditions and information available to FDA remaining acceptable. When the application receives final approval, the product may be legally marketed. The effective approval date will be listed in this publication and in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list published by FDA. Additional information on these applications will become available to the public when the applications receive final approval.

THERE ARE NO ORIGINAL ABBREVIATED AND 505(b)(2) NDA TENTATIVE APPROVALS FOR DECEMBER 1993.

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-759 01-DEC-93	SODIUM CHLORIDE 0.45% IN PLASTIC CONTAINER (INJECTABLE)	ABBOTT ABBOTT PARK, IL 60064	SODIUM CHLORIDE 450MG/100ML (LABELING REVISION -- HOW SUPPLIED)
11-958 02-DEC-93	HYDROPRES 25 (TABLET) 19486	MSD WEST POINT, PA RESERPINE 0.125MG	HYDROCHLOROTHIAZIDE 25MG (LABELING REVISION -- PRECAUTIONS)
11-958 02-DEC-93	HYDROPRES 50 (TABLET) 19486	MSD WEST POINT, PA RESERPINE 0.125MG	HYDROCHLOROTHIAZIDE 50MG (LABELING REVISION -- PRECAUTIONS)
19-687 02-DEC-93	LUTREPULSE PUMP KIT (INJECTABLE) 10901	FERRING SUFFERN, NY 3.2MG/VIAL	GONADORELIN ACETATE 0.8MG/VIAL (LABELING REVISION -- DESCRIPTION; WARNINGS; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)
17-563 06-DEC-93	FLAVORED COLESTID (GRANULE) 49001	UPJOHN KALAMAZOO, MI 5GM/SCOOP	COLESTIPOL HYDROCHLORIDE 5GM/PACKET (LABELING REVISION -- DESCRIPTION)

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

19-614	VERELAN	ELAN	VERAPAMIL HYDROCHLORIDE
06-DEC-93	(CAPSULE, EXTENDED RELEASE)	GAINESVILLE, GA 30504	120MG 180MG 240MG (LABELING REVISION -- HOW SUPPLIED)
20-014	MAXAIR	3M	PIRBUTEROL ACETATE
06-DEC-93	(AEROSOL, METERED) 55144	SAINT PAUL, MN	EQ 0.2MG BASE/INH (LABELING REVISION -- HOW SUPPLIED; PATIENT PACKAGE INSERT)
20-092	DILACOR XR	RHONE POULENC RORER	DILTIAZEM HYDROCHLORIDE
06-DEC-93	(CAPSULE, EXTENDED RELEASE)	COLLEGEVILLE, PA 19426	120MG 180MG 240MG (LABELING REVISION -- PRECAUTIONS)
50-370	ILOTYCIN GLUCEPTATE	LILLY	ERYTHROMYCIN GLUCEPTATE
07-DEC-93	(INJECTABLE) 46285	INDIANAPOLIS, IN	EQ 1GM BASE/VIAL (LABELING REVISION -- CONTRAINDICATIONS; PRECAUTIONS)
19-715	DIPENTUM	KABI	OLSALAZINE SODIUM
08-DEC-93	(CAPSULE) 08855	PISCATAWAY, NJ	250MG (LABELING REVISION -- ADVERSE REACTIONS)
18-086	TIMOPTIC	MERCK	TIMOLOL MALEATE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

09-DEC-93	(SOLUTION/DROPS) 19486	WEST POINT, PA	EQ 0.25% BASE EQ 0.5% BASE (LABELING REVISION -- CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; PRECAUTIONS)
18-201 09-DEC-93	MODURETIC 5-50 (TABLET) 19486	MSD WEST POINT, PA	AMILORIDE HYDROCHLORIDE EQ 5MG ANHYDROUS HYDROCHLOROTHIAZIDE 50MG (LABELING REVISION -- PRECAUTIONS)
19-463 09-DEC-93	TIMOPTIC IN OCUDOSE (SOLUTION/DROPS) 19486	MERCK WEST POINT, PA	TIMOLOL MALEATE EQ 0.25% BASE EQ 0.5% BASE (LABELING REVISION -- INDICATIONS AND USAGE)
19-888 09-DEC-93	ZESTORETIC 10-12.5 (TABLET) 19897	ZENECA WILMINGTON, DE	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL 10MG (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)
19-888 09-DEC-93	ZESTORETIC 20-12.5 (TABLET) 19897	ZENECA WILMINGTON, DE	HYDROCHLOROTHIAZIDE 12.5MG LISINOPRIL

