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


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In the Federal Register of March 12, 1999 (64 FR 12341), FDA announced the availability of the draft guidance of the same title. As of January 1999, FDA received six comments on the draft guidance, five were from the pharmaceutical industry and one was from a consumer.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related to requests to provide additional clarifications and examples related to the individual recommendations in the draft guidance.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 not otherwise established by 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


Leslie Kux, Acting Assistant Commissioner for Policy.

[FR Doc. 2012–1431 Filed 1–24–12; 8:45 am]
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
[Docket No. FDA–2011–N–0754]

Pediatric Medical Devices; Public Workshop; Reopening of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; reopening of comment period.

SUMMARY: The Food and Drug Administration (FDA) is reopening until March 5, 2012, the comment period for the notice entitled “Pediatric Medical Devices; Public Workshop; Request for Comments” that appeared in the Federal Register of Tuesday, November 1, 2011 (76 FR 67463). In the notice, FDA announced a public workshop to consider factors affecting the use of scientific research data to support pediatric medical device efficacy claims. This is part of an on-going effort to address the ways scientific research data can be used to support pediatric effectiveness claims for medical devices and pediatric device approvals or clearance; the scientific and regulatory limitations and issues of using existing scientific research data to support pediatric effectiveness claims and pediatric indication approvals for medical devices; and methods to overcome the pitfalls and data gaps, including statistical approaches and modeling. The agency is taking this action to allow interested persons additional time to submit comments on the use of scientific research data, including published scientific literature, to support and establish pediatric indications for medical devices.

DATES: Submit either electronic or written comments by March 5, 2012.

ADDRESSES: Submit electronic comments 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: Carol Krueger, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5437, Silver Spring, MD 20993–0002, (301) 796–3241, Carol.krueger@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In 2007, Congress passed the Pediatric Medical Device Safety and Improvement