

Attachment 7

DEC 21 2001

K013054

510(k) Summary

September 1, 2001

1. Submission Applicant & Correspondent:

Name: Sinclair Pharmaceuticals, Ltd.

Address:

Borough Road
Godalming
Surrey
GU7 2AB
United Kingdom

Phone No.: +44 1483 428 611

Contact Person: Denise Swift, Director of Regulatory Affairs

2. Name of Device: Gelclair® CONCENTRATED ORAL GEL
Trade/Proprietary/Model Name: Gelclair® CONCENTRATED ORAL GEL
Common or Usual Name: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic
Classification Names: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

3. Devices to Which New Device is Substantially Equivalent:

Carrington Laboratories Radiacare™ Oral Wound Rinse.

4. Device Description:

Sinclair Pharmaceuticals, Ltd. Gelclair® CONCENTRATED ORAL GEL is a viscous gel formulation, which is presented in a sachet of 15ml for mixing with 40ml of water. This combination of substances, when washed around the mouth, forms a protective layer over the oral mucosa.

5. Intended Use of the Device:

Sinclair Gelclair® CONCENTRATED ORAL GEL, has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, and traumatic ulcers caused by braces or ill fitting dentures, or disease. Also indicated also for diffuse aphthous ulcers.

6. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:

The Gelclair® CONCENTRATED ORAL GEL has the same intended/indications for use as the predicate Carrington Laboratories Radiacare™ Oral Wound Rinse.

| Product Name | Sinclair Pharmaceuticals Gelclair® | Carrington Labs Radiacare™ |
|---------------------------------------|---|---|
| Ingredients | Purified Water, Propylene Glycol, Polyvinylpyrrolidone, Sodium Hyaluronate, Potassium Sorbate, Sodium Benzoate, Hydroxyethylcellulose, PEG-40 Hydrogenated Castor Oil, Disodium Edetate, Benzalkonium Chloride, Flavor, Saccharin Sodium, Glycyrrhetic Acid | Acemannan hydrogel, Aspartame, Flavor, Fructose, Maltodextrin, Polyvinylpyrrolidone, Potassium Sorbate, Sodium Benzoate |
| Method of Use | Mix with water | Mix with water |
| Number of applications per day | Take as needed | Take as needed |
| Claim | Management and relief of pain, does not sting, nonirritating, safe if swallowed | Management and relief of pain, does not sting, nonirritating, safe if swallowed |
| Area of Use | Oral Mucosa | Oral Mucosa |
| Disease State | Oral Mucositis/Stomatitis/Oral Lesions | Oral Mucositis/Stomatitis/Oral Lesions |
| Type of Product | Concentrate for dilution | Concentrate for dilution |
| Presentation | Non Sterile | Non Sterile |

7. Tests and Conclusions:

Extensive functional and performance testing were conducted to assess the safety and effectiveness of Gelclair® CONCENTRATED ORAL GEL. All results are satisfactory.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

**Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850**

Sinclair Pharmaceuticals, Incorporated
Ms. Priscilla Cox
Director, RA/QA
Otterbrook Engineering
1 Alder Brook
Chinley, High Peak,
UNITED KINGDOM

DEC 21 2001

Re: K013056

Trade/Device Name: Gelclair Concentrated Oral Gel
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MGQ
Dated: December 10, 2001
Received: December 11, 2001

Dear Ms. Cox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Page 2 – Ms. Cox

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3

Indications for Use Statement

**510(k) Number
(if known)**

Device Name

Sinclair Gelclair® CONCENTRATED ORAL GEL

Indications for Use

Sinclair Gelclair® CONCENTRATED ORAL GEL, has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery and traumatic ulcers caused by braces or ill fitting dentures or disease. Also indicated also for diffuse aphthous ulcers.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER
PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(per 21 CFR 801.109)

OR

Over-The Counter Use



(Division Sign-Off)

Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K013056

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: **JUL 12 2002**

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K013056/A1

To: Division Director: DE/DAGID

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN])

Additional information requires a new 510(k); please process [This information will be made into a new 510(k)]

No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

responded by telephone 7/16/02, MGA is code of predicate device. It can not be changed.
CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: Angela Blackwell
Date: 7/16/02

Draft #2 : 9/8/99
Draft #3: 1/3/00

AUG 15
DNO

KO13056/P1
SINCLAIR

Food and Drug Administration,
Center for Devices and Radiological Health (CDRH),
Office of Device Evaluation,
9200 Corporate Boulevard,
Rockville MD 20850.
USA.

10th July 2002.

RE: KO13056

Trade/Device Name: Gelclair Concentrated Oral Gel
Subject: Request for Reclassification.


Dear Sir/Madam,

The substantial equivalence letter dated December 21st 2001 that we received from the FDA, stated that the above product is Unclassified, MGQ.

As Gelclair Concentrated Oral Gel does not contain a drug/biologic we believe that the product code MGQ is possibly not applicable and that we may have miscoded our original application. Gelclair is a hydrogel wound dressing without drug/biologic (Product Code NAE).

We would therefore respectfully request that you reconsider the Regulatory Class of this product to a Class I.

Yours faithfully,

 [DR GEOFFREY HILL, C.O.O.]

PP Denise Swift
Director of Regulatory Affairs

SK9

Sinclair Pharmaceuticals Limited Borough Road, Godalming, Surrey, UK, GU7 2AB
Tel: +44 (0)1483 426644 Fax: +44 (0)1483 860927 Web: www.sinclairpharma.com Email: info@sinclairpharma.com

Registered in England No. 1007146 Registered Office: Borough Road, Godalming VAT No: GB 211 9043 05
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

Date: 8/1/02

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): K013056/A2

To: Division Director: DE/DAGID

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

Answered by telephone. 8/14

Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

Can't change code after decision.

Additional information requires a new 510(k); please process [This information will be made into a new 510(k)]

No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

Code updated is exempt. Product is not exempt.

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

Information requires a CLIA CATEGORIZATION; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

Additional information requires a CLIA CATEGORIZATION; however, the information submitted is incomplete; (call or fax firm)

No response necessary

This information should be returned to the DMC within 10 working days from the date of this memorandum.

Reviewed by: Angela Blackwell
Date: 8/15/02

Draft #2 : 9/8/99
Draft #3: 1/3/00

DMC

K013056/A2

SINCLAIR

Ms Angela Blackwell
Document Mail Center (HFZ-401)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

29th July 2002

Subject: K013056
Device name: Gelclair Concentrated Oral Gel

Dear Ms Blackwell

Thank you for your telephone call of 16th July 2002 and for the information concerning the classification of devices of this type. I have now had the opportunity to discuss further the classification issue within the company.

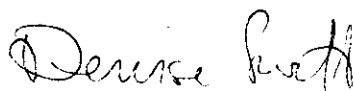
We understand that the MGQ code is considered by the FDA to apply to the above product because it is considered to be resorbable. However, since the product is an oral rinse and dwell time in the mouth is short lived, we are of the opinion that the amount of uptake through the mucosa is minimal. Although a thin film of the product remains inside the mouth, this exposure is transient due to the normal friction of tongue, teeth, gums and saliva.

Additionally, all ingredients used in the product are GRAS listed with the exception of the sodium hyaluronate and this has well-established internal uses ranging from ocular surgery to orthopaedic surgery with other medical devices. Therefore given the miniscule amounts possibly swallowed, Gelclair does not pose a safety risk to the patient.

On this basis of a demonstrated low risk device, we wish to raise again with the FDA our belief that this product is a Class I hydrogel wound dressing without drug/biologic (Product code NAE) and respectfully request that this petition for a change in the product classification be reconsidered.

If it is considered appropriate, we would be pleased to meet with FDA representatives to discuss the above issues.

Yours sincerely



Denise Swift
Director of Regulatory Affairs

RECEIVED
JUL 31 11 09 AM '02
FDA/CDRH/ODE/DMC

Sk. 8

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Services
Food and Drug Administration

Memorandum

Date: 10-8-08

From: DMC (HFZ-401)

Subject: Premarket Notification Number(s): 1013056/A³

To: Division Director: DE/DAG ID

The attached information has been received by the 510(k) DMC on the above referenced 510(k) submission(s). Since a final decision has been rendered, this record is officially closed.

Please review the attached document and return it to the DMC, with one of the statements checked below.

_____ Information does not change the status of the 510(k); no other action required by the DMC; please add to image file. (Prepare K-25) THIS DOES NOT APPLY TO TRANSFER OF OWNERSHIP. PLEASE BRING ANY TRANSFER OF OWNERSHIP TO POS.

_____ Additional information requires a new 510(k); however, the information submitted is incomplete; (Notify company to submit a new 510(k); [Prepare the K30 Letter on the LAN]

_____ No response necessary (e.g., hard copy of fax for the truthful and accuracy statement, 510(k) statement, change of address, phone number, or fax number).

CLIA CATEGORIZATION refers to laboratory test system devices reviewed by the Division of Clinical Laboratory Devices (HFZ-440)

_____ Information requires a **CLIA CATEGORIZATION**; the complexity may remain the same as the original 510(k) or may change as a result of the additional information (Prepare a CAT letter)

_____ Additional information requires a **CLIA CATEGORIZATION**; however, the information submitted is incomplete; (call or fax firm)

No response necessary

This information should be returned to the DMC within 10 working days from the date of this Memorandum.

Reviewed by: [Signature]

Date: 10/9/08

DMC
10/9

K 013056/A 3



Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

Research & Development

October, 1 2008

Re: Gelclair – Annual Report

Dear Sirs/Madame:

Pursuant to Section 510(k) of the Federal Food, Drug, and Cosmetic Act we hereby submit the Annual Report for the MEDICAL DEVICE referenced above.

This report covers the period from 1st January 2007- 31st December 2007.

No adverse events have been reported on the Devices in the territory of United States.

No other changes requiring notification of FDA are anticipated.

If you have any questions or comments, please do not hesitate to contact me at 011-41-91-985 21 21 in Lugano, Switzerland or our US agent Mike Killeen, Phone +1 972-478-4380 or Fax +1 972-478-4416.

Sincerely,

HELINN HEALTHCARE SA
Marco Ell, M. Pharm.
Manager Corporate Regulatory Affairs

FDA CDRH DMC

OCT 8 2008

Received

K 21



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Sinclair Pharmaceuticals, Incorporated
Ms. Priscilla Cox
Director, RA/QA
Otterbrook Engineering
1 Alder Brook
Chinley, High Peak,
UNITED KINGDOM

DEC 21 2001

Re: K013056

Trade/Device Name: Gelclair Concentrated Oral Gel
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: MGQ
Dated: December 10, 2001
Received: December 11, 2001

Dear Ms. Cox:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

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Page 2 – Ms. Cox

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3

Indications for Use Statement

**510(k) Number
(if known)**

Device Name

Sinclair Gelclair® CONCENTRATED ORAL GEL

Indications for Use

Sinclair Gelclair® CONCENTRATED ORAL GEL, has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery and traumatic ulcers caused by braces or ill fitting dentures or disease. Also indicated also for diffuse aphthous ulcers.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER
PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(per 21 CFR 801.109)

OR

Over-The Counter Use

Helena Cuevas for Review

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number

K013056

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Angela Blackwell
Subject: 510(k) Number 1K013056/s'
To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
 - Requires additional information (other than refuse to accept).
 - Is substantially equivalent to marketed devices.
 - NOT substantially equivalent to marketed devices.
- De Novo Classification Candidate? YES NO

- Other (e.g., exempt by regulation, not a device, duplicate, etc.)
- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

- Truthful and Accurate Statement Requested Enclosed (required for originals received 3-14-95 and after)
- A 510(k) summary OR A 510(k) statement
- The required certification and summary for class III devices
- The indication for use form (required for originals received 1-1-96 and after)
- Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

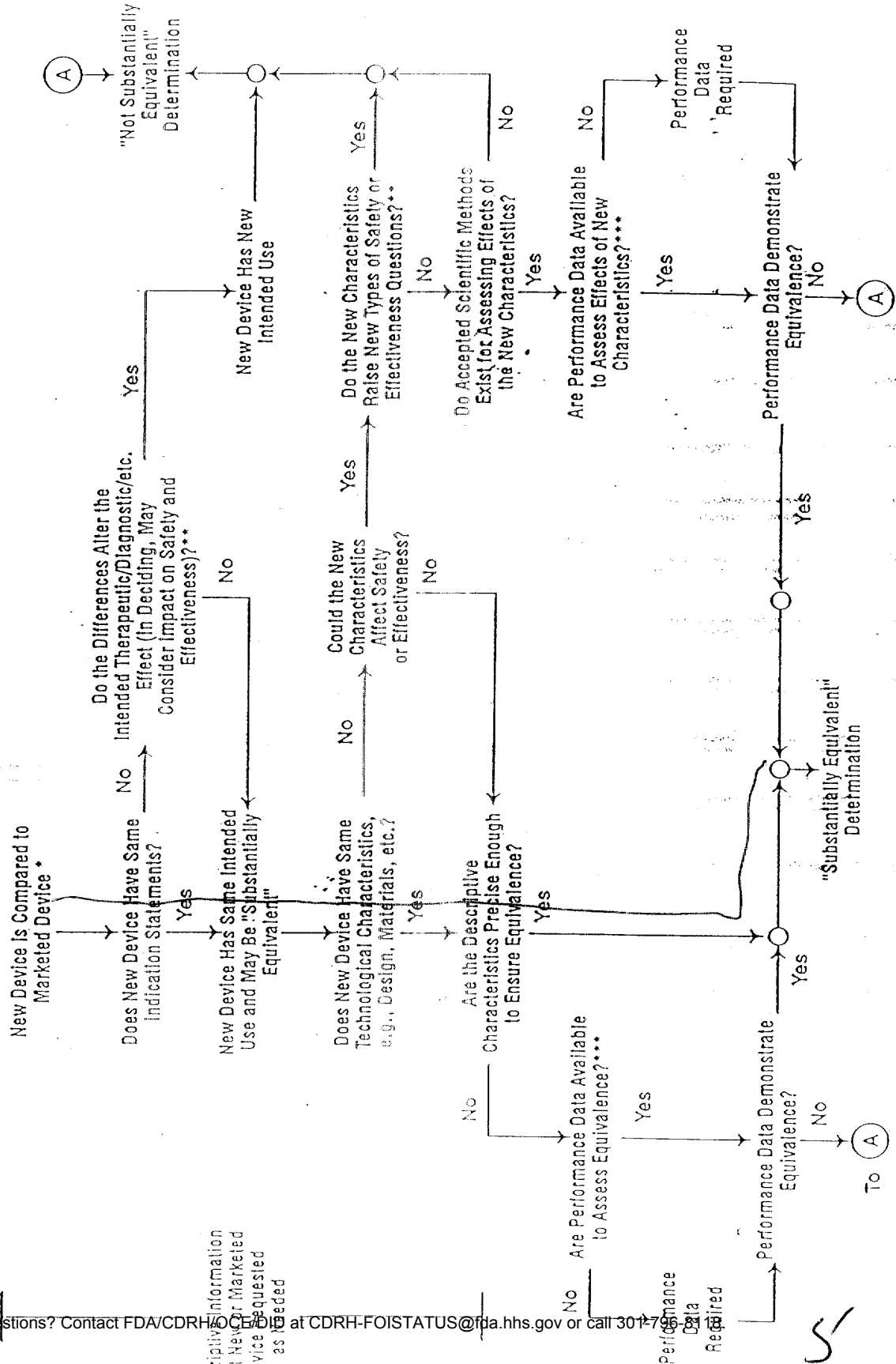
- No Confidentiality
- Confidentiality for 90 days
- Continued Confidentiality exceeding 90 days

Predicate Product Code with class: _____ Additional Product Code(s) with panel (optional): _____

MGR unclassified
Review: Patricia Ciccone for S. Bremer DEDIB
(Branch Chief) (Branch Code) (Date) 12/21/01

Final Review: Patricia Ciccone for TAMC
(Division Director) (Date) 12/21/01

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



* 510(k) Submissions Compare New Devices to Marketed Devices, FDA Requests Additional Information About New or Marketed Devices Requested as Needed
 ** This Decision is Normally Based on Descriptive Information Alone, But Limited Textual Information is Sometimes Required.
 *** Data May Be Available in the Device's Classification Files, or the Literature.

5

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K013056

Reviewer: Angela Blackwell

Division/Branch: DDIGD/ DEDB

Device Name: Gelclair Concentrated Oral Gel

Company: Sinclair Pharmaceuticals Ltd.