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

20MG
(LABELING REVISION --
PRECAUTIONS;
ADVERSE REACTIONS)

19-888	ZESTORETIC 20-25	ZENECA	HYDROCHLOROTHIAZIDE
09-DEC-93	(TABLET)	WILMINGTON, DE	25MG
	19897	LISINOPRIL	

20MG
(LABELING REVISION --
PRECAUTIONS;
ADVERSE REACTIONS)

19-080	PROSOM	ABBOTT	ESTAZOLAM
13-DEC-93	(TABLET)	ABBOTT PARK, IL	1MG
	60064	2MG	

(LABELING REVISION --
OVERDOSAGE)

18-164	ANAPROX	SYNTEX	NAPROXEN SODIUM
15-DEC-93	(TABLET)	HUMACAO, PR	EQ 250MG BASE
	00661	(LABELING REVISION -- DESCRIPTION)	

18-164	ANAPROX DS	SYNTEX	NAPROXEN SODIUM
15-DEC-93	(TABLET)	HUMACAO, PR	EQ 500MG BASE
	00661	(LABELING REVISION -- DESCRIPTION)	

18-150	THALLOUS	MALLINCKRODT	THALLOUS CHLORIDE, TL-201
16-DEC-93	CHLORIDE TL 201	SAINT LOUIS, MO	1MCI/ML
	(INJECTABLE)	63134	(LABELING REVISION -- DOSAGE AND ADMINISTRATION)

20-035	ERGAMISOL	JANSSEN	LEVAMISOLE HYDROCHLORIDE
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NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

17-DEC-93	(TABLET) 08855	PISCATAWAY, NJ	EQ 50MG BASE (LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)
07-942 20-DEC-93	SUS-PHRINE (INJECTABLE) 10155	FOREST LABS NEW YORK, NY	EPINEPHRINE 5MG/ML (LABELING REVISION -- DESCRIPTION; PRECAUTIONS; ADVERSE REACTIONS; DOSAGE AND ADMINISTRATION)
20-033 20-DEC-93	LOTENSIN HCT (TABLET) 07901	CIBA SUMMIT, NJ	BENAZEPRIL HYDROCHLORIDE 5MG HYDROCHLOROTHIAZIDE 6.25MG (LABELING REVISION -- PRECAUTIONS)
20-033 20-DEC-93	LOTENSIN HCT (TABLET) 07901	CIBA SUMMIT, NJ	BENAZEPRIL HYDROCHLORIDE 10MG HYDROCHLOROTHIAZIDE 12.5MG (LABELING REVISION -- PRECAUTIONS)
20-033 20-DEC-93	LOTENSIN HCT (TABLET) 07901	CIBA SUMMIT, NJ	BENAZEPRIL HYDROCHLORIDE 20MG HYDROCHLOROTHIAZIDE

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

12.5MG
(LABELING REVISION --
PRECAUTIONS)

20-033	LOTENSIN HCT	CIBA	BENAZEPRIL HYDROCHLORIDE
20-DEC-93	(TABLET)	SUMMIT, NJ	20MG
	07901		HYDROCHLOROTHIAZIDE
			25MG
			(LABELING REVISION -- PRECAUTIONS)

16-131	CLOMID	MARION MERRELL DOW	CLOMIPHENE CITRATE
21-DEC-93	(TABLET)	KANSAS CITY, MO	50MG
	64134		(LABELING REVISION -- DESCRIPTION; CLINICAL PHARMACOLOGY; INDICATIONS AND USAGE; CONTRAINDICATIONS; WARNINGS; PRECAUTIONS; ADVERSE REACTIONS; OVERDOSAGE; DOSAGE AND ADMINISTRATION; HOW SUPPLIED)

