



Updates from FDA/CDER: Product Title and Initial U.S. Approval in the Highlights of Prescribing Information

Eric Brodsky, M.D.

Associate Director

Labeling Development Team, Office of New Drugs
Center for Drug Evaluation and Research (CDER), FDA



**U.S. FOOD & DRUG
ADMINISTRATION**

Disclaimer

The views and opinions expressed in the following PowerPoint slides are those of the individual presenter; should not be attributed to DIA, its directors, officers, employees, volunteers, members, chapters, councils, Communities or affiliates; and do not necessarily represent an official FDA position.

The labeling examples in this presentation are provided only to demonstrate current labeling development challenges and should not be considered FDA recommended templates.

For work prepared by US government employees representing their agencies, there is no copyright and these work products can be reproduced freely. Drug Information Association, Drug Information Association Inc., DIA and DIA logo are registered trademarks.



DIA
2019

GLOBAL ANNUAL MEETING
SAN DIEGO | JUNE 23-27



DIA
2019

GLOBAL ANNUAL MEETING
SAN DIEGO | JUNE 23-27

Prescribing Information (PI)

- Written for healthcare practitioners and must:¹
 - Contain a summary of essential scientific information needed for safe and effective use of **human prescription drug and biological products**
 - Be informative and accurate and neither promotional in tone nor false or misleading
 - Be updated when new information becomes available that causes labeling to become inaccurate, false, or misleading
- There are only two PI formats:
 - “Physician Labeling Rule” (PLR) labeling² (based on 2006 rule)
 - “Old” (non-PLR) format labeling³ (based on 1979 rule)

Product Titles Guidance* (January 2018)

Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products — Content and Format Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to <https://www.regulations.gov>. Submit written comments to the Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document, contact (CDER) Debra Beitzell at (301) 796-0900, or (CBER) the Office of Communication, Outreach, and Development at 800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

* When finalized this guidance will represent the Agency's current thinking.
Thanks to Debra Beitzell for her assistance with the product title and Initial U.S. Approval slides

Product Title in Highlights of Prescribing Information¹

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use PROPRIETARY NAME safely and effectively. See full prescribing information for PROPRIETARY NAME.

PROPRIETARY NAME (nonproprietary name) dosage form, route of administration, controlled substance symbol

Initial U.S. Approval: YYYY

WARNING: TITLE OF WARNING

See full prescribing information for complete boxed warning.

- Text (4)
- Text (5.x)

RECENT MAJOR CHANGES

Section Title, Subsection Title (x.x)

M/YYYY

Section Title, Subsection Title (x.x)

M/YYYY

INDICATIONS AND USAGE

PROPRIETARY NAME is a (insert FDA established pharmacologic class text phrase) indicated for ... (1)

Limitations of Use

Text (1)

DOSAGE AND ADMINISTRATION

- Text (2.x)
- Text (2.x)



DIA
2019

GLOBAL ANNUAL MEETING
SAN DIEGO | JUNE 23-27

DOSAGE FORMS AND STRENGTHS

Dosage form(s): strength(s) (3)

CONTRAINDICATIONS

- Text (4)
- Text (4)

WARNINGS AND PRECAUTIONS

- Text (5.x)
- Text (5.x)

ADVERSE REACTIONS

Most common adverse reactions (incidence > x%) are text (6.x)

To report SUSPECTED ADVERSE REACTIONS, contact name of manufacturer at toll-free phone # or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

DRUG INTERACTIONS

- Text (7.x)
- Text (7.x)

USE IN SPECIFIC POPULATIONS

- Text (8.x)
- Text (8.x)

See 17 for PATIENT COUNSELING INFORMATION and FDA-approved patient labeling OR and Medication Guide.

Revised: M/YYYY



885

APPENDIX A:

886

DOSAGE FORM TERMS FOR USE IN HUMAN DRUG PRODUCT LABELING

887

888 The following list of dosage forms has been created to assist the reader in selecting the proper
889 dosage form terminology for use in the nomenclature of human drug products.

890

891 The basic dosage form terms appear along the left margin. Examples of how the basic dosage
892 form terms are used when combined with other modifiers and/or routes of administration are
893 provided as indented text.