Product To Which Compared (510(K) Number If Known): K983182

YES NO

| | YES | NO | |
|--|------------|-----------|---|
| 1. Is Product A Device | x | | If NO = Stop |
| 2. Is Device Subject To 510(k)? | x | | If NO = Stop |
| 3. Same Indication Statement? | x | | If YES = Go To 5 |
| 4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness? | | | If YES = Stop NE |
| 5. Same Technological Characteristics? | x | | If YES = Go To 7 |
| 6. Could The New Characteristics Affect Safety Or Effectiveness? | | | If YES = Go To 8 |
| 7. Descriptive Characteristics Precise Enough? | x | | If NO = Go To 10 If YES = Stop SE |
| 8. New Types Of Safety Or Effectiveness Questions? | | | If YES = Stop NE |
| 9. Accepted Scientific Methods Exist? | | | If NO = Stop NE |
| 10. Performance Data Available? | | | If NO = Request Data |
| 11. Data Demonstrate Equivalence? | | | Final Decision: SE |

1. Intended Use: Sinclair Gelclair concentrated oral gel has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: oral mucositis/stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, and traumatic ulcers caused by braces or ill fitting dentures, or disease. Also indicated for diffuse aphthous ulcers.
2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device for home use or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the device's design, materials, physical properties and toxicology profile if important.

The device is similar to Radiacare in indication.

Memorandum

To: K013056
 Device: Gelclair Concentrated Oral Gel
 Company: Sinclair Pharmaceuticals
 From: Angela Blackwell
 Date: December 7, 2001

Background

The device is similar to the predicate device Radiacare Oral Wound Rinse. Both rinses are gels. Radiacare is particulates in a bottle to which water is added and Gelclair is a concentrated gel in a packet which you add to a glass of water.

Composition Comparison

| Ingredients | Gelclair | Function | CFR | Radiacare |
|-----------------------|----------|-------------------------|----------|-----------|
| Purified water | (b)(4) | diluent | | 88.65 |
| Acemannan hydrogel | (b)(4) | | | 0.30 |
| Hydroxyethylcellulose | (b)(4) | thickener | 172.874 | |
| Benzalkonium chloride | (b)(4) | preservative | 310.545 | |
| Polyvinylpyrrolidone | (b)(4) | thickener | 173.55 | 5.00 |
| Potassium Sorbate | (b)(4) | preservative | 182.3640 | 0.05 |
| Sodium Benzoate | (b)(4) | preservative | 184.1733 | 0.05 |
| Maltodextrin | (b)(4) | thickener | 184.1444 | 4.50 |
| Fructose | | sweetener | | 1.25 |
| Vanilla Flavor | | flavoring | | 0.20 |
| Aspartame | | sweetener | | 0.2 |
| Propylene Glycol | (b)(4) | solvent | 184.1666 | |
| PEG-40 Hydrogenated | (b)(4) | stabilizer | 178.3280 | |
| Castor Oil | | | | |
| Licorice Flavor | (b)(4) | flavoring | 582.10 | |
| Disodium Edetate | (b)(4) | antioxidant | 172.135 | |
| Sodium Hyaluronate | (b)(4) | film-forming agent | | |
| Saccharin Sodium | (b)(4) | sweetener | 180.37 | |
| Glycyrrhetic Acid | (b)(4) | flavoring/ sweetener | 582.10 | |

All the ingredients of Gelclair have a CFR reference for use in non-device products except for the sodium hyaluronate. Sodium Hyaluronate is the main ingredient of two PMA products for joint lubricant/repair products. (b)(4) Confidential

(b)(4) Confidential and Proprietary Information

(b)(4) Confidential and Proprietary Information None of the ingredients are present in quantities above that allowed in the CFR. Gelclair appears to be as safe as Radiacare.

Preclinical Testing

The level of exposure is considered to be the quantity of substance, expressed in mg/kg, completely absorbed by the user of the product. Level of exposure calculations for adults and children show that the gel is innocuous if ingested and suitable for pediatric use. Children are not excluded in the labeling but they are not included either. Their use of the product is implied because many braces wearers are children.



Indications

The indications are the same as the predicate device.

Conclusions

The labeling is clear and correct for prescription use. The reviewer finds the device substantially equivalent to legally marketed devices.

Angela Blackwell
12/20/01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

December 11, 2001

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

SINCLAIR PHARMACEUTICALS, LTD.
C/O OTTERBROOK ENGINEERING
1 ALDER BROOK
CHINLEY, HIGH PEAK,
UNITED KINGDOM
ATTN: PRISCILLA COX

510(k) Number: K013056
Product: GELCLAIR
CONCENTRATED
ORAL GEL

The additional information you have submitted has been received.

We will notify you when the processing of this submission has been completed or if any additional information is required. Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official.

The Safe Medical Devices Act of 1990, signed on November 28, states that you may not place this device into commercial distribution until you receive a letter from FDA allowing you to do so. As in the past, we intend to complete our review as quickly as possible. Generally we do so 90 days. However, the complexity of a submission or a requirement for additional information may occasionally cause the review to extend beyond 90 days. Thus, if you have not received a written decision or been contacted within 90 days of our receipt date you may want to check with FDA to determine the status of your submission.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisory Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

K013056 / S

SINCLAIR

December 10, 2001

Document Mail Center (HFZ-401)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

RECEIVED

DEC 11 10 53 AM '01

FDA/CDRH/OBE/DHC

Subject: K013056 Additional Information

Dear Ms. Blackwell,

In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, and 21 CFR 807.87, Sinclair Pharmaceuticals, Ltd. is submitting, in duplicate, additional information as requested for Premarket Notification 510(k) K013056 *Sinclair Pharmaceuticals, Ltd. Gelclair® Concentrated Oral Gel*. The following pages (attached) have been amended to remove the words ageing and medication:

- Page 6 Section G Indication from labeling
- Page 9 Section VI Labeling and Intended Use
- Page 13 Label Copy
- Page 16 Instructions for Use
- Page 19 Attachment 3 Indications for Use
- Page 36 Attachment 7 510(k) Summary

Confidentiality

We regard our intent to market this product as confidential. The existence of this 510(k) has not been revealed to anyone other than our employees. Therefore we request that the Agency not disclose this intent until the 510(k) clearance is granted.

All items marked "Confidential" may be trade secret, confidential commercial or financial information as defined in 21 CFR 20.61. We request that the Agency not make public disclosure of this information without prior consultation with *Sinclair Pharmaceuticals, Ltd.* as provided by 21 CFR 20.45.

We would appreciate your earliest attention to this 510(k) and we trust that the information provided will enable the Agency to reach a substantial equivalence determination. Should you have any further questions, please contact me via phone at 011 44 1663 750 410, fax at 011 44 1663 751 449, or email at otterbrookeng@aol.com

Sincerely,

Priscilla Cox
Director RA/QA
Otterbrook Engineering

SK10

||

Attn: Angela Blackwell

CONFIDENTIAL

CONFIDENTIAL

510(k) #K013056
Additional Information

| INGREDIENT | % NEAT | % DILUTED | FUNCTION | CFR 21 REFERENCE | LEGALLY MARKETED PRODUCTS |
|--------------------------------|---|--|----------|------------------|--|
| PURIFIED WATER | (b)(4) Confidential and Proprietary Information | | | NA | ABREVA® COLD SORE MEDICINE / GLAXOSMITHKLINE |
| POLYVINYLPIRROLIDONE (PVP) | | | | 173.55 | RADIACARE™ ORAL RINSE / K96482 / CARRINGTON LABS |
| MALTODEXTRIN | | | | 184.1444 | MULTIDEX® GEL WOUND DRESSING / K961085 / DEROYAL |
| PROPYLENE GLYCOL | | | | 184.1666 | ABREVA® COLD SORE MEDICINE / GLAXOSMITHKLINE |
| PEG-40 HYDROGENATED CASTOR OIL | | | | 178.3280 | THERA BREATH™ ORAL RINSE / FRESH START, LLC |
| HYDROXYETHYLCELLULOSE | | | | 172.874 | VIRACTIN® COLD SORE & FEVER BLISTER MEDICATION / J.B. WILLIAMS |
| POTASSIUM SORBATE | | | | 182.3640 | RADIACARE™ ORAL RINSE / K96482 / CARRINGTON LABS |
| SODIUM BENZOATE | | | | 184.1733 | BIOTENE MOUTHWASH / LACLEDE INC. |
| BENZALKONIUM CHLORIDE | | | | 310.545 | VISINE® ADVANCED RELIEF EYE DROPS / PFIZER |
| FLAVOUR (LICORICE) | | | | 172.515 | ADVANCE BREATH CARE ORAL RINSE / ARM & HAMMER |
| DISODIUM EDTATE | 172.135 | VISINE® ADVANCED RELIEF EYE DROPS / PFIZER | | | |
| SODIUM HYALURONATE | NA | *STARVISC II / P000046 / ANIKA THERAPEUTICS & P8100125 / BAUSCH & LOMB | | | |
| SACCHARIN SODIUM | 180.37 | ACT® FLUORIDE ORAL RINSE / J&J | | | |
| GLYCERYLRHETINIC ACID | 582.10 | CHEWABLE LICORICE TABLET / RX VITAMINS INC | | | |

* Starvisc II is 12 mg per ml of high molecular weight (> 1MM Daltons) sodium hyaluronate. P000046 references P8100125. It is supplied sterile, non pyrogenic, viscoelastic, highly purified and dissolved in physiologic saline. The device is indicated for use during surgery in the anterior and posterior segments of the human eye. Gelclair sodium hyaluronate is .00027 mg per ml of Gelclair at label indication.

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CONFIDENTIAL

| | | | | | |
|---|-------|---|----|--|----|
| Product codes of devices to which substantial equivalence is claimed: | | | | Summary of, or statement concerning, safety and effectiveness data: | |
| 1 FRO | 2 MGQ | 3 | 4 | <input checked="" type="checkbox"/> 510(k) summary attached <input type="checkbox"/> 510(k) statement | |
| 5 | 6 | 7 | 8 | | |
| Information on devices to which substantial equivalence is claimed: | | | | | |
| 510(k) Number | | Trade or proprietary or model name | | Manufacturer | |
| 1 K964852 | | Radiacare™ Oral Wound Rinse | | Carrington Labs | |
| 2 | | | | | |
| Section F: Product Information Applicable to all Applications | | | | | |
| Common or usual or classification name: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic | | | | | |
| Trade or proprietary or model name | | | | Model Number | |
| Gelclair® Concentrated Oral Gel | | | | NA | |
| 2 | | | | | |
| FDA document numbers of all prior related submissions (regardless of outcome): none | | | | | |
| 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 |
| Data included in submission: <input checked="" type="checkbox"/> Laboratory testing <input type="checkbox"/> Animal trials <input type="checkbox"/> Human trials | | | | | |
| Section G: Product Classification - Applicable to all Applications | | | | | |
| Product Code: MGQ | | C.F.R. section 878.4022 | | Device Class: <input checked="" type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified | |
| Classification panel: General & Plastic Surgery | | | | | |
| Indications (from labeling): Gelclair® CONCENTRATED ORAL GEL, has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, and traumatic ulcers caused by braces or ill fitting dentures, or disease. Also indicated also for diffuse aphthous ulcers. | | | | | |

From Page 6 of Original Document

CONFIDENTIAL

**VI. Labeling
and Intended
Use**

A draft, preprinted product pouch, carton and the package insert (which contains Instructions for Use) can be found in Attachment 1.

Intended Use

Sinclair Gelclair® CONCENTRATED ORAL GEL, has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery and traumatic ulcers caused by braces or ill fitting dentures, or disease. Also indicated also for diffuse aphthous ulcers.

The Indications for Use statement is included in Attachment 3.

From Page 9 of Original Document

**VII. Device
Description**

Sinclair Gelclair® CONCENTRATED ORAL GEL is a viscous gel comprised of Purified Water, Propylene Glycol, Polyvinylpyrrolidone, Sodium Hyaluronate, Potassium Sorbate, Sodium Benzoate, Hydroxyethylcellulose, PEG-40 Hydrogenated Castor Oil, Disodium Edetate, Benzalkonium Chloride, Flavor, Saccharin Sodium, Glycyrrhetic Acid.

Gelclair® CONCENTRATED ORAL GEL has a mechanical action which provides pain relief by adhering to the mucosal surface of the mouth, soothing mouth lesions.

The gel concentrate is provided in a single use 15 ml foil pouches ready to be mixed with 40ml of water for use. The pouch is preprinted with instructions for use.


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**Gelclair 510(k) #K013056
Label Copy**

SINCLAIR

Gelclair® has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, and traumatic ulcers caused by braces or ill fitting dentures, or disease. Also indicated also for diffuse aphthous ulcers.

Directions for use: Pour the entire contents of the single-dose Gelclair™ sachet into a glass and add 40 ml of water. Stir mixture well and use at once. Rinse around the mouth for at least one minute or as long as possible to coat tongue, palate, throat, inside of cheeks and all oral tissue thoroughly. Gargle and spit out. Use 3 times a day or as needed. Do not eat or drink for at least one hour following treatment. If swallowed accidentally no adverse effects are anticipated.

Best Before:


Manufactured by:

Sinclair Pharmaceuticals Ltd - Borough Road
Godalming - Surrey GU7 2AB - England, UK

CE Medical Device Class I

LOT



AP121701/1

SINCLAIR

From Page 13 of Original Document

15

SINCLAIR

**Gelclair®
Concentrated Oral Gel**

Ingredients: Purified Water, Maltodextrin, Propylene Glycol, PVP, Sodium Hyaluronate, Potassium Sorbate, Sodium Benzoate, Hydroxyethyl cellulose, PEG-40 Hydrogenated Castor Oil, Disodium Edetate, Benzalkonium Chloride, Flavor, Saccharin Sodium, Glycyrrhetic Acid.

Patient use form: **Concentrated oral gel.**

Contents: 15 ml per single-dose sachet. 1 Box contains 21 single dose sachets.

Therapeutic group or type of activity: Oral Gel for the relief of pain.

Indications: Gelclair®, has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, traumatic ulcers caused by braces or ill fitting dentures, or disease. Also indicated also for diffuse aphthous ulcers.

Contra-indications: The administration of Gelclair® is contra-indicated in any patient with a known history of hypersensitivity to any of the ingredients.

Special Precautions for use: Avoid eating or drinking for at least one hour after use Do not use any sachet that is not intact (torn, split or otherwise damaged in any way). If no improvement is noticed after 7 days, consult a physician.

Warning: Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

Interactions with other medicinal products and other forms of interaction: There are no known interactions with medicinal or other products.

Directions for use: Pour the entire contents of the single-dose Gelclair®, sachet into a glass and add 40ml or 4 tablespoonfuls of water. Stir mixture well and use at once. Rinse around the mouth for at least one minute or as long as possible to coat tongue, palate, throat, inside of cheeks and all oral tissue thoroughly. Gargle and spit out. Use 3 times a day or as needed. Do not eat or drink for least one hour following treatment. If Gelclair® is swallowed accidentally no adverse effects are anticipated. In the unlikely event that water is not available, the product may be used undiluted.

Side effects: At the time of producing this leaflet there have been no reported side effects with Gelclair®, however the product is not recommended for use in patients with a known or suspected allergy to any of the product's ingredients.

Store at room temperature, out of direct sunlight. Do not refrigerate.

KEEP OUT OF THE REACH OF CHILDREN.

Please note: The gel may become a little darker and thicker over time, but this does not affect its efficacy or safety. Do not use after the 'Best Before' date shown on the box.

Overdose: At the time of producing this leaflet no cases of overdose have been reported. However, no serious adverse effects should be expected from ingestion of several sachets of Gelclair®.

Manufactured by:
Sinclair Pharmaceuticals Ltd -Borough Road -Godalming -Surrey GU7 2AB -England, UK.

Date of Revision: December 2001

From Page 16 of Original Document

CONFIDENTIAL

Attachment 3

Indications for Use Statement

510(k) Number
(if known)

Device Name

Sinclair Gelclair® **CONCENTRATED ORAL GEL**

Indications for Use

Sinclair Gelclair® **CONCENTRATED ORAL GEL**, has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery and traumatic ulcers caused by braces or ill fitting dentures or disease. Also indicated also for diffuse aphthous ulcers.

**PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER
PAGE IF NEEDED**

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(per 21 CFR 801.109) _____

OR

Over-The Counter Use _____

From Page 19 of Original Document

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Attachment 7

510(k) Summary

September 1, 2001

1. Submission Applicant & Correspondent:

Name: Sinclair Pharmaceuticals, Ltd.

Address:

Borough Road
Godalming
Surrey
GU7 2AB
United Kingdom

Phone No.: +44 1483 428 611

Contact Person: Denise Swift, Director of Regulatory Affairs

2. Name of Device:

Gelclair® CONCENTRATED ORAL GEL

Trade/Proprietary/Model Name:

Gelclair® CONCENTRATED ORAL GEL

Common or Usual Name:

Dressing, Wound & Burn, Hydrogel w/Drug or
Biologic

Classification Names:

Dressing, Wound & Burn, Hydrogel w/Drug or
Biologic

3. Devices to Which New Device is Substantially Equivalent:

Carrington Laboratories Radiacare™ Oral Wound Rinse.

4. Device Description:

Sinclair Pharmaceuticals, Ltd. Gelclair® CONCENTRATED ORAL GEL is a viscous gel formulation, which is presented in a sachet of 15ml for mixing with 40ml of water. This combination of substances, when washed around the mouth, forms a protective layer over the oral mucosa.