11-860	HUMORSOL	MSD	DEMECARIUM BROMIDE
22-DEC-93	(SOLUTION/DROPS)	WEST POINT, PA	0.125%
	19486		0.25%
			(LABELING REVISION -- PRECAUTIONS)

19-757	CHIBROXIN	MERCK	NORFLOXACIN
22-DEC-93	(SOLUTION/DROPS)	WEST POINT, PA	0.3%
	19486		(LABELING REVISION --

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

PRECAUTIONS)

04-782	PREMARIN	WYETH AYERST	ESTROGENS, CONJUGATED
23-DEC-93	(TABLET)	PHILADELPHIA, PA	0.3MG
	19101	0.625MG	

0.9MG
1.25MG
2.5MG
(LABELING REVISION --
INDICATIONS AND USAGE)

16-619	SUBLIMAZE	JANSSEN	FENTANYL CITRATE
23-DEC-93	(INJECTABLE)	PISCATAWAY, NJ	EQ 0.05MG BASE/ML
	08854	(LABELING REVISION -- WARNINGS; PRECAUTIONS)	

20-210	PROPULSID	JANSSEN	CISAPRIDE MONOHYDRATE
23-DEC-93	(TABLET)	PISCATAWAY, NJ	EQ 10MG BASE
	08855	EQ 20MG BASE (LABELING REVISION --	

DESCRIPTION;

HOW SUPPLIED)

50-662	BIAXIN	ABBOTT	CLARITHROMYCIN
23-DEC-93	(TABLET)	ABBOTT PARK, IL	250MG
	60064	500MG (LABELING REVISION --	

DESCRIPTION;

CLINICAL PHARMACOLOGY;
INDICATIONS AND USAGE;
PRECAUTIONS;

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

ADVERSE REACTIONS;
 DOSAGE AND ADMINISTRATION;
 HOW SUPPLIED)

18-841	DAYPRO	SEARLE	OXAPROZIN
27-DEC-93	(TABLET)	SKOKIE, IL	600MG
	60077		(LABELING REVISION -- PRECAUTIONS; ADVERSE REACTIONS)

08-126	CORTISONE ACETATE	UPJOHN	CORTISONE ACETATE
28-DEC-93	(TABLET)	KALAMAZOO, MI	5MG
	49001	10MG 25MG	(LABELING REVISION -- WARNINGS; PRECAUTIONS)

08-697	CORTEF	UPJOHN	HYDROCORTISONE
28-DEC-93	(TABLET)	KALAMAZOO, MI	5MG
	49001	10MG 20MG	(LABELING REVISION --

PRECAUTIONS)

WARNINGS;

09-866	SOLU-CORTEF	UPJOHN	HYDROCORTISONE
28-DEC-93	(INJECTABLE)	KALAMAZOO, MI	SODIUM SUCCINATE
	49001	EQ 100MG BASE/VIAL EQ 250MG BASE/VIAL EQ 500MG BASE/VIAL EQ 1GM BASE/VIAL	(LABELING REVISION --

WARNINGS;

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

PRECAUTIONS)

09-900	CORTEF	UPJOHN	HYDROCORTISONE CYPIONATE
28-DEC-93	(SUSPENSION)	KALAMAZOO, MI	EQ 10MG BASE/5ML
	49001	(LABELING REVISION --	

WARNINGS; PRECAUTIONS)

09-986	DELTASONE	UPJOHN	PREDNISONE	
28-DEC-93	(TABLET)	KALAMAZOO, MI	2.5MG	49001
		10MG		
		20MG		
		50MG		

(LABELING REVISION

-- WARNINGS; PRECAUTIONS)

11-153	MEDROL	UPJOHN	METHYLPREDNISOLONE
28-DEC-93	(TABLET)	KALAMAZOO, MI	2MG
	49001	4MG	
		8MG	
		16MG	
		24MG	
		32MG	
		(LABELING REVISION --	
		WARNINGS; PRECAUTIONS)	

18-467	HEPATOLITE	DUPONT	TECHNETIUM TC-99M
29-DEC-93	(INJECTABLE)	WILMINGTON, DE	DISOFENIN KIT
	19880	N/A	
		(LABELING REVISION --	
		CLINICAL PHARMACOLOGY;	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
		LABELING CHANGE(S)	