894

- 895 • A **bolded and underlined** term means both the FDA and the United States Pharmacopeia
896 (USP) recommend use of the term
- 897
- 898 • A **bolded** term means the FDA recommends use of the term
- 899
- 900 • An underlined term means USP recommends use of the term
- 901
- 902 • A term neither bolded nor underlined means the term is a nonpreferred term
- 903
- 904 • *Italicized* examples are the subject of discussion between the FDA and USP
- 905

906 Dosage form terms that appear only in bolded or underlined print are being discussed by the
907 FDA and USP and represent terminology that may be changed at a later date. If the term is
908 neither bolded nor underlined, then the term is a nonpreferred term and the reader is directed to
909 preferred terminology. In some cases, USP monographs using nonpreferred terms still exist.
910 However, these older, noncompliant terms found in monographs should not be cited as a
911 precedent for future use of the dosage form terms.

912

913 Indented beneath the basic dosage form term is a list of examples of how the dosage form term
914 has been used in the nomenclature of drug products. Although an attempt has been made to



932

Terminology

933

Aerosol

934

Aerosols are packaged under pressure. All aerosols are assumed to be metered except topical aerosols. Topical aerosols are assumed not to be metered unless labeling indicates they are metered.

935

inhalation aerosol — assumed to be for oral inhalation

936

lingual aerosol

937

nasal aerosol

938

topical aerosol

939

Bead — not preferred, see “Pellet”

940

Caplet — not preferred, see “Tablet”

941

Capsule

942

Capsules are assumed to be oral.

943

Note: In the past, the terminology “vaginal capsules” was used, but these drug products are now referred to as “vaginal inserts.”

944

capsules

945

delayed-release capsules

946

extended-release capsules

947

Collodion — not preferred, see “Solution”

Product Title Guidance: Route of Administration Appendix



DIA
2019

GLOBAL ANNUAL MEETING
SAN DIEGO | JUNE 23-27

1346
1347
1348
1349
1350
1351
1352
1353
1354

APPENDIX B: ROUTE OF ADMINISTRATION TERMS FOR USE IN THE PRODUCT TITLE

The following table lists the most commonly used route of administration terms for use in the product title. This list is derived from the FDA Data Standards Manual Route of Administration list with minor differences made to create a list that is appropriate for use in the product title. If an applicant determines that a route of administration term different from any of the examples is appropriate, the applicant is encouraged to initiate discussions with the FDA.

Name	Definition
Buccal	Administration directed toward the cheek, generally from within the mouth
Dental	Administration to a tooth or teeth
Endocervical	Administration within the canal of the cervix uteri
Endotracheal	Administration directly into the trachea
Enteral	Administration directly into the intestines
Epidural	Administration on or over the dura mater
Extracorporeal (For certain radiopharmaceuticals, it may be appropriate to use the phrase "for radiolabeling" instead of the route of administration "extracorporeal.")	Administration outside of the body
Hemodialysis	Administration through hemodialysate fluid
Infiltration	Administration that results in substances passing

Product Titles in Highlights of Prescribing Information Consistent with Requirements Under 21 CFR 201.57(a)(2) and Recommendations in Draft Guidance for Industry: *Product Title and Initial U.S. Approval in the Highlights of Prescribing Information for Human Prescription Drug and Biological Products - Content and Format*