5. Intended Use of the Device:

Sinclair Gelclair® CONCENTRATED ORAL GEL, has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, and traumatic ulcers caused by braces or ill fitting dentures, or disease. Also indicated also for diffuse aphthous ulcers.

From Page 36 of Original Document

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
Center for Devices and
Radiological Health
Office of Device Evaluation
Document Mail Center (HFZ-401)
9200 Corporate Blvd.
Rockville, Maryland 20850

December 10, 2001

SINCLAIR PHARMACEUTICALS, LTD.
C/O OTTERBROOK ENGINEERING
1 ALDER BROOK
CHINLEY, HIGH PEAK,
UNITED KINGDOM
ATTN: PRISCILLA COX

510(k) Number: K013056
Product: GELCLAIR
CONCENTRATED
ORAL GEL

We are holding your above-referenced Premarket Notification (510(k)) for 30 days pending receipt of the additional information that was requested by the Office of Device Evaluation. Please remember that all correspondence concerning your submission MUST cite your 510(k) number and be sent in duplicate to the Document Mail Center (HFZ-401) at the above letterhead address. Correspondence sent to any address other than the one above will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefax material as part of your official premarket notification submission unless specifically requested of you by an FDA official.

The deficiencies identified represent the issues that we believe need to be resolved before our review of your 510(k) submission can be successfully completed. In developing the deficiencies, we carefully considered the statutory criteria as defined in Section 513(i) of the Federal Food, Drug, and Cosmetic Act for determining substantial equivalence of your device. We also considered the burden that may be incurred in your attempt to respond to the deficiencies. We believe that we have considered the least burdensome approach to resolving these issues. If, however, you believe that information is being requested that is not relevant to the regulatory decision or that there is a less burdensome way to resolve the issues, you should follow the procedures outlined in the "A Suggested Approach to Resolving Least Burdensome Issues" document. It is available on our Center web page at: <http://www.fda.gov/cdrh/modact/leastburdensome.html>

If after 30 days the requested information, or a request for an extension of time, is not received, we will discontinue review of your submission and proceed to delete your file from our review system. Pursuant to 21 CFR 20.29, a copy of your 510(k) submission will remain in the Office of Device Evaluation. If you then wish to resubmit this 510(k) notification, a new number will be assigned and your submission will be considered a new premarket notification submission.

Please remember that the Safe Medical Devices Act of 1990 states that you may not place this device into commercial distribution until you receive a decision letter from FDA allowing you to do so.

If you have procedural or policy questions, please contact the Division of Small Manufacturers International and Consumer Assistance (DSMICA) at (301) 443-6597 or at their toll-free number (800) 638-2041, or contact me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
Supervisor Consumer Safety Officer
Premarket Notification Section
Office of Device Evaluation
Center for Devices and
Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

Memorandum

From: Reviewer(s) - Name(s) Angela Blackwell

Subject: 510(k) Number K 013056

To: The Record - It is my recommendation that the subject 510(k) Notification:

- Refused to accept.
- Requires additional information (other than refuse to accept).
- Is substantially equivalent to marketed devices.
- NOT substantially equivalent to marketed devices.

telephone hold

De Novo Classification Candidate?

YES NO

Other (e.g., exempt by regulation, not a device, duplicate, etc.)

- Is this device subject to Postmarket Surveillance? YES NO
- Is this device subject to the Tracking Regulation? YES NO
- Was clinical data necessary to support the review of this 510(k)? YES NO
- Is this a prescription device? YES NO
- Was this 510(k) reviewed by a Third Party? YES NO
- Special 510(k)? YES NO
- Abbreviated 510(k)? Please fill out form on H Drive 510k/boilers YES NO

This 510(k) contains:

Truthful and Accurate Statement Requested Enclosed
(required for originals received 3-14-95 and after)

A 510(k) summary OR A 510(k) statement

The required certification and summary for class III devices

The indication for use form (required for originals received 1-1-96 and after)

Material of Biological Origin YES NO

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

No Confidentiality Confidentiality for 90 days Continued Confidentiality exceeding 90 days

Predicate Product Code with class:

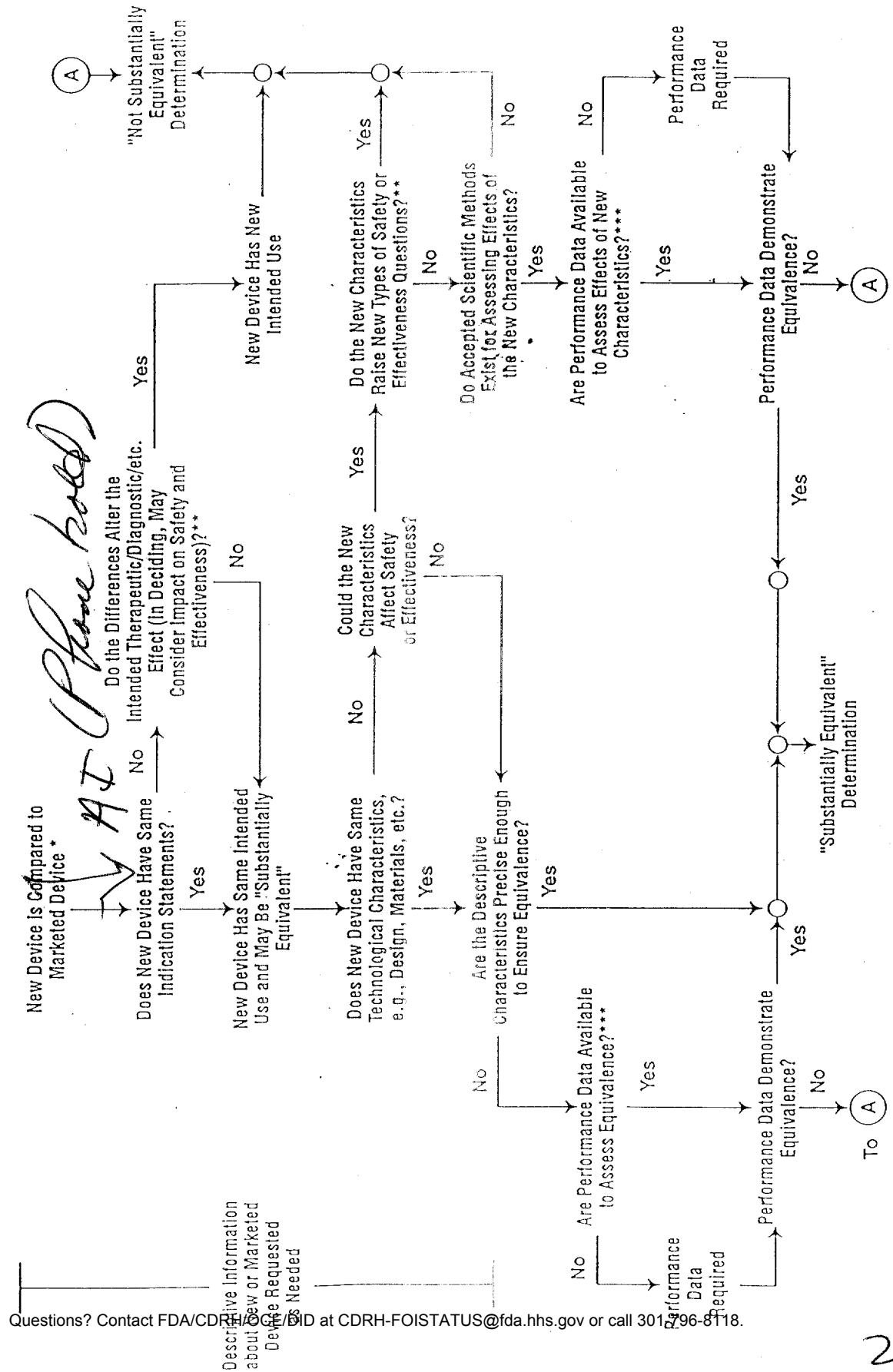
Additional Product Code(s) with panel (optional):

MGA unclassified

Review: R. Betz DDS for Dr. Bruner DEDB 12-10-01
(Branch Chief) (Branch Code) (Date)

Final Review: _____ (Date)
(Division Director)

510(k) "Substantial Equivalence" Decision-Making Process (Detailed)



** This Decision Is Normally Based on Descriptive Information Alone, But Limited Technical Information is Sometimes Required.
 *** Data May Include the 510(k), Other 510(k)'s, The Center's Classification Files, or the Literature.

* 510(k) Submissions Compare New Devices to Marketed Devices. FDA Requests Additional Information if the Relationship Between Marketed and "Predicate" (Pre-Amendment or Reclassified Post-Amendments) Devices is Unclear.

Telephone Memorandum

Call To: Priscilla Cox
Company: Otterbrook Engineering for Sinclair Pharmaceuticals
Document: K013056
Device: Gelclair Concentrated Gel
Call From: Angela Blackwell *aeb*
Date: December 10, 2001

I am putting your document on hold. I have not received the new indications for use form I requested on Friday by email. It was too late in the day to call you. If you have questions you can reach me at 301-827-5283 x119.

RJB/MSK

Blackwell, Angela

From: Blackwell, Angela
Sent: Friday, December 07, 2001 3:24 PM
To: 'Otterbrookeng@aol.com'
Subject: k013056

Ms. Cox:

Your indications for use statement needs to be changed to remove the reference to ageing and the reference to medication. These are not indications of the predicate device. Please send this ASAP since the document is due Monday. Please make sure a paper copy of everything you have sent by fax or email is sent in (I don't have to have the paper copy to close the file but I must know that it is on it's way).

Angela Blackwell

Dragon's Lair, 1 Alder Brook, Chinley, High Peak SK23 6DN
Tel: +44 (0) 1663 750 410 Fax: +44 (0) 1663 751 449
Email: otterbrookeng@aol.com

**Otter Brook
Engineering**

Fax

To: Angela Blackwell **From:** Priscilla Cox

Fax: 001 301 480 3002 **Pages:** 2

Phone: 001 301 827 5283 ext 119 **Date:** 12/03/01

Re: K013056 **CC:**

Urgent **For Review** **Please Comment** **Please Reply** **Please Recycle**

Ms. Blackwell,

Thank you for your fax regarding K013056, Gelclair Concentrated Oral Gel. The information sent yesterday had some errors in the percentages. Please find the corrected version following. If you will send your email address I can send an electronic copy. Other wise a hard copy will be sent by mail. If you have any further questions, please contact me at your earliest convenience.

Regards,

Priscilla Cox

For Sinclair Pharmaceuticals

Surrey, England

Attn: Angela Blackwell

CONFIDENTIAL

510(K) #K013056
Additional Information

| INGREDIENT | % NEAT | % DILUTED | FUNCTION | CFR 21 REFERENCE | LEGALLY MARKETED PRODUCTS |
|--------------------------------|---|-----------|----------|------------------|--|
| PURIFIED WATER | (b)(4) Confidential and Proprietary Information | | | NA | ABREVA® COLD SORE MEDICINE / GLAXOSMITHKLINE |
| POLYVINYLPIRROLIDONE (PVP) | | | | 173.55 | RADIACARE™ ORAL RINSE / K96482 / CARRINGTON LABS |
| MALTODEXTRIN | | | | 184.1444 | MULTIDEX® GEL WOUND DRESSING / K961085 / DEROTAL |
| PROPYLENE GLYCOL | | | | 184.1666 | ABREVA® COLD SORE MEDICINE / GLAXOSMITHKLINE |
| PEG-40 HYDROGENATED CASTOR OIL | | | | 178.3280 | THERA BREATH™ ORAL RINSE / FRESH START, LLC |
| HYDROXYETHYLCELLULOSE | | | | 172.874 | VIRACTIN® COLD SORE & FEVER BLISTER MEDICATION / J.B. WILLIAMS |
| POTASSIUM SORBATE | | | | 182.3640 | RADIACARE™ ORAL RINSE / K96482 / CARRINGTON LABS |
| SODIUM BENZOATE | | | | 184.1733 | BIOTENE MOUTHWASH / LACLEDE INC. |
| BENZALKONIUM CHLORIDE | | | | 310.545 | VISINE® ADVANCED RELIEF EYE DROPS / PFIZER |
| FLAVOUR (LICORICE) | | | | 172.515 | ADVANCE BREATH CARE ORAL RINSE / ARM & HAMMER |
| DISODIUM EDTATE | | | | 172.135 | VISINE® ADVANCED RELIEF EYE DROPS / PFIZER |
| SODIUM HYALURONATE | | | | NA | *STARVISC II / P000046 / ANIKA THERAPEUTICS & P8100125 / BAUSCH & LOMB |
| SACCHARIN SODIUM | | | | 180.37 | ACT® FLUORIDE ORAL RINSE / J&J |
| GLYCERYRHETINIC ACID | | | | 582.10 | CHEWABLE LICORICE TABLET / RX VITAMINS INC |

* Starvisc II is 12 mg per ml of high molecular weight (> 1MM Daltons) sodium hyaluronate. P000046 references P8100125. It is supplied sterile, non pyrogenic, viscoelastic, highly purified and dissolved in physiologic saline. The device is indicated for use during surgery in the anterior and posterior segments of the human eye. Gelclair sodium hyaluronate is .00027 mg per ml of Gelclair at label indication.

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Attn: Angela Blackwell

CONFIDENTIAL

510(k) #K013056
Additional Information

| INGREDIENT | % NEAT | % DILUTED | FUNCTION | CFR 21 REFERENCE | LEGALLY MARKETED PRODUCTS |
|--------------------------------|--------|-----------|----------|---|--|
| PURIFIED WATER | | | | NA | ABREVA® COLD SORE MEDICINE / GLAXOSMITHKLINE |
| POLYVINYLPIRROLIDONE (PVP) | | | | Food additive 173.55 | RADIACARE™ ORAL RINSE / K96482 / CARRINGTON LABS |
| MALTODEXTRIN | | | | AD 184.1444 limit of theophylline comp had evidence 30% allowed 184.1666 in foods | MULTIDEX® GEL WOUND DRESSING / K961085 / DEROTAL |
| PROPYLENE GLYCOL | | | | used in - 178.3280 Food contact additive | ABREVA® COLD SORE MEDICINE / GLAXOSMITHKLINE |
| PEG-40 HYDROGENATED CASTOR OIL | | | | used in - 178.3280 Food contact additive | THERA BREATH™ ORAL RINSE / FRESH START, LLC |
| HYDROXYETHYLCELLULOSE | | | | Food additive 172.874 had evidence 30% allowed 172.874 in foods | VIRACTIN® COLD SORE & FEVER BLISTER MEDICATION / J.B. WILLIAMS |
| POTASSIUM SORBATE | | | | GLRS 182.3640 184.1733 Food additive | RADIACARE™ ORAL RINSE / K96482 / CARRINGTON LABS |
| SODIUM BENZOATE | | | | < 1% allowed in food 184.1733 | BIOTENE MOUTHWASH / LACLEDE INC. |
| BENZALKONIUM CHLORIDE | | | | dan drugh drugs (A) 310.545 | VISINE® ADVANCED RELIEF EYE DROPS / PEIZER |
| FLAVOUR (LICORICE) | | | | 172.515 172.515 | ADVANCE BREATH CARE ORAL RINSE / ARM & HAMMER |
| DISODIUM EDETATE | | | | 172.135 | VISINE® ADVANCED RELIEF EYE DROPS / PEIZER |
| SODIUM HYALURONATE | | | | NA | *STARVISC II / P000046 / ANIKA THERAPEUTICS & P8100125 / BAUSCH & LOMB |
| SACCHARIN SODIUM | | | | below max 180.37 allowed in food | ACT® FLUORIDE ORAL RINSE / J&J |
| GLYCYRRHETINIC ACID | | | | 582.10 | CHEWABLE LICORICE TABLET / RX VITAMINS INC |

(b)(4) Confidential and Proprietary Information

Glycyrrhiza GLRS

* Starvisc II is 12 mg per ml of high molecular weight (> 1MM Daltons) sodium hyaluronate. P000046 references P8100125. It is supplied sterile, non pyrogenic, viscoelastic, highly purified and dissolved in physiologic saline. The device is indicated for use during surgery in the anterior and posterior segments of the human eye. Gelclair sodium hyaluronate is .00027 mg per ml of Gelclair at label indication.

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Dragon's Lair, 1 Alder Brook, Chinley, High Peak SK23 6DN
Tel: +44 (0) 1663 750 410 Fax: +44 (0) 1663 751 449
Email: otterbrookeng@aol.com



Fax

To: Angela Blackwell **From:** Priscilla Cox

Fax: 001 301 480 3002 **Pages:** 2

Phone: 001 301 827 5283 ext 119 **Date:** 30/11/01

Re: K013056 **CC:**

Urgent For Review Please Comment Please Reply Please Recycle

Ms. Blackwell,

Thank you for your fax regarding K013056, Gelclair Concentrated Oral Gel. The information sent yesterday had some errors in the percentages. Please find the corrected version following. If you will send your email address I can send an electronic copy. Other wise a hard copy will be sent by mail. If you have any further questions, please contact me at your earliest convenience.

