W

Warfarin Sodium

Z

Zolmitriptan
Zolpidem

III. Drug Products for Which Revised Draft Product-Specific BE Recommendations Are Available

FDA is announcing revised draft BE product-specific recommendations for drug products containing the following active ingredients. These recommendations were previously posted on the FDA's Web site:

A

Amantadine HCl
Atorvastatin

B

Bupropion HBr

C

Calcipotriene
Calcium Acetate
Calcitriol
Capecitabine (multiple RLDs)
Cefditoren Pivoxil
Ciclopirox
Clotrimazole
Colesevelam HCl (multiple RLDs)

D

Darunavir Ethanolate
Desogestrel; Ethinyl Estradiol
Desvenlafaxine Succinate
Diclofenac Sodium
Diclofenac Sodium; Misoprostol
Disulfiram
Donepezil HCl (multiple RLDs)

E

Emtricitabine
Esomeprazole Magnesium
Estradiol
Ethinyl Estradiol; Ethynodiol Diacetate (multiple RLDs)
Ethinyl Estradiol; Norethindrone

F

Felbamate (multiple RLDs)
Fentanyl
Fentanyl Citrate
Fluorouracil (multiple RLDs)

G

Glyburide Metformin
Granisetron HCl

L

Labetalol HCl
Lamotrigine (multiple RLDs)
Lapatinib Ditosylate
Levofloxacin
Levonorgestrel (multiple RLDs)
Linezolid

M

Memantine HCl
Mercaptopurine (multiple RLDs)
Metformin HCl (multiple RLDs)
Minoxidil
Morphine

N

Nebivolol
Niacin
Nilutamide
Nitroglycerin

O

Omeprazole
Orlistat (multiple RLDs)
Oxymorphone HCl

P

Prednisolone
Progesterone

R

Rivastigmine
Rivastigmine Tartrate
Ropinirole

S

Scopolamine
Sevelamer Carbonate (multiple RLDs)
Sevelamer HCl (multiple RLDs)
Sirolimus

T

Telmisartan
Tiagabine HCl
Topiramate
Tranexamic Acid
Triamcinolone Acetonide (multiple RLDs)

V

Varenicline Tartrate
Venlafaxine HCl

For a complete history of previously published **Federal Register** notices, please go to *http://www.regulations.gov* and enter docket number FDA–2007–D–0369.

These draft and revised draft guidances are being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidances represent the Agency's current thinking on product-specific design of BE studies to support ANDAs. They do not create or confer any rights for or on any person and do not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

IV. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments on any of the specific BE recommendations posted on FDA's Web site. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. The guidance, notices, and received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

V. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

Dated: January 19, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–1433 Filed 1–24–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–1999–D–4079 (Formerly Docket No. 1999D–0254)]

Guidance for Industry on Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance document entitled ''Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling.'' The guidance is intended to clarify for applicants the requirements for product name placement, size, prominence, and frequency in promotional labeling and advertising for prescription human and animal drugs and biological products. This guidance finalizes the draft guidance published in January 1999.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of the guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002; or Office of Communication, Outreach and Development (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT:

Regarding Human Prescription Drugs

Ernest S. Voyard, Jr., Center for Drug Evaluation and Research, Food and Drug Administration, 10903 Hampshire Ave., Bldg. 51, Rm. 3276, Silver Spring, MD 20993, (301) 796–1200.

Regarding Prescription Human Biological Products

Stephen Ripley, Center for Biologics Evaluation and Research (HFM–17), Food and Drug Administration, 1401 Rockville Pike, Suite 200N, Rockville, MD 20852–1448, (301) 827–6210.

Regarding Animal Prescription Drugs

Julie Garnier, Center for Veterinary Medicine, Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, (240) 276–9300.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance document entitled ''Product Name Placement, Size, and Prominence in Advertising and Promotional Labeling.'' This guidance discusses the requirements for product name placement, size, prominence, and frequency in promotional labeling and advertising for prescription human and animal drugs and biological products. The disclosure of the product name in promotional labeling and advertising for all prescription human and animal drug and biological products is important for the proper identification of such products to ensure their safe and effective use.

The placement, size, prominence, and frequency of the proprietary and established names for human and animal prescription drug products are specified in labeling and advertising regulations (21 CFR 201.10(g) and (h); 202.1(b), (c), and (d)). These regulations are also applicable to biological product labeling and advertising materials.

The recommendations in this guidance pertain to product names in traditional print media promotion (e.g., journal ads, detail aids, brochures), audiovisual promotional labeling (e.g., videos shown in a health care provider's office), broadcast media promotion (e.g., television advertisements, radio advertisements), and electronic and computer-based promotional labeling and advertisements, such as Internet promotion, social media, emails, CD–ROMs, and DVDs.

In the **Federal Register** of March 12, 1999 (64 FR 12341), FDA announced the availability of the draft guidance of the same title, dated January 1999. FDA received six comments on the draft guidance, five were from the pharmaceutical industry and one was from a consumer. The majority of the comments related to requests to provide additional clarifications and examples related to the individual recommendations in the draft guidance. These comments were considered carefully during the finalization of the guidance document. The guidance has been revised in the following ways: (1) It clarifies certain concepts previously discussed in the draft guidance and adds definitions for certain terms; (2) it provides examples to illustrate the appropriate juxtaposition and prominence of proprietary and established names for products with one active ingredient and examples to illustrate the juxtaposition of products with two or more active ingredients; (3) it reorganizes and renames the draft guidance's sections pertaining to the frequency of the disclosure of proprietary and established names in various media into one section with three subsections—traditional print promotional labeling and advertisements, audiovisual promotional labeling and broadcast advertisements, and electronic and computer-based promotional labeling and advertisements; and (4) it discusses the use of proprietary and established names in columns in traditional print promotional labeling and advertisements.

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents FDA's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) either electronic or written comments regarding this document. It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/Drugs/GuidanceCompliance RegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceCompliance RegulatoryInformation/default.htm*, or *http://www.regulations.gov*.

Dated: January 19, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–1431 Filed 1–24–12; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2012–N–0001]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). At least one portion of the meeting will be closed to the public.

Name of Committee: Vaccines and Related Biological Products Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on February 28, 2012, from approximately 8 a.m. to 4 p.m. and February 29, 2012, from approximately 8 a.m. to 1 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You'', click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

For those unable to attend in person, the meeting will also be webcast. The link for the webcast is available at: *https://collaboration.fda.gov/cberac.*

Contact Person: Donald W. Jehn or Denise Royster, Center for Biologics Evaluation and Research (HFM–71), Food and Drug Administration, 1401 Rockville Pike Rockville, MD 20852, (301) 827–0314, or FDA Advisory Committee Information Line, 1-(800) 741–8138 (301) 443–0572 in the Washington, DC area), and follow the