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In the **Federal Register** of March 12, 1999 (64 FR 12341), FDA announced the availability of the draft guidance of the same title, dated January 1999. FDA received six comments on the draft guidance, five were from the pharmaceutical industry and one was from a consumer.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related to requests to provide additional clarifications and examples related to the individual recommendations in the draft guidance.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

prompts to the desired center or product area. Please call the Information Line for up-to-date information on this meeting. A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On February 28, 2012, the committee will meet in open session to hear an overview of the research program in the Laboratory of Mycobacterial Diseases and Cellular Immunology, Division of Bacterial, Parasitic and Allergenic Products, Office of Vaccines Research and Review, Center for Biologics Evaluation and Research, FDA. The committee will then discuss and make recommendations on the selection of strains to be included in the influenza virus vaccine for the 2012 to 2013 influenza season. On February 29, 2012, the committee will discuss licensure pathways for pandemic influenza vaccines.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at *http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm*. Scroll down to the appropriate advisory committee link.

Procedure: On February 28, 2012, between approximately 8 a.m. and 9:45 a.m. and between approximately 10:15 p.m. and 4 p.m., the meeting is open to the public. On February 29, 2012, the entire meeting is open to the public. Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before February 21, 2012. Oral presentations from the public will be scheduled between approximately 2:40 p.m. and 3:10 p.m. on February 28, 2012, and between approximately 10:45 a.m. and 11:15 a.m. on February 29, 2012. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 13, 2012. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 14, 2012.

Closed Committee Deliberations: On February 28, 2012, between approximately 9:45 a.m. and 10:15 a.m., the meeting will be closed to permit discussion where disclosure would constitute a clearly unwarranted invasion of personal privacy (5 U.S.C. 552b(c)(6)). The committee will discuss the report of the intramural research programs and make recommendations regarding personnel staffing decisions.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Donald W. Jehn or Denise Royster at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 17, 2012.

Leslie Kux,

Acting Assistant Commissioner for Policy.

[FR Doc. 2012–1456 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–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