Regards,

Priscilla Cox

For Sinclair Pharmaceuticals

Surrey, England

510(k) #K013056
Additional Information

Attn: Angela Blackwell

CONFIDENTIAL

| INGREDIENT | % NEAT | % DILUTED | FUNCTION | CFR 21 REFERENCE | LEGALLY MARKETED PRODUCTS |
|--------------------------------|--------|-----------|---|------------------|---|
| PURIFIED WATER | | | (b)(4) Confidential and Proprietary Information | NA | ABREVA® COLD SORE MEDICINE / GLAXOSMITHKLINE |
| POLYVINYLPIRROLIDONE (PVP) | | | | 173.55 | RADIACARE™ ORAL RINSE / K96482 / CARRINGTON LABS |
| MALTODEXTRIN | | | | 184.1444 | MULTIDEX® GEL WOUND DRESSING / K961085 /DEROYAL |
| PROPYLENE GLYCOL | | | | 184.1666 | ABREVA® COLD SORE MEDICINE / GLAXOSMITHKLINE |
| PEG-40 HYDROGENATED CASTOR OIL | | | | 178.3280 | THERA BREATH™ ORAL RINSE / FRESH START, LLC |
| HYDROXYETHYLCELLULOSE | | | | 172.874 | VIRACTIN® COLD SORE & FEVER BLISTER MEDICATION / J.B. WILLIAMS |
| POTASSIUM SORBATE | | | | 182.3640 | RADIACARE™ ORAL RINSE / K96482 / CARRINGTON LABS |
| SODIUM BENZOATE | | | | 184.1733 | BIOTENE MOUTHWASH / LACLEDE INC. |
| BENZALKONIUM CHLORIDE | | | | 310.545 | VISINE® ADVANCED RELIEF EYE DROPS / PFIZER |
| FLAVOUR (LICORICE) | | | | 172.515 | ADVANCE BREATH CARE ORAL RINSE / ARM & HAMMER |
| DISODIUM EDETATE | | | | 172.135 | VISINE® ADVANCED RELIEF EYE DROPS / PFIZER |
| SODIUM HYALURONATE | | | | NA | *STAARVISC II / P000046 / ANIKA THERAPEUTICS & P8100125 / BAUSCH & LOMB |
| SACCHARIN SODIUM | | | | 180.37 | ACT® FLUORIDE ORAL RINSE / J&J |
| GLYCERYRHETINIC ACID | | | | 582.10 | CHEWABLE LICORICE TABLET / RX VITAMINS INC |

* Staarvisc II is 12 mg per ml of high molecular weight (> 1MM Daltons) sodium hyaluronate. P000046 references P8100125. It is supplied sterile, non pyrogenic, viscoelastic, highly purified and dissolved in physiologic saline. The device is indicated for use during surgery in the anterior and posterior segments of the human eye. Gelclair sodium hyaluronate is .00027 mg per ml of Gelclair at label indication.

Dragon's Lair, 1 Alder Brook, Chinley, High Peak SK23 6DN
Tel: +44 (0) 1663 750 410 Fax: +44 (0) 1663 751 449
Email: otterbrookeng@aol.com



Fax

| | |
|--|----------------------------|
| To: Angela Blackwell | From: Priscilla Cox |
| Fax: 001 301 480 3002 | Pages: 2 |
| Phone: 001 301 827 5283 ext 119 | Date: 30/11/01 |
| Re: K013056 | CC: |

Urgent
 For Review
 Please Comment
 Please Reply
 Please Recycle

Ms. Blackwell,

Thank you for your fax regarding K013056, Gelclair Concentrated Oral Gel. The information sent yesterday had some errors in the percentages. Please find the

Dragon's Lair, 1 Alder Brook, Chinley, High Peak SK23 6DN
Tel: +44 (0) 1663 750 410 Fax: +44 (0) 1663 751 449
Email: otterbrookeng@aol.com



Fax

| | |
|--|----------------------------|
| To: Angela Blackwell | From: Priscilla Cox |
| Fax: 001 301 480 3002 | Pages: 2 |
| Phone: 001 301 827 5283 ext 119 | Date: 29/11/01 |
| Re: K013056 | CC: |

Urgent
 For Review
 Please Comment
 Please Reply
 Please Recycle

Ms. Blackwell,

Thank you for your fax regarding K013056, Gelclair Concentrated Oral Gel. The information you requested is following. If you will send your email address I can send an electronic copy. If you have any further questions, please contact me at your earliest convenience.

Regards,



Priscilla Cox

For Sinclair Pharmaceuticals

Surrey, England

510(k) #K013056
Additional Information

Attn: Angela Blackwell

CONFIDENTIAL

| INGREDIENT | % NEAT | % DILUTED | FUNCTION | CFR 21 REFERENCE | LEGALLY MARKETED PRODUCTS |
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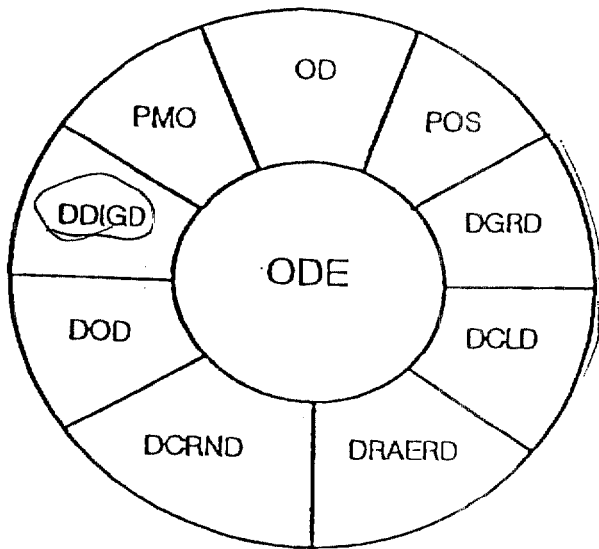
Records processed under FOIA Request #2016-3977; Released by CDRH on 08-29-2016.

*** TX REPORT ***

TRANSMISSION OK

| | |
|----------------|------------------|
| TX/RX NO | 1182 |
| CONNECTION TEL | 9011441663751449 |
| SUBADDRESS | |
| CONNECTION ID | |
| ST. TIME | 11/28 02:24 |
| USAGE T | 00'41 |
| PGS. | 2 |
| RESULT | OK |

**DHHS/PHS/FDA/CDRH
DIVISION OF DENTAL, INFECTION CONTROL,
AND GENERAL HOSPITAL DEVICES
9200 CORPORATE BOULEVARD, HFZ-480
ROCKVILLE, MARYLAND 20850**



DATE: 11/28/2001

FROM: Angela Blackwell

NO. OF PAGES: 2

PHONE NO: 301-443-8879

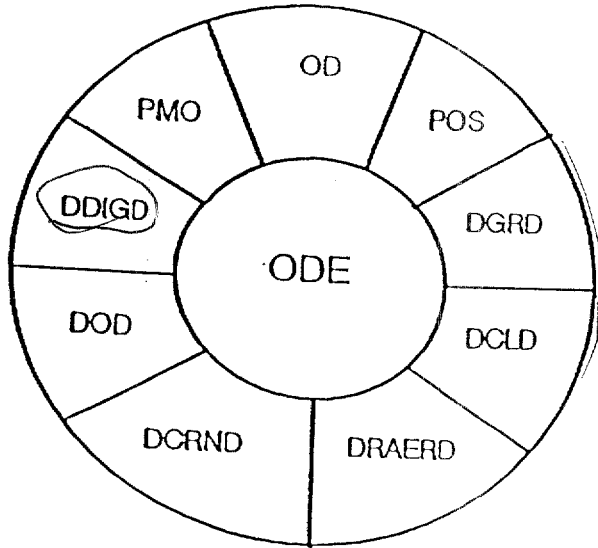
FAX NO: 301-480-3002

TO: Priscilla Cox

FAX NO: 9011 44 1663 751 449

SUBJECT: K013056
Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

DHHS/PHS/FDA/CDRH
DIVISION OF DENTAL, INFECTION CONTROL,
AND GENERAL HOSPITAL DEVICES
9200 CORPORATE BOULEVARD, HFZ-480
ROCKVILLE, MARYLAND 20850



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SUBJECT: K013056

ADDITIONAL COMMENTS:

THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND MAY CONTAIN INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW. If you are not the addressee, or a person authorized to deliver the document to the addressee, you are hereby notified that any review, disclosure, dissemination or other action based on the content of the communication is not authorized. If you have received this document in error, please immediately notify us by telephone and return it to us at the above address by mail. Thank you.

Fax Memorandum

To: Priscilla Cox
Company: Sinclair Pharmaceuticals
Document No.: K013056
Device: Gelclair Concentrated Oral Gel
From: Angela Blackwell
Date: November 28, 2001

Ms. Cox,

I am reviewing your 510(k) for Gelclair. My email is down today so I must fax instead. I need to know the complete chemical composition of the gel, including the percentage of each component. For each component I need information on another product marketed legally in the U.S. which contains the same ingredient. If there is a U.S. code of federal regulations (cfr) reference allowing the use of the component in drug, foods, cosmetics, etc. then please give me the reference.

Thank you,
Angela Blackwell
Biomedical Engineer
Dental Devices Branch
(301) 827-5283 ext 119

Screening Checklist

For all Premarket Notification 510(k) Submissions

3-30-01

| | | | | | | | | | | | | |
|--|--|--|--|--|--|--|----|---|----|---|----|------------------------------------|
| Device Name: <u>Helclair Concentrated Oral Gel</u> | | | | | | K013056 | | | | | | |
| Submitter (Company): <u>Sinclair Pharmaceuticals Ltd.</u> | | | | | | | | | | | | |
| Items which should be included (circle missing & needed information) | | | | | | S P E C I A L | | A B B R E V I A T E D | | T R A D I T I O N A L | | ✓ IF ITEM IS NEEDED AND IS MISSING |
| | | | | | | YES | NO | YES | NO | YES | NO | |
| 1. Cover Letter clearly identifies Submission as: | | | | | | GO TO # 2,3 | | GO TO # 2,4,5 | | GO TO #2, 5 | ✓ | |
| 2. GENERAL INFORMATION: REQUIRED IN ALL 510(K) SUBMISSIONS | | | | | | | | | | | | ✓ IF ITEM IS NEEDED |
| Financial Certification or Disclosure Statement for 510(k)s with a Clinical Study 807.87(i) including forms 3454 and/or 3455 | | | | | | NA | | YES | | NO | | AND IS MISSING |
| | | | | | | SPECIALS | | ABBREVIATED | | TRADITIONAL | | |
| | | | | | | YES | NO | YES | NO | YES | NO | |
| a) trade name, classification name, establishment registration number, device class | | | | | | | | | | | ✓ | |
| b) OR a statement that the device is not yet classified | | | | | | FDA-may be a classification request; see coordinator | | | | | | |
| c) identification of legally marketed equivalent device | | | | | | NA | | | | | ✓ | |
| d) compliance with Section 514 - performance standards | | | | | | NA | | | | | ✓ | |
| e) address of manufacturer | | | | | | | | | | | ✓ | |
| f) Truthful and Accurate Statement | | | | | | | | | | | ✓ | |
| g) Indications for Use enclosure | | | | | | | | | | | ✓ | |
| h) SMDA Summary or Statement (FOR ALL DEVICE CLASSES) | | | | | | | | | | | ✓ | |
| i) Class III Certification & Summary (FOR ALL CLASS III DEVICES) | | | | | | | | | | | ✓ | |
| j) Description of device (or modification) including diagrams, engineering drawings, photographs, service manuals | | | | | | | | | | | ✓ | |
| k) Proposed Labeling: | | | | | | | | | | | ✓ | |
| i) package labeling (user info) | | | | | | | | | | | ✓ | |
| ii) statement of intended use | | | | | | | | | | | ✓ | |
| iii) advertisements or promotional materials | | | | | | | | | | | ✓ | |
| i) MRI compatibility (if claimed) | | | | | | | | | | | ✓ | |
| l) Comparison Information (similarities and differences) to named legally marketed equivalent device (table preferred) should include: | | | | | | | | | | | ✓ | |
| i) Labeling | | | | | | | | | | | ✓ | |
| ii) intended use | | | | | | | | | | | ✓ | |
| iii) physical characteristics | | | | | | | | | | | ✓ | |
| iv) anatomical sites of use | | | | | | | | | | | ✓ | |
| v) performance (bench, animal, clinical) testing | | | | | | NA | | | | | ✓ | |
| vi) safety characteristics | | | | | | NA | | | | | ✓ | |
| m) If kit, kit certification | | | | | | | | | | | ✓ | |
| 3. "SPECIALS" - ONLY FOR MODIFICATIONS TO MANUFACTURER'S OWN CLASS II, III OR RESERVED CLASS I DEVICE | | | | | | | | | | | | |
| a) Name & 510(k) number of legally marketed (unmodified) predicate device | | | | | | | | | | | | |
| b) STATEMENT - INTENDED USE AND INDICATIONS FOR USE OF MODIFIED DEVICE AS DESCRIBED IN ITS | | | | | | | | | | | | * If no - STOP not a special |

36

| | | | | |
|---|--|--|--|------------------------------|
| LABELING HAVE NOT CHANGED* | | | | |
| c) STATEMENT - FUNDAMENTAL SCIENTIFIC TECHNOLOGY OF THE MODIFIED DEVICE HAS NOT CHANGED* | | | | * If no - STOP not a special |
| d) Design Control Activities Summary | | | | |
| i) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis | | | | |
| ii) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied | | | | |
| iii) A declaration of conformity with design controls. The declaration of conformity should include: | | | | |
| 1) A statement signed by the individual responsible, that, as required by the risk analysis, all verification and validation activities were performed by the designated individual(s) and the results demonstrated that the predetermined acceptance criteria were met | | | | |
| 2) A statement signed by the individual responsible, that manufacturing facility is in conformance with design control procedure Requirements as specified in 21 CFR 820.30 and the records are available for review. | | | | |

| | SPECIALS | | ABBREVIATED | | TRADITIONAL | | ✓ IF ITEM IS NEEDED AND IS MISSING |
|---|----------|----|-------------|----|-------------|----|------------------------------------|
| | YES | NO | YES | NO | YES | NO | |
| 4. ABBREVIATED 510(K): SPECIAL CONTROLS/CONFORMANCE TO RECOGNIZED STANDARDS - PLEASE FILL OUT THE STANDARDS ABBREVIATED FORM ON THE H DRIVE | | | | | | | |
| a) For a submission, which relies on a guidance document and/or special control(s), a summary report that describes how the guidance and/or special control(s) was used to address the risks associated with the particular device type | | | | | | | |
| b) If a manufacturer elects to use an alternate approach to address a particular risk, sufficient detail should be provided to justify that approach. | | | | | | | |
| c) For a submission, which relies on a recognized standard, a declaration of conformity to the standard. The declaration should include the following: | | | | | | | |
| i) An identification of the applicable recognized consensus standards that were met | | | | | | | |
| ii) A specification, for each consensus standard, that all requirements were met, except for inapplicable requirements or deviations noted below | | | | | | | |
| iii) An identification, for each consensus standard, of | | | | | | | |

| | | | |
|---|--|--|--|
| any way(s) in which the standard may have been adapted for application to the device under review, e.g., an identification of an alternative series of tests that were performed | | | |
| iv) An identification, for each consensus standard, of any requirements that were not applicable to the device | | | |
| v) A specification of any deviations from each applicable standard that were applied | | | |
| vi) A specification of the differences that may exist, if any, between the tested device and the device to be marketed and a justification of the test results in these areas of difference | | | |
| vii) Name/address of test laboratory/certification body involved in determining the conformance of the device with applicable consensus standards and a reference to any accreditations for those organizations | | | |
| d) Data/information to address issues not covered by guidance documents, special controls, and/or recognized standards | | | |

| 5. Additional Considerations: (may be covered by Design Controls) | | | | | | | | | |
|--|--|--|--|--|--|--|--|--|--|
| a) Biocompatibility data for all patient-contacting materials, OR certification of identical material/formulation: | | | | | | | | | |
| i) component & material | | | | | | | | | |
| ii) identify patient-contacting materials | | | | | | | | | |
| iii) biocompatibility of final sterilized product | | | | | | | | | |
| b) Sterilization and expiration dating information: | | | | | | | | | |
| i) sterilization method | | | | | | | | | |
| ii) SAL | | | | | | | | | |
| iii) packaging | | | | | | | | | |
| iv) specify pyrogen free | | | | | | | | | |
| v) ETO residues | | | | | | | | | |
| vi) radiation dose | | | | | | | | | |
| c) Software validation & verification: | | | | | | | | | |
| i) hazard analysis | | | | | | | | | |
| ii) level of concern | | | | | | | | | |
| iii) development documentation | | | | | | | | | |
| iv) certification | | | | | | | | | |

Items shaded under "NO" are necessary for that type of submission. Circled items and items with checks in the "Needed & Missing" column must be submitted before acceptance of the document.