LABELING SUPPLEMENTS TO ORIGINAL NDAs

INDICATIONS AND USAGE;
 PRECAUTIONS;
 RADIATION DOSIMETRY)

19-949	DIFLUCAN	PFIZER	FLUCONAZOLE
30-DEC-93	(TABLET)	GROTON, CT	50MG
	06340	100MG	
		200MG	
		(LABELING REVISION --	
		DESCRIPTION;	
		INDICATIONS AND USAGE;	
		DOSAGE AND ADMINISTRATION;	
		HOW SUPPLIED)	

19-950	DIFLUCAN	PFIZER	FLUCONAZOLE
30-DEC-93	(INJECTABLE)	NEW YORK, NY	2MG/ML
	10017	(LABELING REVISION --	
		DESCRIPTION;	
		INDICATIONS AND USAGE;	
		DOSAGE AND ADMINISTRATION;	
		HOW SUPPLIED)	

20-144*	TRANSDERM-NITRO	CIBA GEIGY	NITROGLYCERIN
30-DEC-93	(FILM,	SUMMIT, NJ	0.1MG/HR
	EXTENDED RELEASE)	07901	0.2MG/HR
		0.4MG/HR	
		0.6MG/HR	
		0.8MG/HR	
		(LABELING REVISION --	
		DESCRIPTION;	
		HOW SUPPLIED)	

NDA NUMBER	TRADE NAME	APPLICANT	ACTIVE INGREDIENTS(S)
APPROVAL DATE	(DOSAGE FORM)		STRENGTH(S)
LABELING CHANGE(S)			

LABELING SUPPLEMENTS TO ORIGINAL NDAs

[NEW STRENGTH]

20-145*	NITRO-DUR	KEY	NITROGLYCERIN
30-DEC-93	(FILM, EXTENDED RELEASE)	KENILWORTH, NJ 07033	0.1MG/HR 0.2MG/HR
		0.3MG/HR	
		0.4MG/HR	
		0.6MG/HR	
		0.8MG/HR	
		(LABELING REVISION -- DESCRIPTION; HOW SUPPLIED)	
		[NEW STRENGTH]	

* - Permitted

LICENSE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
LICENSE DATE	(DOSAGE FORM)		(DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

938	NONE	CHAMPLAIN VALLEY	PLATELETS
02-DEC-93	(INJECTABLE)	PHYS HOSP MED CTR	(TRANSFUSION)
		PLATTSBURGH, NY	(B)
		12901	
203	NONE	INLAND NW BLOOD CTR	PLATELETS
08-DEC-93	(INJECTABLE)	SPOKANE, WA	(TRANSFUSION)
		99210	(B)
1048	PULMOZYME	GENENTECH	DORNASE ALFA
30-DEC-93	(SOLUTION)	S SAN FRANCISCO, CA	(TREATMENT OF CYSTIC
	94080	FIBROSIS)	
		(B)	

LICENSE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
LICENSE DATE	(DOSAGE FORM)		(DESCRIPTION)

BIOLOGICAL PRODUCT LICENSES ISSUED

(B) Product License Issued

DEVICE NUMBER	TRADE NAME	MANUFACTURER	PROPER NAME
APPROVAL DATE		(DESCRIPTION)	

BIOLOGICAL PRODUCT DEVICE APPROVALS

THERE ARE NO BIOLOGICAL PRODUCT DEVICE APPROVALS FOR DECEMBER 1993.

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PREMARKET APPROVAL APPLICATIONS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL
HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION
RESOURCES PRIOR TO PUBLICATION

THERE ARE NO PREMARKET APPROVAL APPLICATIONS FOR DECEMBER 1993.

