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 This guidance finalizes the draft guidance published in January 1999.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:

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Regarding prescription human biological products:

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Regarding animal prescription drugs:

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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/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/default.htm, or http://www.regulations.gov.

Dated: January 19, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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