Passed Screening Yes No
 Date: SEP 14 2016

Reviewer: _____
 Concurrence by Review Branch: _____

REVISED:3/14/95

THE 510(K) DOCUMENTATION FORMS ARE AVAILABLE ON THE LAN UNDER 510(K) BOILERPLATES TITLED "DOCUMENTATION" AND MUST BE FILLED OUT WITH EVERY FINAL DECISION (SE, NSE, NOT A DEVICE, ETC.).

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K _____

Reviewer: _____

Division/Branch: _____

Device Name: _____

Product To Which Compared (510(K) Number If Known): _____

| | YES | NO | |
|--|-----|----|--------------------------------------|
| 1. Is Product A Device | | | If NO = Stop |
| 2. Is Device Subject To 510(k)? | | | If NO = Stop |
| 3. Same Indication Statement? | | | If YES = Go To 5 |
| 4. Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness? | | | If YES = Stop NE |
| 5. Same Technological Characteristics? | | | If YES = Go To 7 |
| 6. Could The New Characteristics Affect Safety Or Effectiveness? | | | If YES = Go To 8 |
| 7. Descriptive Characteristics Precise Enough? | | | If NO = Go To 10 If YES = Stop SE |
| 8. New Types Of Safety Or Effectiveness Questions? | | | If YES = Stop NE |
| 9. Accepted Scientific Methods Exist? | | | If NO = Stop NE |
| 10. Performance Data Available? | | | If NO = Request Data |
| 11. Data Demonstrate Equivalence? | | | Final Decision: |

Note: In addition to completing the form on the LAN, "yes" responses to questions 4, 6, 8, and 11, and every "no" response requires an explanation.

1. Intended Use:

2. Device Description: Provide a statement of how the device is either similar to and/or different from other marketed devices, plus data (if necessary) to support the statement. Is the device life-supporting or life sustaining? Is the device implanted (short-term or long-term)? Does the device design use software? Is the device sterile? Is the device for single use? Is the device over-the-counter or prescription use? Does the device contain drug or biological product as a component? Is this device a kit? Provide a summary about the device's design, materials, physical properties and toxicology profile if important.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. Explain why not a device:
2. Explain why not subject to 510(k):
3. How does the new indication differ from the predicate device's indication:
4. Explain why there is or is not a new effect or safety or effectiveness issue:
5. Describe the new technological characteristics:
6. Explain how new characteristics could or could not affect safety or effectiveness:
7. Explain how descriptive characteristics are not precise enough:
8. Explain new types of safety or effectiveness questions raised or why the questions are not new:
9. Explain why existing scientific methods can not be used:
10. Explain what performance data is needed:
11. Explain how the performance data demonstrates that the device is or is not substantially equivalent:

ATTACH ADDITIONAL SUPPORTING INFORMATION

Internal Administrative Form

| | YES | NO |
|---|-----|----|
| 1. Did the firm request expedited review? | | ✓ |
| 2. Did we grant expedited review? | | ✓ |
| 3. Have you verified that the Document is labeled Class III for GMP purposes? | | ✓ |
| 4. If, not, has POS been notified? | ✓ | |
| 5. Is the product a device? | ✓ | ✓ |
| 6. Is the device exempt from 510(k) by regulation or policy? | ✓ | |
| 7. Is the device subject to review by CDRH? | | |
| 8. Are you aware that this device has been the subject of a previous NSE decision? | | ✓ |
| 9. If yes, does this new 510(k) address the NSE issue(s), (e.g., performance data)? | | ✓ |
| 10. Are you aware of the submitter being the subject of an integrity investigation? | | ✓ |
| 11. If, yes, consult the ODE Integrity Officer. | | |
| 12. Has the ODE Integrity Officer given permission to proceed with the review? (Blue Book Memo #I91-2 and Federal Register 90N0332, September 10, 1991. | | ✓ |

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration
 Center for Devices and
 Radiological Health
 Office of Device Evaluation
 Document Mail Center (HFZ-401)
 9200 Corporate Blvd.
 Rockville, Maryland 20850

September 12, 2001

SINCLAIR PHARMACEUTICALS, LTD.
 C/O OTTERBROOK ENGINEERING
 1 ALDER BROOK
 CHINLEY, HIGH PEAK,
 UNITED KINGDOM
 ATTN: PRISCILLA COX

510(k) Number: K013056
 Received: 11-SEP-2001
 Product: GELCLAIR
 CONCENTRATED ORAL
 GEL

The Center for Devices and Radiological Health (CDRH), Office of Device Evaluation (ODE), has received the Premarket Notification you submitted in accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act (Act) for the above referenced product. We have assigned your submission a unique 510(k) number that is cited above. Please refer prominently to this 510(k) number in any future correspondence that relates to this submission. We will notify you when the processing of your premarket notification has been completed or if any additional information is required. YOU MAY NOT PLACE THIS DEVICE INTO COMMERCIAL DISTRIBUTION UNTIL YOU RECEIVE A LETTER FROM FDA ALLOWING YOU TO DO SO.

As a reminder, we would like to mention that FDA requires all 510(k) submitters to provide an indications for use statement on a separate page. If you have not included this indications for use statement in addition to your 510(k) summary (807.92), or a 510(k) statement (807.93), and your Truthful and Accurate statement, please do so as soon as possible. If the above mentioned requirements have been submitted, please do not submit them again. There may be other regulations or requirements affecting your device such as Postmarket Surveillance (Section 522(a)(1) of the Act) and the Device Tracking regulation (21 CFR Part 821). Please contact the Division of Small Manufacturers, International and Consumer Assistance (DSMICA) at the telephone or web site below for more information.

Please remember that all correspondence concerning your submission MUST be sent to the Document Mail Center (DMC)(HFZ-401) at the above letterhead address. Correspondence sent to any address other than the DMC will not be considered as part of your official premarket notification submission. Because of equipment and personnel limitations, we cannot accept telefaxed material as part of your official premarket notification submission, unless specifically requested of you by an FDA official. Any telefaxed material must be followed by a hard copy to the DMC (HFZ-401).

You should be familiar with the manual entitled, "Premarket Notification 510(k) Regulatory Requirements for Medical Devices" available from DSMICA. If you have other procedural or policy questions, or want information on how to check on the status of your submission (after 90 days from the receipt date), please contact DSMICA at (301) 443-6597 or its toll-free number (800) 638-2041, or at their Internet address <http://www.fda.gov/cdrh/dsmamain.html> or me at (301) 594-1190.

Sincerely yours,

Marjorie Shulman
 Consumer Safety Officer
 Premarket Notification Staff
 Office of Device Evaluation

Questions? Contact FDA/CDRH/OCE/DID at CDRH-FOISTATUS@fda.hhs.gov or call 301-796-8118.

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10 013056



Sinclair Pharmaceuticals Limited Borough Road, Godalming, Surrey, UK, GU7 2AB

September 6, 2001

Document Mail Center (HFZ-401)
Food and Drug Administration (FDA)
Center for Devices and Radiological Health (CDRH)
Office of Device Evaluation
9200 Corporate Blvd.
Rockville, MD 20850

RECEIVED
SEP 11 2001
CDRH

Subject: **510(k) Submission for Sinclair Pharmaceuticals, Ltd.
Gelclair® Concentrated Oral Gel**

Dear 510(k) review staff,
In accordance with Section 510(k) of the Federal Food, Drug, and Cosmetic Act, and 21 CFR 807.87, Sinclair Pharmaceuticals, Ltd. is submitting, in duplicate, a Premarket Notification 510(k) for Sinclair Pharmaceuticals, Ltd. Gelclair® Concentrated Oral Gel.

Confidentiality

We regard our intent to market this product as confidential. The existence of this 510(k) has not been revealed to anyone other than our employees. Therefore we request that the Agency not disclose this intent until the 510(k) clearance is granted.

All items marked "Confidential" may be trade secret, confidential commercial or financial information as defined in 21 CFR 20.61. We request that the Agency not make public disclosure of this information without prior consultation with Sinclair Pharmaceuticals, Ltd. as provided by 21 CFR 20.45.

We would appreciate your earliest attention to this 510(k) and we trust that the information provided will enable the Agency to reach a substantial equivalence determination. Should you have any questions, please contact me via phone at 011 44 1663 750 410, fax at 011 44 1663 751 449, or email at pwcox@cwcom.net.

Sincerely,

PwCox

Priscilla Cox
Director RA/QA
Otterbrook Engineering

SK II

Enclosure: 510(k) Submission for Sinclair Pharmaceuticals Gelclair® Concentrated Oral Gel

SK B 43



510(k) Pre-market Notification

Sinclair Pharmaceuticals, Ltd* *Gelclair® Concentrated Oral Gel

**Sinclair Pharmaceuticals, Ltd.
Borough Road
Godalming
Surrey
GU7 2AB
United Kingdom**

**Tel: +44 01483 426 644
Fax: +44 01483 427 633**

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I. CDRH Submission Cover Sheet

| | | | | |
|---|---|---|--|--|
| Date Of submission: September 6, 2001 | | FDA Document Number: | | |
| Section A: Type of Submission | | | | |
| PMA <input type="checkbox"/> Original Submission <input type="checkbox"/> Modules Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Report <input type="checkbox"/> Report Amendment | PMA Supplement <input type="checkbox"/> Regular <input type="checkbox"/> Special <input type="checkbox"/> Panel Track <input type="checkbox"/> 30-day Supplement <input type="checkbox"/> 135-day Supplement <input type="checkbox"/> Real time Review <input type="checkbox"/> Amendment to PMA Supplement | PDP <input type="checkbox"/> Presubmission summary <input type="checkbox"/> Original PDP <input type="checkbox"/> Notice of Intent to start clinical trials <input type="checkbox"/> Intention to submit Notice of Completion <input type="checkbox"/> Notice of Completion <input type="checkbox"/> Amendment to PDP <input type="checkbox"/> Report | 510(k) <input checked="" type="checkbox"/> Original Submission <input type="checkbox"/> Traditional <input type="checkbox"/> Abbreviated <input checked="" type="checkbox"/> Special <input type="checkbox"/> Additional information <input type="checkbox"/> Traditional <input type="checkbox"/> Abbreviated <input type="checkbox"/> Special | Meeting <input type="checkbox"/> Pre-IDE <input type="checkbox"/> Pre-PMA <input type="checkbox"/> Pre-PDP <input type="checkbox"/> 180-day meeting <input type="checkbox"/> Other (specify) |
| IDE <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement | Humanitarian Device Exemption <input type="checkbox"/> Original Submission <input type="checkbox"/> Amendment <input type="checkbox"/> Supplement <input type="checkbox"/> Report | Class II Exemption <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional info | Evaluation of Automatic Class III Designation <input type="checkbox"/> Original Submission <input type="checkbox"/> Additional info | Other Submission Describe Submission |
| Section B: Applicant or Sponsor | | | | |
| Company Name: Sinclair Pharmaceuticals, Ltd. | | Establish registration Number: pending | | |
| Division name (if applicable): NA | | Phone number: +44 01483 426 644 | | |
| Street Address: Borough Road | | Fax number: +44 01483 427 633 | | |
| City: Godalming, Surrey GU7 2AB | State: NA | Country: UK | | |
| Contact Name: Denise Swift | | | | |
| Contact Title: Director of Regulatory Affairs | | Contact e-mail address: dswift@sinclairpharma.com | | |
| Section C: Submission correspondent (if different from above) | | | | |
| Company Name: Otterbrook Engineering | | Establish registration Number: NA | | |
| Division name (if applicable): NA | | Phone number: +44 1663 750 410 | | |
| Street Address: 1 Alder Brook | | Fax number: +44 1663 751 449 | | |
| City: Chinley, High Peak SK23 6DN | State: NA | Country: UK | | |
| Contact Name: Priscilla Cox | | | | |
| Contact Title: Director QA/RA | | Contact e-mail address: pwcox@cwcom.net | | |

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| Section 312 - New Device, Change in Design, or Change in Location | | |
|--|---|---|
| <input type="checkbox"/> New Device: <input type="checkbox"/> Withdrawal <input type="checkbox"/> Additional or expanded indications <input type="checkbox"/> Licensing agreement | <input type="checkbox"/> Change in design, component, or specifications: <input type="checkbox"/> software <input type="checkbox"/> Color Additive <input type="checkbox"/> Material <input type="checkbox"/> Specifications <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Location Change: <input type="checkbox"/> Manufacturer <input type="checkbox"/> Sterilizer <input type="checkbox"/> Packager <input type="checkbox"/> Distributor |
| <input type="checkbox"/> Process Change: <input type="checkbox"/> Manufacturing <input type="checkbox"/> Sterilization <input type="checkbox"/> Packaging <input type="checkbox"/> Other (specify below) | <input type="checkbox"/> Labeling change: <input type="checkbox"/> Indications <input type="checkbox"/> Instructions <input type="checkbox"/> Performance characteristics <input type="checkbox"/> Shelf life <input type="checkbox"/> Trade Name <input type="checkbox"/> Other (specify below) | Report Submissions: <input type="checkbox"/> Annual or periodic <input type="checkbox"/> Post-approval study <input type="checkbox"/> Adverse reaction <input type="checkbox"/> Device defect <input type="checkbox"/> Amendment |
| <input type="checkbox"/> Response to FDA correspondence: <input type="checkbox"/> Request for applicant hold <input type="checkbox"/> Request for removal of applicant hold <input type="checkbox"/> Request for extension <input type="checkbox"/> Request to remove or add manufacturing site | | <input type="checkbox"/> Change in ownership <input type="checkbox"/> Change in correspondent |
| <input type="checkbox"/> Other reason (specify): | | |
| Section 312 - Change in Design, Change in Correspondent, or Response to FDA Letter | | |
| <input type="checkbox"/> New device <input type="checkbox"/> Addition of Institution <input type="checkbox"/> Expand/Extend Study <input type="checkbox"/> IRB Certification <input type="checkbox"/> Request hearing <input type="checkbox"/> Request waiver <input type="checkbox"/> Termination of Study <input type="checkbox"/> Withdrawal of Application <input type="checkbox"/> Unanticipated Adverse Event <input type="checkbox"/> Notification of Emergency Use <input type="checkbox"/> Compassionate Use Request <input type="checkbox"/> Treatment IDE <input type="checkbox"/> Continually availability request <input type="checkbox"/> Other reason (specify): | <input type="checkbox"/> Change in: <input type="checkbox"/> Correspondent <input type="checkbox"/> Design <input type="checkbox"/> Informed Consent <input type="checkbox"/> Manufacturer <input type="checkbox"/> Manufacturing Process <input type="checkbox"/> Protocol - Feasibility <input type="checkbox"/> Protocol - Other <input type="checkbox"/> Sponsor <input type="checkbox"/> Report Submission <input type="checkbox"/> Current Investigator <input type="checkbox"/> Annual Progress <input type="checkbox"/> Site waiver limit reached <input type="checkbox"/> Final | <input type="checkbox"/> Response to FDA letter concerning: <input type="checkbox"/> Conditional Approval <input type="checkbox"/> Deemed Approval <input type="checkbox"/> Deficient final report <input type="checkbox"/> Deficient progress report <input type="checkbox"/> Deficient investigator report <input type="checkbox"/> Disapproval <input type="checkbox"/> Request extension of time to respond to FDA <input type="checkbox"/> Request meeting |
| Section 312 - Change in Design, Change in Technology, or Change in Materials | | |
| <input checked="" type="checkbox"/> New device <input type="checkbox"/> Addition or expanded indications <input type="checkbox"/> other reason (specify): | <input type="checkbox"/> Change in technology <input type="checkbox"/> Change in design | <input type="checkbox"/> Change in materials <input type="checkbox"/> Change in manufacturing process |

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| Section F: Product Information Applicable to 510(k) Submissions | | | | | |
|--|-------|------------------------------------|----|---|----|
| Product codes of devices to which substantial equivalence is claimed: | | | | Summary of, or statement concerning, safety and effectiveness data: | |
| 1 FRO | 2 MGQ | 3 | 4 | <input checked="" type="checkbox"/> 510(k) summary attached | |
| 5 | 6 | 7 | 8 | <input type="checkbox"/> 510(k) statement | |
| Information on devices to which substantial equivalence is claimed: | | | | | |
| 510(k) Number | | Trade or proprietary or model name | | Manufacturer | |
| 1 K964852 | | Radiacare™ Oral Wound Rinse | | Carrington Labs | |
| 2 | | | | | |
| Section F: Product Information Applicable to all Applications | | | | | |
| Common or usual or classification name: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic | | | | | |
| Trade or proprietary or model name | | | | Model Number | |
| Gelclair® Concentrated Oral Gel | | | | NA | |
| 2 | | | | | |
| FDA document numbers of all prior related submissions (regardless of outcome): none | | | | | |
| 1 | 2 | 3 | 4 | 5 | 6 |
| 7 | 8 | 9 | 10 | 11 | 12 |
| Data included in submission: <input checked="" type="checkbox"/> Laboratory testing <input type="checkbox"/> Animal trials <input type="checkbox"/> Human trials | | | | | |
| Section G: Product Classification Applicable to all Applications | | | | | |
| Product Code: MGQ | | C.F.R. section 878.4022 | | Device Class: <input checked="" type="checkbox"/> Class I <input checked="" type="checkbox"/> Class II <input type="checkbox"/> Class III <input type="checkbox"/> Unclassified | |
| Classification panel: General & Plastic Surgery | | | | | |
| Indications (from labeling): Gelclair® CONCENTRATED ORAL GEL, has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, ageing and traumatic ulcers caused by braces or ill fitting dentures, medication, or disease. Also indicated also for diffuse aphthous ulcers. | | | | | |

