Act (the FD&C Act) regarding ingredients and labeling.

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 Office of Nutrition, Labeling, and Dietary Supplements, Center for Food Safety and Applied Nutrition (HFS–800), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, or to the Office of Food Additive Safety, Center for Food Safety and Applied Nutrition (HFS–200), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740. Send two self-addressed adhesive labels to assist those offices in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance.

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: Corey J. Hilmas, Center for Food Safety and Applied Nutrition (HFS–810), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–2375.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance entitled ''Guidance for Industry: Distinguishing Liquid Dietary Supplements From Beverages.'' This guidance is being issued consistent with our good guidance practices regulation (21 CFR 10.115). The guidance represents our 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 alternate approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

In the **Federal Register** of December 4, 2009 (74 FR 63759), we made available a draft guidance entitled ''Draft Guidance for Industry: Factors That Distinguish Liquid Dietary Supplements From Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods'' and gave interested parties an opportunity to submit comments by February 2, 2010, for us to consider before beginning work on the final version of the guidance. The guidance is intended to help dietary supplement and beverage manufacturers and distributors determine whether a product in liquid form is properly classified as a dietary supplement or as a beverage.

We have observed an increase in the marketing of liquid products with a wide array of ingredients and intended uses. Some of these products are marketed as dietary supplements, and others as conventional foods. In some instances, products may be misbranded because their labeling or other representations made about them are inconsistent with the product category under which they are being marketed. In addition, products may be excluded from the dietary supplement category because of representations that they are for use as conventional foods. The guidance is intended to describe the factors that dietary supplement and beverage manufacturers and distributors should consider when deciding whether to market a liquid product as a dietary supplement or a conventional food. Further, this guidance reminds manufacturers and distributors of dietary supplements and beverages about the requirements of the FD&C Act regarding ingredients and labeling.

We received several comments on the draft guidance and have modified the final guidance where appropriate. In addition, we made editorial changes to improve clarity. The guidance announced in this notice finalizes the draft guidance dated December 2009.

II. Comments

Interested persons may submit either electronic comments regarding the guidance to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). 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, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the guidance at either *http://www.fda.gov/FoodGuidances* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: January 8, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–00498 Filed 1–13–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–N–0001]

Pediatric 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). The meeting will be open to the public.

Name of Committee: Pediatric 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 March 3, 2014, from 8 a.m. to 4:30 p.m.

Location: Bethesda Marriott, 5151 Pooks Hill Road, Bethesda, MD 20814, 301–897–9400, or visit the hotel's Web site at *http://www.marriott.com/hotels/travel/wasbt-bethesda-marriott/.*

Contact Person: Walter Ellenberg, Office of the Commissioner, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5154, Silver Spring, MD 20993–0002, 301–796–0885, email *walter.ellenberg@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On March 3, 2014, the Pediatric Advisory Committee (PAC) will meet to discuss pediatric focused safety reviews, as mandated by the Best Pharmaceuticals for Children Act (Pub. L. 107–109) and the Pediatric Research Equity Act (Pub. L. 108–155). The PAC will meet to discuss ACTIVA Dystonia Therapy, ADVATE [Antihemophilic Factor (Recombinant)], FAMVIR (famciclovir), INTELENCE (etravirine), KEPPRA (levetiracetam), MAXALT and MAXALT MLT (rizatriptan), NATAZIA

(estradiol valerate and estradiol valerate/dienogest), PERTZYE (pancrelipase), PREZISTA (darunavir), REYATAZ (atazanavir), SKLICE (ivermectin), TISSEEL (Fibrin Sealant), TORISEL (temsirolimus), ULTRESA (pancrelipase), Vertical Expandable Prosthetic Titanium Rib (VEPTR), VIREAD (tenofovir disoproxil fumarate).

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: 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 24, 2014. Oral presentations from the public will be scheduled on March 3, 2014, between approximately 11:30 a.m. and 12:30 p.m. 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 14, 2014. 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 18, 2014.

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 Walter Ellenberg 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 8, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–00475 Filed 1–13–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2004–N–0451]

Food and Drug Administration Modernization Act of 1997: Modifications to the List of Recognized Standards, Recognition List Number: 033

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing a publication containing modifications the Agency is making to the list of standards FDA recognizes for use in premarket reviews (''FDA Recognized Consensus Standards''). This publication, entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 033'' (''Recognition List Number: 033''), will assist manufacturers who elect to declare conformity with consensus standards to meet certain requirements for medical devices.

DATES: Submit either electronic or written comments concerning this document at any time. See section VII of this document for the effective date of the recognition of standards announced in this document.

ADDRESSES: Submit written requests for single copies of the document entitled ''Modifications to the List of Recognized Standards, Recognition List Number: 033'' to the Division of Small Manufacturers, International, and Consumer Assistance, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4613, Silver Spring, MD 20993–0002. Send two self-addressed adhesive labels to assist that office in processing your requests, or fax your request to 301–847–8149.

Submit electronic comments concerning this document, or recommendations for additional standards for recognition, by email to *standards@cdrh.fda.gov*. Submit written comments to the contact person (see **FOR FURTHER INFORMATION CONTACT**). This document may also be accessed on FDA's Internet site at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm*. See section VI of this document for electronic access to the searchable database for the current list of FDA recognized consensus standards, including Recognition List Number: 033 modifications and other standards related information.

FOR FURTHER INFORMATION CONTACT: Scott A. Colburn, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 3632, Silver Spring, MD 20993–0002, 301–796–6287.

SUPPLEMENTARY INFORMATION:

I. Background

Section 204 of the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105–115) amended section 514 of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360d). Amended section 514 allows FDA to recognize consensus standards developed by international and national organizations for use in satisfying portions of device premarket review submissions or other requirements.

In a notice published in the **Federal Register** of February 25, 1998 (63 FR 9561), FDA announced the availability of a guidance entitled ''Recognition and Use of Consensus Standards.'' The notice described how FDA would implement its standard recognition program and provided the initial list of recognized standards.

Modifications to the initial list of recognized standards, as published in the **Federal Register**, can be accessed at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Standards/ucm123792.htm*.

These notices describe the addition, withdrawal, and revision of certain standards recognized by FDA. The Agency maintains hypertext markup language (HTML) and portable document format (PDF) versions of the list of FDA Recognized Consensus Standards. Both versions are publicly accessible at the Agency's Internet site. See section VI of this document for electronic access information. Interested persons should review the