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

THE FOLLOWING DATA IS RECEIVED FROM THE CENTER FOR DEVICES AND RADIOLOGICAL HEALTH AND IS NOT EDITED BY THE DIVISION OF DRUG INFORMATION RESOURCES PRIOR TO PUBLICATION

N16420/S04	POLYTEF PASTE FOR INJECTION	MENTOR CORPORATION SANTA BARBARA, CA	NEW SECONDARY CONTRACT STERILIZATION FACILITY
12/08/93	93111		

N18331/S23	PDS II (POLYDIOXANONE) SUTURE, DYED & UNDYED	ETHICON, INC. SOMERVILLE, NJ	USE OF AN ALTERNATE DILUENT IN THE STERILIZATION PROCESS
12/09/93		08876-0151	

P790007/S12	HANCOCK MODIFIED ORIFICE (M.O.) AORTIC BIOPROSTHESIS (MODEL 250)	MEDTRONIC HEART VALVES MINNEAPOLIS, MN	MANUFACTURING MODIFICATIONS
12/08/93	55440		

P790020/S54	PERMAFLEX UV NATURALS (VASURFILCON A) SOFT CONTACT LENSES	PILKINGTON BARNES HIND, USA SUNNYVALE, CA	RELOCATION OF THE MANUFACTURE AND PREPARATION OF THE MOLDS AND THE POLYMERIZATION OF THE DRY CONTACT LENSES
12/22/93	94086-5200		

P810006/S18	COLLASTAT COLLAGEN ABSORBABLE HEMOSTATIC SPONGE, OTOFOAM ABSORBABLE HEMOSTATIC SPONGE	INTEGRA LIFESCIENCES CORPORATION PLAINSBORO, NJ	DISTRIBUTION OF SPONGE BY SMITH & NEPHEW RICHARDS, INC.
12/21/93	08536		

P820076/S15	DIPLOS CARDIAC	BIOTRONIK, INC.	APPROVAL TO
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APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

12/08/93	PACING SYSTEM, GEMNOS 04-A CARDIAC PACEMAKER	LAKE OSWEGO, OR 97035-5369	COMMERCIALLY DISTRIBUTE THE GEMNOS 04-A CARDIAC PACEMAKER
P830034/S23 12/02/93	OPTI-SOFT SOLUTION, OPTI-CLEAN DAILY CLEANER, AND OPTI-TEARS COMFORT DROPS, OPTI-FREE RINSING, DISINFECTING AND STORAGE SOLUTION	ALCON LABORATORIES, INC. FORT WORTH, TX 76134-2099	APPROVAL TO MODIFY THE EYECARE PROFESSIONALS' TRIAL LENS DISINFECTION INSTRUCTIONS TO REDUCE THE RECOMMENDED STORAGE TIME
P830060/S33 12/14/93	VENTAK MODEL 6910 LEAD ADAPTER	CARDIAC PACEMAKERS, INC. ST. PAUL, MN 55112-5798	APPROVAL FOR THE MODEL 6910 LEAD ADAPTER
P830061/S19 12/21/93	STER TIP PACING LEAD MODELS 4003 AND 4503, CAPSURE AND CAPSURE SP PACING LEADS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576	MODIFICATIONS TO THE GENERIC TECHNICAL MANUAL
P840001/S29 12/07/93	MEDTRONIC ITREL AND ITREL II SPINAL CORD STIMULATION SYSTEM	MEDTRONIC, INC. MINNEAPOLIS, MN 55440-9087	MODIFICATIONS TO PHYSICIAN AND HOSPITAL STAFF MANUAL AND PATIENT MANUAL
P850007/S10	PHYSIO-STIM	AMERICAN MEDICAL	CONCURRENCE WITH

APPLICATION NO.	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
APPROVAL DATE			