DIA
2019

GLOBAL ANNUAL MEETING
SAN DIEGO | JUNE 23-27

OTHER INJECTION DOSAGE FORMS	INVEGA SUSTENNA (paliperidone palmitate) extended-release injectable suspension, for intramuscular use ABILITY MAINTENA (aripiprazole) for extended-release injectable suspension, for intramuscular use ARISTADA (aripiprazole lauroxil) extended-release injectable suspension, for intramuscular use CINVANTI (aprepitant) injectable emulsion, for intravenous use OMEGAVEN (fish oil triglycerides) injectable emulsion, for intravenous use CLINOLIPID (lipid injectable emulsion), for intravenous use VARITHENA (polidocanol injectable foam), for intravenous use SIGNIFOR LAR (pasireotide) for injectable suspension, for intramuscular use
TRANSDERMAL SYSTEMS	OXYTROL (oxybutynin transdermal system) IONSYS (fentanyl iontophoretic transdermal system), CII MINIVELLE (estradiol transdermal system) NEUPRO (rotigotine transdermal system) EMSAM (selegiline transdermal system)
DOSAGE FORMS FOR TOPICAL USE	ULESFIA (benzyl alcohol) lotion, for topical use CENTANY (mupirocin) ointment, for topical use XERESE (acyclovir and hydrocortisone) cream, for topical use ESKATA (hydrogen peroxide) topical solution ULESFIA (benzyl alcohol) lotion, for topical use PLIAGLIS (lidocaine and tetracaine) cream, for topical use BACTROBAN (mupirocin calcium) cream, for topical use RHOFADE (oxymetazoline hydrochloride) cream, for topical use XEPI (ozenoxacin) cream, for topical use MIRVASO (brimonidine) topical gel PANDEL (hydrocortisone probutate) cream, for topical use
DOSAGE FORMS FOR INHALATION USE	RELENZA (zanamivir inhalation powder), for oral inhalation use TRELEGY ELLIPTA (fluticasone furoate, umeclidinium, and vilanterol inhalation powder), for oral inhalation use ADASUVE (loxapine) inhalation powder, for oral inhalation use DULERA (mometasone furoate and formoterol fumarate dihydrate) inhalation aerosol, for oral inhalation use KITABIS PAK (tobramycin inhalation solution), for oral inhalation use

Initial U.S. Approval in Highlights of Prescribing Information¹



DIA
2019

GLOBAL ANNUAL MEETING
SAN DIEGO | JUNE 23-27

- The four-digit year in which FDA initially approved an NME, new biological product, or new combination of active ingredients¹
- The year of initial U.S. approval is displayed on line immediately beneath the product title¹ in bold type²
- How do I determine the initial U.S. approval for my product?
 - Perform search in Drugs@FDA by active moiety; identify earliest year of original approval action



DIA
2019

GLOBAL ANNUAL MEETING
SAN DIEGO | JUNE 23-27

Initial U.S. Approval Example #1

- APLENZIN (bupropion hydrobromide extended-release tablets)
 - 1985 was first year that FDA approved a bupropion product: WELLBUTRIN (bupropion hydrochloride tablets)
 - 2008 was year FDA approved APLENZIN
- Initial U.S. Approval for APLENZIN and WELLBUTRIN is 1985



DIA
2019

GLOBAL ANNUAL MEETING
SAN DIEGO | JUNE 23-27

Initial U.S. Approval Example #2

- TYBOST (cobicistat tablets)
 - 2014 was year FDA approved TYBOST
 - 2012 was first year that FDA approved a cobicistat product: STRIBILD (elvitegravir, cobicistat, emtricitabine, and tenofovir disoproxil fumarate tablets)
- Initial U.S. Approval for STRIBILD and TYBOST is 2012

Want to Learn More About Labeling?

2019 CDER Prescription Drug Labeling Conference¹

Topics:

Updates: Prescribing Information, carton/container labeling, and FDA-approved patient labeling



Logistics:

- December 4th and 5th, 2019
- “The HOTEL” at the University of Maryland in College Park, Maryland
- Check website for online or in person registration:
<https://www.fda.gov/drugs/development-approval-process-drugs/cder-small-business-industry-assistance-sbia>

¹ CDER Small Business & Industry Assistance (SBIA): Regulatory Education for Industry (REdI)
www.fda.gov

Thank You!

Eric Brodsky, M.D.

Associate Director

Labeling Development Team, Office of New Drugs

Center for Drug Evaluation and Research, FDA

- For general questions about the Prescribing Information: See the Labeling Development Team webpage: <https://www.fda.gov/about-fda/center-drug-evaluation-and-research/labeling-development-team>
- For specific questions about labeling under an NDA, BLA, or ANDA: Please contact the regulatory project manager assigned to the application



Join the conversation #DIA2019



**U.S. FOOD & DRUG
ADMINISTRATION**



DIA 2019
GLOBAL ANNUAL MEETING
SAN DIEGO | JUNE 23-27