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| | | | |
|--|---|---|---|
| | | FDA Document Number: | |
| Manufacturer / Sterilization Site | | | |
| <input checked="" type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | FDA Establishment Registration Number: NA | <input type="checkbox"/> Manufacturer <input checked="" type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / relabeler | <input type="checkbox"/> Contract sterilizer |
| Company / Institution name: Biokosmes SRL | | Establishment Registration Number: NA | |
| Division name (if applicable) NA | | Phone Number: 011 39 0341 36 81 21 | |
| Street Address: Via Ugo Bassi 1 | | Fax Number: 011 39 0341 36 81 52 | |
| City: Lecco | State: | Country: Italy | Zip Code: 22053 |
| Contact Name: Dr. Gianluca Braguti | | | |
| Contact title: Technical Director | | Contact e-mail address: | |
| <input type="checkbox"/> Original <input type="checkbox"/> Add <input type="checkbox"/> Delete | FDA Establishment Registration Number: | <input type="checkbox"/> Manufacturer <input type="checkbox"/> Contract Manufacturer <input type="checkbox"/> Repackager / relabeler | <input type="checkbox"/> Contract sterilizer |
| Company / Institution name: | | Establishment Registration Number: | |
| Division name (if applicable) NA | | Phone Number: | |
| Street Address: | | Fax Number: | |
| City: | State | Country: USA | Zip Code: |
| Contact Name: | | | |
| Contact title: | | Contact e-mail address: | |

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II. Device Name

The device trade names and common/classifications names are:

| Device Trade Name | Common/Classification Name |
|---------------------------------|---|
| Gelclair® Concentrated Oral Gel | Dressing, Wound & Burn, Hydrogel w/Drug or Biologic |

III. Address and Registration #

The address and registration number of the manufacturer and sterilization sites for the devices are:

| Manufacturer | Sterilization Site |
|--|--------------------|
| Sinclair Pharmaceuticals, Ltd Borough Road Godalming, Surrey GU7 2AB United Kingdom FDA Registration pending | NA |

IV. Device Class

Class I

V. Predicate Device Information

| Trade Name | 510(k) Number | SE Date |
|----------------------------|---------------|----------|
| Radiacare Oral Wound Rinse | K964852 | 03/03/97 |
| | | |

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VI. Labeling and Intended Use

A draft, preprinted product pouch, carton and the package insert (which contains Instructions for Use) can be found in Attachment 1.

Intended Use

Sinclair Gelclair® CONCENTRATED ORAL GEL, has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, ageing and traumatic ulcers caused by braces or ill fitting dentures, medication, or disease. Also indicated also for diffuse aphthous ulcers.

The Indications for Use statement is included in Attachment 3.

VII. Device Description

Sinclair Gelclair® CONCENTRATED ORAL GEL is a viscous gel comprised of Purified Water, Propylene Glycol, Polyvinylpyrrolidone, Sodium Hyaluronate, Potassium Sorbate, Sodium Benzoate, Hydroxyethylcellulose, PEG-40 Hydrogenated Castor Oil, Disodium Edetate, Benzalkonium Chloride, Flavor, Saccharin Sodium, Glycyrrhetic Acid.

Gelclair® CONCENTRATED ORAL GEL has a mechanical action which provides pain relief by adhering to the mucosal surface of the mouth, soothing mouth lesions.

The gel concentrate is provided in a single use 15 ml foil pouches ready to be mixed with 40ml of water for use. The pouch is preprinted with instructions for use.

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VIII. Substantial Equivalence

The Sinclair Pharmaceuticals, Ltd Gelclair® **CONCENTRATED ORAL GEL** is substantially equivalent to Carrington Laboratories Radiacare™ Oral Wound Rinse which is indicated for use for the management of pain associated with oral mucositis / stomatitis caused by radiation therapy and cancer chemotherapy. Predicate device labeling may be found in Attachment 2.

| <i>Product Name</i> | <i>Sinclair Pharmaceuticals Gelclair®</i> | <i>Carrington Labs RadiaCare™</i> |
|---------------------------------------|---|---|
| Ingredients | Purified Water, Propylene Glycol, Polyvinylpyrrolidone, Sodium Hyaluronate, Potassium Sorbate, Sodium Benzoate, Hydroxyethylcellulose, PEG-40 Hydrogenated Castor Oil, Disodium Edetate, Benzalkonium Chloride, Flavor, Saccharin Sodium, Glycyrhethinic Acid | Acemannan hydrogel, Aspartame, Flavor, Fructose, Maltodextrin, Polyvinylpyrrolidone, Potassium Sorbate, Sodium Benzoate |
| Method of Use | Mix with water | Mix with water |
| Number of applications per day | Take as needed | Take as needed |
| Claim | Management and relief of pain, does not sting, nonirritating, safe if swallowed | Management and relief of pain, does not sting, nonirritating, safe if swallowed |
| Area of Use | Oral Mucosa | Oral Mucosa |
| Disease State | Oral Mucositis/Stomatitis/Oral Lesions | Oral Mucositis/Stomatitis/Oral Lesions |
| Type of Product | Concentrate for dilution | Concentrate for dilution |
| Presentation | Non Sterile | Non Sterile |

In summary, the Sinclair Pharmaceuticals, Ltd. Gelclair® **CONCENTRATED ORAL GEL** described in this submission is, in our opinion, substantially equivalent to the predicate device Carrington Laboratories Radiacare™ Oral Wound Rinse .

IX. 510(k) Statement or Summary

The 510(k) Summary is included in Attachment 7.

X. Truthful and Accuracy Certification

A certification of the truthfulness and accuracy of the Sinclair Gelclair® **CONCENTRATED ORAL GEL** information as described in this submission is included in Attachment 8.

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Attachment 1

Labeling & Instructions For Use

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SINCLAIR

Gelclair[®]

For Pain Management and relief of pain caused by Oral Mucositis / Stomatitis which may be associated with chemotherapy or radiation therapy. Also suitable for other types of oral lesions.

Concentrated Oral Gel

15 ml.



Caution: Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

Warning: As with all medications, keep out of the reach of children.

SINCLAIR



Gelclair® has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, ageing and traumatic ulcers caused by braces or ill fitting dentures, medication, or disease. Also indicated also for diffuse aphthous ulcers.

Directions for use: Pour the entire contents of the single-dose Gelclair® sachet into a glass and add 40 ml of water. Stir mixture well and use at once. Rinse around the mouth for at least one minute or as long as possible to coat tongue, palate, throat, inside of cheeks and all oral tissue thoroughly. Gargle and spit out. Use 3 times a day or as needed. Do not eat or drink for at least one hour following treatment. If swallowed accidentally no adverse effects are anticipated.

Best Before:

Manufactured by:

Sinclair Pharmaceuticals Ltd - Borough Road
Godalming - Surrey GU7 2AB - England, UK.

CE Medical Device Class I

LOT



AP121701/1



SS

SINCLAIR

SINCLAIR

**Indications and
Directions for Use**
See enclosed leaflet.

**Keep out of the reach
of children.**

Store at room temperature,
out of direct sunlight.
Do not refrigerate.

Gelclair®

Concentrated Oral Gel

For Pain management and relief of pain
caused by Oral Mucositis / Stomatitis
which may be associated with chemotherapy
or radiation therapy.
Also suitable for other types of oral lesions.



5 015936 456017 >

7x15ml

Single-dose sachets

SINCLAIR

SINCLAIR

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Concentrated Oral Gel
7x15ml / Single-dose sachets



Ingredients

Purified Water, Maltodextrin,
Propylene Glycol, PVP,
Sodium Hyaluronate,
Potassium Sorbate,
Sodium Benzoate,
Hydroxyethylcellulose,
PEG-40 Hydrogenated
Castor Oil, Disodium
Edetate, Benzalkonium
Chloride, Aroma, Saccharin
Sodium, Glycerbom Acid.

CE Medical Device Class I



Caution: Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.
Warning: As with all medication, keep out of the reach of children.

LOT



Manufactured by:

Sinclair Pharmaceuticals Ltd, Borough Road,
Cranford, Essex, GU7 2AB, England, UK.

AP01-301



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**Gelclair®
Concentrated Oral Gel**

Ingredients: Purified Water, Maltodextrin, Propylene Glycol, PVP, Sodium Hyaluronate, Potassium Sorbate, Sodium Benzoate, Hydroxyethylcellulose, PEG-40 Hydrogenated Castor Oil, Disodium Edetate, Benzalkonium Chloride, Flavor, Saccharin Sodium, Glycyrrhetic Acid.

Patient use form: Concentrated oral gel.

Contents: 15 ml per single-dose sachet. 1 Box contains 21 single dose sachets.

Therapeutic group or type of activity: Oral Gel for the relief of pain.

Indications: Gelclair®, has a mechanical action which provides pain relief by adhering to the mucosal surface of the mouth, soothing mouth lesions caused by chemotherapy, medication, disease, radiotherapy, irritation due to oral surgery, ageing and traumatic ulcers caused by braces and ill fitting dentures. May be used to manage the pain from Oral Mucositis/Stomatitis. Also indicated also for diffuse aphthous ulcers.

Contra-indications: The administration of Gelclair® is contra-indicated in any patient with a known history of hypersensitivity to any of the ingredients.

Special Precautions for use: Avoid eating or drinking for at least one hour after use Do not use any sachet that is not intact (torn, split or otherwise damaged in any way). If no improvement is noticed after 7 days, consult a physician.

Warning: Federal law restricts this device to sale by or on the order of a physician or properly licensed practitioner.

Interactions with other medicinal products and other forms of interaction: There are no known interactions with medicinal or other products.

Directions for use: Pour the entire contents of the single-dose Gelclair®, sachet into a glass and add 40ml or 4 tablespoonfuls of water. Stir mixture well and use at once. Rinse around the mouth for at least one minute or as long as possible to coat tongue, palate, throat, inside of cheeks and all oral tissue thoroughly. Gargle and spit out. Use 3 times a day or as needed. Do not eat or drink for least one hour following treatment. If Gelclair® is swallowed accidentally no adverse effects are anticipated. In the unlikely event that water is not available, the product may be used undiluted.

Side effects: At the time of producing this leaflet there have been no reported side effects with Gelclair®, however the product is not recommended for use in patients with a known or suspected allergy to any of the product's ingredients.

Store at room temperature, out of direct sunlight. Do not refrigerate.

KEEP OUT OF THE REACH OF CHILDREN.

Please note: The gel may become a little darker and thicker over time, but this does not affect its efficacy or safety. Do not use after the 'Best Before' date shown on the box.

Overdose: At the time of producing this leaflet no cases of overdose have been reported. However, no serious adverse effects should be expected from ingestion of several sachets of Gelclair®.

Manufactured by:
Sinclair Pharmaceuticals, Ltd -Borough Road -Godalming -Surrey GU7 2AB -England, UK.
Date of Revision: June 2001

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Attachment 2

Competitive Labeling

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Radiacare™ Oral Wound Rinse

For the management and relief of pain associated with oral mucositis/stomatitis caused by radiation therapy and cancer chemotherapy. **RADIA CARE™** relieves the pain by adhering to injured tissue and protecting it from further irritation. Also suitable for other oral lesions.

NDC NO. 83303-011-01

CARRINGTON™

RADIA CARE™

ORAL WOUND RINSE

B

CAREFUL: Federal law restricts this device to sale by or on the order of a physician (or properly licensed practitioner).

Warning: Use with all medications. Keep out of the reach of children.

PRESCRIPTIONS
CONTAIN SPECIAL ADVICE

INDICATIONS: For the management and relief of pain associated with oral mucositis/stomatitis caused by radiation therapy and cancer chemotherapy. **RADIA CARE™** relieves the pain by adhering to injured tissue and protecting it from further irritation. Also suitable for other oral lesions.

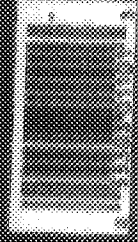
ORAL MUCOSITIS/ STOMATITIS

- Soothing
- Coats
- Does Not Sting
- Non-Irritating
- Pleasant Taste
- Pleasant Smell
- Safe if Swallowed

INGREDIENTS
(alphabetical order)
Aminocaproic hydrogel from Amprol, Acetaminophen from Proctonol, Methylcellulose, Polymyxin B sulfate, Potassium Sorbate, Sodium Benzoate.

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For technical support or further information, call 1-800-333-3333. © 2011 Carrington, Inc. www.carringtonpharma.com



FALL TO INSURE PROPER TISSUE ADHESION

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Attachment 3

Indications for Use Statement

510(k) Number
(if known)

Device Name

Sinclair Gelclair® CONCENTRATED ORAL GEL

Indications for Use

Sinclair Gelclair® CONCENTRATED ORAL GEL, has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, ageing and traumatic ulcers caused by braces or ill fitting dentures, medication, or disease. Also indicated also for diffuse aphthous ulcers.

PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE
IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use
(per 21 CFR 801.109)

OR

Over-The Counter Use

Sinclair Pharmaceuticals, Ltd

510(k) for Sinclair Concentrated Oral Gel

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CONFIDENTIAL

Attachment 4

RISK ANALYSIS

LEVELS OF EXPOSURE

The level of exposure is considered to be the quantity of substance, expressed in mg/Kg (milligrams per kilogram), completely absorbed by the user of the product. In the case of Sinclair **Gelclair®** CONCENTRATED ORAL GEL, the level of exposure was calculated on 3 daily rinses of 10ml each, working on the hypothesis of absorption equal to 100% of the product. Two sets of calculations were used, considering the weight of 60Kg for an adult subject and 10Kg for a child. The exposure expressed in mg/Kg of the substances that make up the mouthwash is compared with their DL50 set out in the single material safety data sheets.

CALCULATION OF THE LEVEL OF EXPOSURE

- 1) % of RM in FP x title of RM
100%

The result will give the effective percentage of finished product.

- 2) effective % of RM in FP x mg/application
100%
- 3) result of 2) x number of applications/day
- 4) result of 3) x % of absorption
100%
- 5) result of 4)
60Kg
- 6) result of 4)
10Kg

N.B.: RM = raw material; FP = finished product.

CONCLUSIONS:

On the basis of the calculations made on the level of exposure to the single substances employed in the formulation of **Gelclair®** CONCENTRATED ORAL GEL, it may be concluded that the product is:

- a) innocuous if ingested:
- b) suitable for pædiatric use.

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CONFIDENTIAL**Attachment 5****Stability Test Data**

| 5.1.1 – STABILITY AT +40°C, THERMOSTATICALLY CONTROLLED | | | |
|---|--|------------------|------------------|
| DERMASSIST™ ORAL GEL | 30 DAYS | 60 DAYS | 90 DAYS |
| APPEARANCE | GELIFIED, STRAW-COLOURED SOLUTION | DITTO | DITTO |
| SMELL | CHARACTERISTIC | DITTO | DITTO |
| TASTE | CHARACTERISTIC, LIQUORICE, SLIGHTLY BITTER | DITTO | DITTO |
| pH | 5.8 | 5.9 | 6.01 |
| VISCOSITY | 4050cps | 3960cps | 3890cps |
| TOTAL MICROBIAL COUNT | <100 CFU/g | <100 CFU/g | <100 CFU/g |
| PATHOGENS | ABSENT | ABSENT | ABSENT |
| 5.1.2 – STABILITY AT +40°C AND +5°C, THERMOSTATICALLY CONTROLLED | | | |
| DERMASSIST™ ORAL GEL | 30 DAYS | 60 DAYS | 90 DAYS |
| APPEARANCE | GELIFIED, STRAW-COLOURED SOLUTION | DITTO | DITTO |
| SMELL | CHARACTERISTIC | DITTO | DITTO |
| TASTE | CHARACTERISTIC, LIQUORICE, SLIGHTLY BITTER | DITTO | DITTO |
| pH | 5.7 | 6.1 | 6.21 |
| VISCOSITY | 3950cps | 3700cps | 368cps |
| TOTAL MICROBIAL COUNT | <100 CFU/g | <100 CFU/g | <100 CFU/g |
| PATHOGENS | ABSENT | ABSENT | ABSENT |
| 5.1.3 – STABILITY AT ROOM TEMPERATURE | | | |
| DERMASSIST™ ORAL GEL | 6 MONTHS | 12 MONTHS | 20 MONTHS |
| APPEARANCE | GELIFIED, DARK STRAW-COLOURED SOLUTION | DITTO | DITTO |
| SMELL | CHARACTERISTIC | DITTO | DITTO |
| TASTE | CHARACTERISTIC, LIQUORICE, SLIGHTLY BITTER | DITTO | DITTO |
| Ph | 5.78 | 5.81 | 5.84 |
| VISCOSITY | 4020cps | 3970cps | 3910cps |
| TOTAL MICROBIAL COUNT | <100 C.F.U./g | <100 C.F.U./g | <100 C.F.U./g |
| PATHOGENS | ABSENT | ABSENT | ABSENT |

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Attachment 6

Efficacy of Gelclair® in Reducing Pain in Patients with Oral Lesions, Preliminary Findings From an Open Pilot Study

Dr Marcello Innocenti, University of Milan; Dr Giancarla Moscatelli and Dr Silvano Lopez, Hospice di Abbiategrasso, Milan, Italy

OBJECTIVE

To evaluate the effectiveness of Gelclair® Concentrated Oral Gel in reducing pain in patients with oral lesions.