MEDICAL DEVICE - PMA SUPPLEMENTALS

12/06/93	ELECTRONICS, INC. RICHARDSON, TX 75081	CONDITIONS OF APPROVAL IN FDA'S FEBRUARY 8, 1991 APPROVABLE LETTER	
P850088/S29 12/15/93	ULTRACARE DISINFECTING SOLUTION/NEUTRALIZER SYSTEM	ALLERGAN OPTICAL IRVINE, CA 92713-9534 CUP	APPROVAL TO INTRODUCE A 4 FL. OZ./12 TABLET CONFIGURATION THAT INCLUDES THE ALLERGAN
P850089/S27 12/06/93	STER TIP PACING LEAD MODELS 5025 AND 5525, MEDTRONIC 5023M, 5523, 5024M AND 5524M CAPSURE SP PACING LEADS AND PACEMAKERS MODEL 4162 AND 4262 PACING LEADS	MEDTRONIC, INC. MINNEAPOLIS, MN 55432-3576 LEADS	MODIFICATIONS TO THE GENERIC TECHNICAL MANUAL FOR THE PACING
P850093/S10 12/22/93	BAUSCH & LOMB FIZZICLEAN AND THERMA-ZYME PROTEIN REMOVER, BAUSCH & LOMB RENU 1 STEP ENZYMATIC CLEANER	BAUSCH & LOMB HEALTHCARE AND OPTICS ROCHESTER, NY 14692-0450 SOLUTION FOR SIMULTANEOUS ENZYMATIC CLEANING	APPROVAL TO COMBINE BAUSCH & LOMB RENU ENZYMATIC CLEANER WITH RENU MULTI-PURPOSE

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

P860003/S20 12/07/93	UVAR PHOTOPHERESIS SYSTEM 19380	THERAKOS, INC. WEST CHESTER, PA	MANUFACTURING MODIFICATION
P860061/S06 12/15/93	ULTRAZYME ENZYMATIC CLEANER 92713-9534	ALLERGAN OPTICAL IRVINE, CA	REVISED LABELING
P880027/S29 12/07/93	SCHNEIDER MICROSOFTTRAC PTCA CATHETER 55442	SCHNEIDER (USA) INC. PLYMOUTH, MN	REVISED LABELING
P890045/S03 12/07/93	GELSEAL TRIAXIAL VASCULAR GRAFT 78752-1793	CARBOMEDICS AUSTIN, TX	REVISED LABELING
P890061/S06 12/14/93	VENTAK MODEL 6910 LEAD ADAPTER 55112-5798	CARDIAC PACEMAKERS, INC. ST. PAUL, MN ADAPTER	APPROVAL FOR THE MODEL 6910 LEAD
P900039/S03 12/09/93	COLLAGRAFT BONE GRAFT MATRIX 94303-3308	COLLAGEN CORPORATION PALO ALTO, CA TO BE USED IN THE POST-APPROVAL STUDY	APPROVAL FOR THE MEDICAL HISTORY FORM
P900056/S05 12/07/93	ROTABLATOR ROTATIONAL ANGIOPLASTY SYSTEM 98005-1887	HEART TECHNOLOGY, INC. BELLEVUE, WA	REVISED OPERATIONS MANUAL
P900060/S02	CARBOMEDICS	CARBOMEDICS, INC.	REVISED LABELING

APPLICATION NO. APPROVAL DATE	TRADE NAME	APPLICANT	DESCRIPTION AND INDICATION OF DEVICE
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MEDICAL DEVICE - PMA SUPPLEMENTALS

12/21/93	PROSTHETIC HEART VALVE	AUSTIN, TX 78752-1793	
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NADA NUMBER	TRADE NAME	SPECIES	APPLICANT	ACTIVE INGREDIENT(S)
APPROVAL DATE	(DOSAGE FORM)			STRENGTH(S)

ORIGINAL VETERINARY NADAs

65-506	COMBICILLIN	CATTLE	ANTHONY PRDTS	PENICILLIN G
11-08-93	(SUSPENSION)	DOGS	ARCADIA, CA	BENZATHINE
	HORSES	91006	150,000 UNITS/ML	
			PENICILLIN G PROCAINE	
			150,000 UNITS/ML	
65-506	COMBICILLIN-AG	CATTLE	ANTHONY PRDTS	PENICILLIN G
11-08-93	(SUSPENSION)	DOGS	ARCADIA, CA	BENZATHINE
	HORSES	91006	150,000 UNITS/ML	
			PENICILLIN G PROCAINE	
			150,000 UNITS/ML	

ORIGINAL ABBREVIATED VETERINARY NADAs

THERE ARE NO ORIGINAL ABBREVIATED VETERINARY NADAs FOR DECEMBER 1993.

SUPPLEMENTAL VETERINARY NADAs

THERE ARE NO SUPPLEMENTAL VETERINARY NADAs FOR DECEMBER 1993.