DESIGN

A prospective, open, uncontrolled, pilot study using a hospital-based group of patients in Milan, Italy.

MATERIALS AND METHODS

Thirty patients between the ages of 30 and 60 with painful lesions of the mouth and oropharynx from various aetiologies received Gelclair® (15ml sachet mixed with 40ml of water) three-times daily for at least seven days. The patients were evaluated for short-term (5-7 hours) and medium-term effects (7-10 days) relative to the severity of pain on swallowing and eating. Pain assessment scores were recorded using a Visual Numerical Scale.

RESULTS

A statistically significant reduction in total and independent pain scores were observed both in the short-term at 5-7 hours following administration of Gelclair® ($t = 42.3$; $df = 29$; $P < 0.005$) and in the medium-term ($t = 5.1$; $df = 29$; $P < 0.005$) at between 7 and 10 days of continuous use, respectively.

CONCLUSIONS

These preliminary results indicate that Gelclair® rapidly and effectively reduces pain associated with oral lesions for up to 10 days with continued use, particularly in patients with oral mucositis. Controlled trials of Gelclair® are recommended to support the use of Gelclair® as a pain management option for patients with oral lesions.

Keywords: Gelclair®, oral mucositis, stomatitis, oral lesions, oral pathologies, pain on eating and swallowing, oncology nutrition

Introduction

Oral soft tissue lesions are common problems of modern society (Miller *et al*, 2001) and can be caused by a number of medical conditions (Ben Slama, 2000; Garlick & Taichman, 1991; Plauth *et al*, 1991; Gillespie & Marino, 1993; Guggenheimer *et al*, 2000), drug treatments (Madinier *et al*, 2000; McCartan & McCreary, 1997) and radio/chemotherapies (Öhrn *et al*, 2001; Adamietz *et al*, 1998). In the past, recurrent aphthous ulceration or stomatitis was recognised as the most common oral mucosal disease, characterised by small, round, clearly defined, painful ulcers that heal in 10-14 days without scarring (Ship, 1996). Today, stomatitis is increasingly interchanged with the term mucositis. Despite this convention, technical differences between mucositis and stomatitis may arise from aetiology (ie chemotherapy versus ionising radiation) or the presence of infection. For the purposes of this study, oral mucositis refers to the inflammation and ulceration of the oral mucosa.

Oral mucositis is a common complication of high-dose radio/chemotherapies in head and neck cancer (Bernhoft & Skaug, 1985; Bundgaard *et al*, 1993; Karlsson 1987; King *et al*, 1985; Kuten *et al*, 1986; Langius *et al*, 1993); a complication of many chemotherapies, in particular that given for colorectal cancer (Jansman *et al*, 2001) and high-dose regimens as administered prior to bone marrow transplantation (McGuire *et al* 1993), (Stiff 2001). Mucositis occurs in an estimated 40% of patients receiving standard-dose chemotherapy (Sonis, Sonis, & Lieberman, 1978) and occurs in about 75% of patients receiving high-dose regimens and undergoing stem cell transplantation (Woo *et al*, 1993; Pico *et al*, 1998; Bearman *et al*, 1988). Oral mucositis is also a common condition in patients with reduced immune response, such as HIV/AIDS patients.

Although radio- and chemotherapies have advanced over the past decade with improvements in side-effects such as myelosuppression (Karthaus, Rosenthal, Ganser, 1999), oral mucositis has emerged as a common toxicity, with no treatment that has been demonstrated to be uniformly efficacious (Jansman *et al*, 2001).

Course of Oral Mucositis

Oral mucositis usually starts with erythema of the oral mucosa, which develops into discrete pseudomembraneous lesions that can eventually become deeply ulcerated and necrotic. This is usually accompanied by oral discomfort, severe pain and dysphagia. Over 90% of ulceration is localised to non-keratinised mucosa (Woo *et al*, 1993); and mucositis may be limited or can involve more than 50% of the oral cavity (Overholser 1996). There are also differences in onset and resolution of oral mucositis in radiotherapy and chemotherapy treatment regimens.

Chemotherapy-induced mucositis usually starts between 5 and 7 days after chemotherapy is first administered, presenting with erythematous lesions in the soft palate (Karthaus *et al*, 1998), the buccal mucosa, the ventral surface of the tongue, and the floor of the mouth (Woo *et al* 1993). It may last for about five days after the treatment has finished, and longer if the oral mucosa is infected.

In radiotherapy-induced oral mucositis, symptoms start after 1-2 weeks of radiation, and continue for 1-3 weeks after the last dose if there are no complicating factors such as infection. In a similar sequence to chemotherapy-induced mucositis, the first symptom is erythema of the oral mucosa, which develops into ulceration.

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Mucositis is also associated with infection. The impaired mucosal barrier may become colonised by abnormal bacterial flora particularly in patients with reduced immune responses. Damage to the oral mucosa caused by infection may result in serious life-threatening complications during neutropenia (Hughes *et al*, 1990; Dreizen *et al*, 1981).

Oral mucositis and pain

Oral mucositis remains one of the most debilitating complications of intense anticancer treatments. Severe ulceration experienced by patients undergoing radiochemotherapy means that they are often unable to eat or drink because of treatment-induced pain. Problems of feeding and hydration may often lead to intravenous hydration and/or enteral (or sometimes parenteral) feeding. Mucositis pain is characterised as chronic, being exacerbated by activities such as mouth care, speaking, swallowing, vomiting, and sleeping as a result of mouth breathing (McGuire *et al*, 1993). In one study (Kolbinson *et al*, 1988), 70% of patients required intravenous narcotics to relieve oral pain following bone marrow transplantation. At present the most common forms of treatment include local anaesthetics, corticosteroids, systemic analgesics and systemic or topical anti-inflammatory drugs. In many patients, the severity of pain means that cancer therapy is reduced or stopped altogether (NIH monograph 9), potentially affecting the outcome of that patient's oncology therapy.

Chemotherapy-induced mucositis

Cytotoxic agents targeting tumours also affect other high-turnover cells such as the oral epithelium. Therefore oral mucositis is a significant toxic effect of many chemotherapeutic regimens. Oral mucositis occurs with an overall incidence of about 40% in standard-dose chemotherapeutic agents such as 5-fluorouracil with or without folinic acid, doxorubicin, etoposide, vinblastine, taxanes, and methotrexate (Symonds 1998; Karthus, Rosenthal, Ganser 1999), increasing further to an incidence of more than 50% with higher doses (Karthus, Rosenthal, and Ganser 1999). Patients receiving stem cell transplantation as part of dose-intensified treatment are at high risk, with about 75% developing oral mucositis (Woo *et al*, 1993; Pico *et al*, 1998; Bearman *et al*, 1988).

Radiotherapy-induced oral mucositis

Ionising radiation to the head and neck can cause similar damage to the oral mucosa. When the treatment field includes the oral cavity, patients will almost certainly experience oral mucositis although the incidence of mucositis varies between studies (Bundgaard *et al*, 1993; Kuten *et al*, 1986; Posner 1985). Patients receiving concomitant chemotherapy will inevitably experience oral mucositis.

Gelclair® - a new solution to an old problem

Gelclair® is a concentrated oral gel that contains the barrier-forming ingredients polyvinylpyrrolidone and sodium hyaluronate. When rinsed around the oral cavity, it forms an adhesive barrier over the oral mucosa. This mechanism appears to offer good pain relief, by shielding the exposed or sensitised nerve endings in the mucosa from over stimulation. It also enables patients to eat and drink more easily thus aiding hydration and nutrition. Because it has a mechanical mode of action, the pain relief is universal whatever the cause of the oral lesion. It has offered pain relief to patients who have recently had oral surgery, and those with diffuse aphthous ulcers.

Subjects, materials, and methods

Design

A prospective, descriptive, repeated-measures design for a single population group was used. Data were collected from self-recording on a Visual Numerical Scale (VNS), interviews with patients after patients had been diagnosed with a painful oral condition (either oral mucositis/stomatitis, pain due to oral surgery, diffuse aphthous ulcers). There was no placebo or control group in the design.

Subjects

A total of 30 patients were enrolled in the study. Subjects were selected on the basis of symptoms of oral pain as a result of oral lesions. Thirty patients of both genders were entered into the study aged between 30 and 60 years. All patients suffered from inflammatory/ulcerative pathologies of the oral cavity of varying aetiology including mucositis/stomatitis of the oropharynx ($n = 21$) (ten patients with presenting AIDS who were undergoing specific anti-retroviral therapy which had resulted in painful oral lesions, the remainder various aetiologies); severe diffuse aphthous lesions of the oral cavity from unknown cause ($n = 4$); and after-effects of surgery to the oral cavity ($n = 5$). Patients with allergic diatheses, those who had used steroids in the month preceding the study and those addicted to drugs or alcohol were excluded from the study. In addition, patients who had taken part in other studies of any kind in the two weeks prior to enrolment in this study were also excluded.

Instruments

Experiences of pain symptoms were rated on a Visual Numerical Scale (VNS) ranging from zero to 10 with the higher number related to worst pain experienced. Patients assessed pain on short-term effects and medium-term effects of Gelclair®. Short-term effect VNS total pain scores were recorded at baseline (prior to intervention) and at 5-7 hours following the intervention. Medium-term effect pain scores were recorded at baseline and then between 7 and 10 days following the intervention. For the medium-term effects, independent pain scores were recorded for six conditions including:

- A. Pain on swallowing saliva
- B. Pain on swallowing liquids only
- C. Pain on swallowing liquids and creams
- D. Pain on swallowing semisolid foods
- E. Pain on eating chopped food/rice/pasta
- F. Pain on eating a normal diet (ie 3-course meal)

Medical intervention

Gelclair® Concentrated Oral Gel is presented as a concentrated gel solution in 15 ml sachets. It has a pleasant smell, is pale yellow, with a slightly bitter liquorice taste. Its pH value lies between 5.5 and 6.5 and it contains the film-forming agents polyvinylpyrrolidone (PVP) and sodium hyaluronate. Gelclair® is administered as a 15ml dose diluted with 40ml water to make approximately two mouthfuls of oral solution. The resulting solution appears as a slightly viscous liquid, and is prone to creating a film. The solution is kept in the mouth for 2-3 minutes and then expelled. During this time it is rinsed around the mouth, to ensure even distribution over the surface of the oral mucosa. Patients are advised to use Gelclair® three-times daily, and about one hour before a meal.

Procedure

All patients who entered into the study gave their written consent and were assessed on the presence of pain due to oral lesions prior to the study. Assessment of pain was carried out by using VNS within a questionnaire administered by the attendant nurse or physician. Baseline VNS measurements were determined at the start of intervention with Gelclair® for both short- and medium-term effects. Patients were given 15ml sachets of Gelclair® (for mixing) and were asked to self-administer three times daily. Short-term effects were measured by asking patients to rate, on the VNS, the overall levels of oral pain experienced between 5 and 7 hours post intervention. Medium-term effects were measured 7-10 days after first intervention. The medium-term pain recordings were related to independent levels of oral pain during swallowing of saliva and fluid foods, and the eating of semi-solid food and a normal 3-course meal at both the start of the treatment period, and again at 7-10 days following constant Gelclair® use.

Data analysis

The effect of Gelclair® on patients' experiences of oral pain pre and post intervention was evaluated by the use of descriptive statistics and by within-group paired *t*-test analysis. These were performed between baseline and at a 5-7 hour period after first intervention (for short-term effects), and at baseline and 7-10 days after continuous intervention (for medium-term effects). A *P*-value of <0.05 was regarded as statistically significant.

Results

In general, 57% of patients reported that the optimum effect of Gelclair® lasted more than three hours, and a further 40% reported that it lasted 2-3 hours. No patients reported side effects of Gelclair® and the taste, smell, texture, ease-of-use and handling were found acceptable.

Effects of Gelclair® on pain associated with oral lesions in the short term

Total oral pain associated with oral lesions was significantly reduced in the 5-7-hour period following administration with Gelclair® compared with baseline measurements (*t* = 42.3; *df* = 29; *P* <0.005) (Table 1). Descriptive statistics are shown in Table 2.

Table 1: Mean, T-value and probability statistics of short-term effects of Gelclair® on pain related to oral lesions.

| | Mean | T-value | P |
|----------------------------|-------|---------|--------|
| Baseline | 8.167 | 42.3 | <0.005 |
| 5-7 Hour Post Intervention | 0.633 | | |

A line plot of the short-term effects of Gelclair® on pain are shown in Figures 1 and 2. The linearity of the scores shows the direct effect of Gelclair® in reducing overall after a period of 5-7 hours. Figure 1 shows individual pain scores (*n* = 30). whereas Figure 2 shows the mean scores for the two data sets.

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Figure 1: Linear representation of individual pain scores ($n = 30$) related to oral lesions pre and post Gelclair[®] intervention.

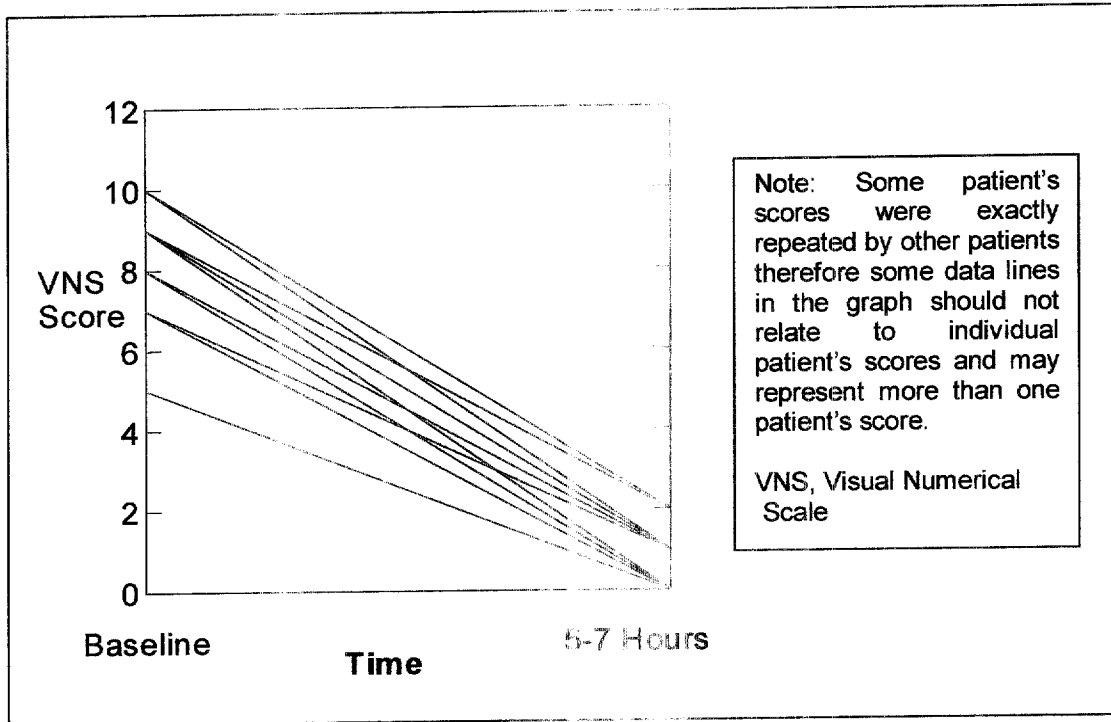


Figure 2: Mean scores of the reduction of pain related to oral lesions pre and post Gelclair[®] intervention.

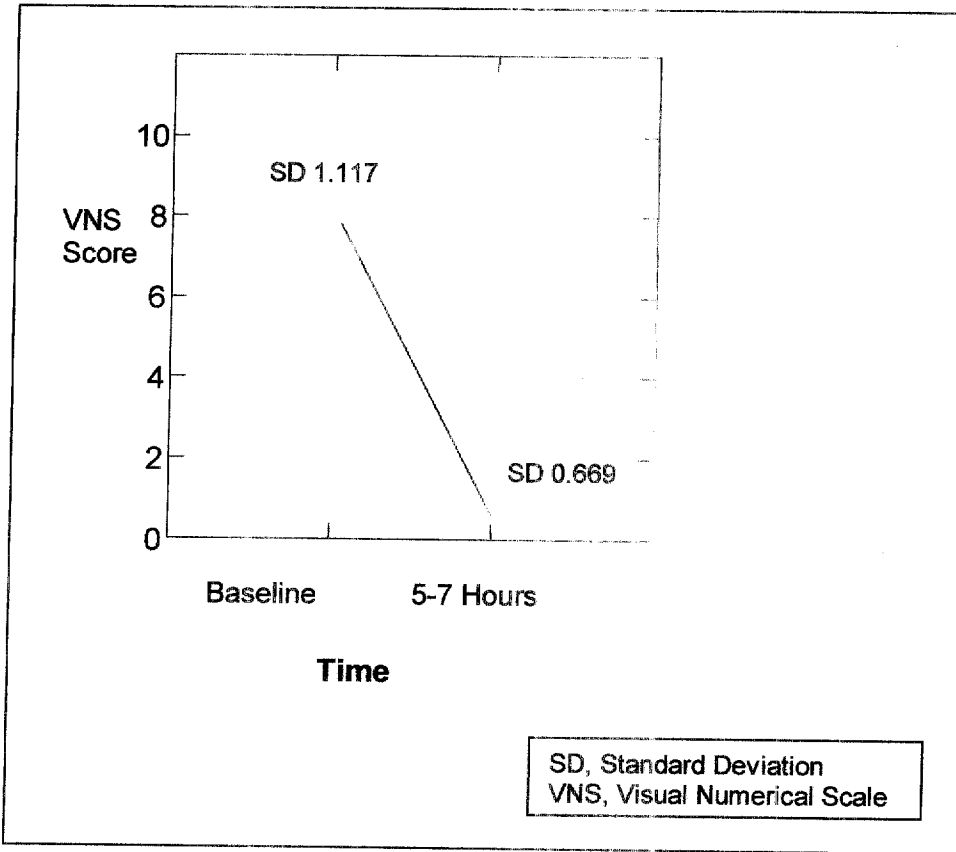


Table 2: Descriptive statistics of the short-term effect of Gelclair[®] on overall pain related to oral lesions at baseline and at 5-7 hours after intervention.

| | BASELINE | 5-7 HOURS |
|---------------|----------|-----------|
| N | 30 | 30 |
| Lowest score | 5 | 0.000 |
| Highest score | 10 | 2 |
| Sum | 245.0 | 19.0 |
| Mean | 8.167 | 0.633 |
| CI 95% Upper | 8.584 | 0.883 |
| CI 95% Lower | 7.750 | 0.384 |
| SD Error | 0.204 | 0.122 |
| SD Deviation | 1.117 | 0.669 |

A dot matrix plot (Figure 3) reveals the distribution of individual scores related to pain before and after intervention with Gelclair[®]. The data show that scores are clearly reduced in the 5-7-hour period following administration of Gelclair[®].

Effects of Gelclair® on pain associated with oral lesions in the medium term

In general, after one week of treatment with Gelclair®, 87% of patients reported overall improvements from baseline scores related to pain on swallowing food, liquids and saliva. Statistical analysis reveal significant results across all six categories of VNS pain scoring compared with baseline results (Table 3). Also, collective analysis of all independent pain scores produces significant results relative to the effect of Gelclair® in reducing overall oral pain on swallowing, eating, and drinking at 7-10 days of continued use ($n = 30$; $t = 5.1$; $df = 29$; $P < 0.005$).

Table 3: Statistical data for six independent groups of pain scores plus total pain scores at baseline and at 7-10 days of continued use with Gelclair®.

| | N | Mean | | MD | 95% CI | | SD | | T-Value | P |
|--|----|------|------|------|-----------|-----------|------|------|---------|--------|
| | | B | AI | | U/L | U/L | B | AI | | |
| Pain on swallowing saliva | 30 | 6.0 | 2.7 | 3.3 | 7.0/5.0 | 3.6/1.9 | 2.6 | 2.3 | 6.9 | <0.005 |
| Pain on swallowing liquids only | 30 | 3.4 | 2.0 | 1.4 | 4.5/2.3 | 2.9/1.0 | 3.0 | 2.5 | 2.07 | 0.053 |
| Pain on swallowing liquids and creams | 30 | 4.3 | 2.4 | 1.9 | 5.4/3.1 | 3.3/1.4 | 2.9 | 2.5 | 2.6 | 0.013 |
| Pain on swallowing semisolid foods | 30 | 4.8 | 2.5 | 2.2 | 5.9/3.6 | 3.4/1.6 | 3.1 | 2.4 | 3.1 | 0.004 |
| Pain on swallowing chopped food/rice/pasta | 30 | 4.1 | 2.0 | 2.0 | 5.2/2.9 | 2.9/1.2 | 3.1 | 2.2 | 3.8 | 0.001 |
| Pain on eating a normal diet (3-course meal) | 30 | 5.5 | 2.3 | 3.2 | 6.6/4.4 | 3.0/1.5 | 2.9 | 2.1 | 5.8 | <0.005 |
| Total pain | 30 | 28.3 | 14.0 | 14.2 | 33.6/22.9 | 17.9/10.1 | 14.3 | 10.5 | 5.1 | <0.005 |

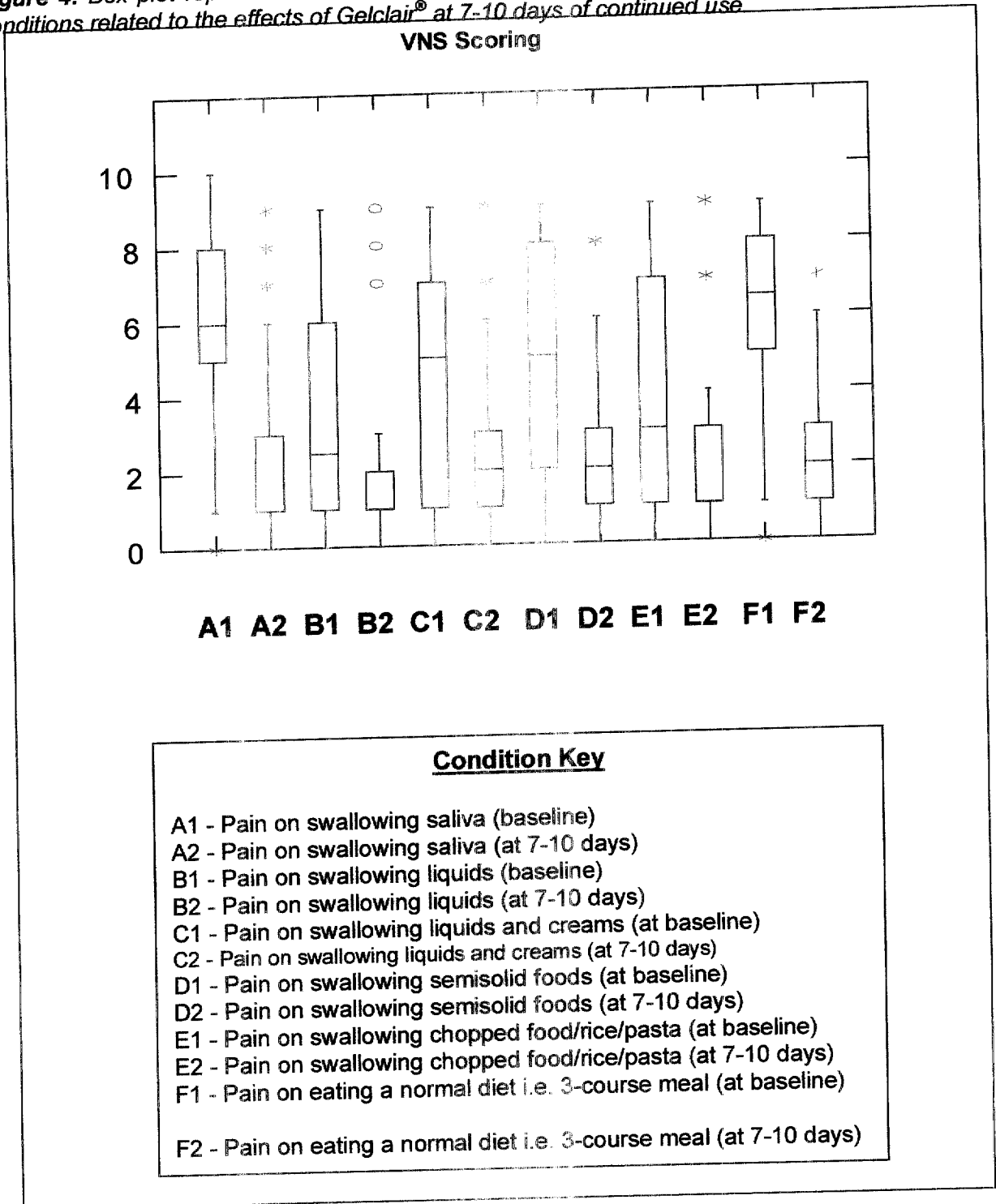
SD, standard deviation; B, baseline, AI, After intervention; MD, mean difference; U/L, upper/ lower

Interestingly, there appears to be no difference in the experience of pain dependant on the condition, as shown by the similarity of scores for the 'pain on swallowing' and scores for the 'pain on eating a normal diet' where the mean difference between the two data sets is 3.3 and 3.2, respectively ($P < 0.005$).

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A box plot of independent VNS scores related to oral pain is shown in Figure 4. This shows the distribution of pain scores both prior to the intervention with Gelclair® and after continued use at 7-10 days. The data show obvious reduction in pain assessments at 7-10 days as a result of continued use of Gelclair®.

Figure 4: Box plot representation of independent Visual Numerical Scale pain scoring in six conditions related to the effects of Gelclair® at 7-10 days of continued use



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Overall data demonstrate that, in this small uncontrolled study of 30 patients with painful oral lesions, Gelclair® produces statistically significant reductions in pain assessment scores in the short-term (5-7 hours) and in the medium-term (at 7-10 days of continued use). This analysis suggests that Gelclair® is effective as an intervention option to manage the pain caused by oral mucositis and stomatitis, lesions from oral surgery, and ulcerative conditions of unknown origin.

Discussion

Although these preliminary findings are optimistic, randomised, placebo-controlled trials of the effects of Gelclair® are needed to support the pain-reducing effects of Gelclair®. Drawbacks to the current study include a limited sample size, uncontrolled population sample, and a restrictive design. Within-group measurements are also confounded by lack of control over the course of oral lesions suggesting that pain assessments could have improved, in the medium-term effects, as a result of the natural course of healing for the oral lesions. Despite these confounding variables, raw data from this study and previous anecdotal evidence strongly suggests that Gelclair® benefits patients by reducing pain severity associated with oral lesions in mucositis, stomatitis, post-operative surgery, and in ulcerative conditions of unknown origin. The mechanism of action of Gelclair® may also benefit the patient by creating a barrier to infectious organisms that cause life-threatening complications (Hughes *et al*, 1990; Dreizen *et al*, 1981), but this has yet to be determined.

As many as 400,000 citizens in the US alone, and hundreds of thousands elsewhere in the world diagnosed with cancer will develop oral complications from their treatments or their condition. These patients and their healthcare providers may benefit greatly from Gelclair® particularly in relation to oral mucositis - which has been shown to significantly increase the burden of care in several studies. One study (Manzullo *et al*, 1998) showed that patients with standard-dose chemotherapy-induced mucositis were hospitalised 3-6 days longer per cycle of therapy compared with patients without mucositis (who often do not need hospitalisation); and another separate study (Sonis *et al*, 2001) found that in high-dose chemotherapy patients, a 1-point increase in grade of mucositis was associated with one additional day of fever; a 2.1-fold risk of additional infection; 2.7 days of additional TPN (total parenteral nutrition); 2.6 days of injectable narcotic therapy; and 2.6 additional days in hospital. In short, oral mucositis has a direct impact on duration of disease, remission, cure rates and long-term survival (Peterson 1999). This impact would be caused mainly by incidences where mucositis forces changes in a treatment plan.

Poor satisfaction with existing treatments for painful oral lesions of the mouth and oropharynx make oral mucositis a difficult condition to treat. However, Gelclair® may offer a unique management option for pain relief allowing partial or full restoration of normal eating and drinking in patients with painful oral lesions caused by a variety of aetiologies. The unusual mechanical mode of action of Gelclair® over pharmacological mechanisms offers the advantage of a non-systemic pain-relief device with added protection through barrier effects. In addition, the soothing effect remains for a sufficiently long time to give the patient effective relief, and helps to restore the ability to eat and drink more normally.

There is currently no gold-standard treatment for relieving the pain associated with such oral conditions (Jansman *et al*, 2001) and the ability to restore a satisfactory quality of life and provide symptomatic improvement is currently unattainable. However, in this study Gelclair improved pain levels and eating and drinking ability in patients with painful oral lesions.

Gelclair® may therefore offer a solution to this unmet clinical need by improving the quality of life of patients with painful oral conditions such as oral mucositis. By improving eating and drinking patterns and pain tolerance levels, the dose-limiting aspect of mucositis may be reduced, and the protective barrier formed by Gelclair® may also convey protection of the oral mucosa from further damage due to mechanical stimulation. To support these preliminary findings, two UK controlled clinical trials are currently underway to investigate further the hypothesis that Gelclair® offers rapid and effective pain relief for chronic debilitating conditions such as oral mucositis, lesions caused by oral surgery, and persistent ulcerative lesions of unknown origin.

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Attachment 7

510(k) Summary

September 1, 2001

1. Submission Applicant & Correspondent:

Name: Sinclair Pharmaceuticals, Ltd.
Address: Borough Road
Godalming
Surrey
GU7 2AB
United Kingdom

Phone No.: +44 (0) 1483 428 611

Contact Person: Denise Swift, Director of Regulatory Affairs

2. Name of Device: Gelclair® CONCENTRATED ORAL GEL
Trade/Proprietary/Model Name: Gelclair® CONCENTRATED ORAL GEL
Common or Usual Name: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic
Classification Names: Dressing, Wound & Burn, Hydrogel w/Drug or Biologic

3. Devices to Which New Device is Substantially Equivalent:

Carrington Laboratories Radiacare™ Oral Wound Rinse.

4. Device Description:

Sinclair Pharmaceuticals, Ltd. Gelclair® CONCENTRATED ORAL GEL is a viscous gel formulation, which is presented in a sachet of 15ml for mixing with 40ml of water. This combination of substances, when washed around the mouth, forms a protective layer over the oral mucosa.

5. Intended Use of the Device:

Sinclair Gelclair® CONCENTRATED ORAL GEL, has a mechanical action indicated for the management of pain and relief of pain, by adhering to the mucosal surface of the mouth, soothing oral lesions of various etiologies, including: Oral Mucositis/Stomatitis (may be caused by chemotherapy or radiotherapy), irritation due to oral surgery, ageing and traumatic ulcers caused by braces or ill fitting dentures, medication, or disease. Also indicated also for diffuse aphthous ulcers.

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6. Summary of Technological Characteristics of the Device Compared to the Predicate Devices:

The Gelclair® CONCENTRATED ORAL GEL has the same intended/indications for use as the predicate Carrington Laboratories Radiacare™ Oral Wound Rinse.

| Product Name | Sinclair Pharmaceuticals Gelclair® | Carrington Labs RadiCare™ |
|---------------------------------------|---|---|
| Ingredients | Purified Water, Propylene Glycol, Polyvinylpyrrolidone, Sodium Hyaluronate, Potassium Sorbate, Sodium Benzoate, Hydroxyethylcellulose, PEG-40 Hydrogenated Castor Oil, Disodium Edetate, Benzalkonium Chloride, Flavor, Saccharin Sodium, Glycyrrhetic Acid | Acemannan hydrogel, Aspartame, Flavor, Fructose, Maltodextrin, Polyvinylpyrrolidone, Potassium Sorbate, Sodium Benzoate |
| Method of Use | Mix with water | Mix with water |
| Number of applications per day | Take as needed | Take as needed |
| Claim | Management and relief of pain, does not sting, nonirritating, safe if swallowed | Management and relief of pain, does not sting, nonirritating, safe if swallowed |
| Area of Use | Oral Mucosa | Oral Mucosa |
| Disease State | Oral Mucositis/Stomatitis/Oral Lesions | Oral Mucositis/Stomatitis/Oral Lesions |
| Type of Product | Concentrate for dilution | Concentrate for dilution |
| Presentation | Non Sterile | Non Sterile |

7. Tests and Conclusions:
 Extensive functional and performance testing were conducted to assess the safety and effectiveness of Gelclair® CONCENTRATED ORAL GEL. All results are satisfactory.


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Attachment 8

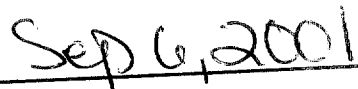
Truthful and Accuracy Statement

The following statement is provided as required by 21 CFR 807.87 (j):

I certify that, in my capacity as Regulatory Consultant, I believe to the best of my knowledge, that all data and information submitted in this pre-market notification are truthful and accurate and that no material facts for a review of the substantial equivalence of this device have been knowingly omitted from this submission.



Priscilla Cox
Director QA/RA
Otterbrook Engineering



Date