conventional foods, including beverages. This guidance also is intended to remind dietary supplement manufacturers and distributors that the same requirements apply to certain substances that are added to dietary supplements; namely, those that are not dietary ingredients as defined in the FD&C Act.

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 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 that office 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: Negash Belay, Center for Food Safety and Applied Nutrition (HFS–255), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740, 240–402–1200.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of a guidance entitled ''Guidance for Industry: Considerations Regarding Substances Added to Foods, Including Beverages and Dietary Supplements.'' 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In the **Federal Register** of December 4, 2009 (74 FR 63759), we made available a draft guidance entitled ''Draft Guidance for Industry: Factors That Distinguish Liquid Dietary Supplements From Beverages, Considerations Regarding Novel Ingredients, and Labeling for Beverages and Other Conventional Foods'' (draft guidance) and gave interested parties an opportunity to submit comments by February 2, 2010, for us to consider before beginning work on the final version of the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. Elsewhere in this issue of the **Federal Register**, we announce the availability of the final guidance, now entitled ''Guidance for Industry: Distinguishing Liquid Dietary Supplements From Beverages.''

The draft guidance included a section entitled ''Ingredients in Beverages and Other Conventional Foods are Subject to the Federal Food, Drug, and Cosmetic Act's Requirements for Substances Added to Food'' (ingredients section). The ingredients section of the draft guidance described the general requirements of the FD&C Act regarding substances added to beverages and other conventional foods. We received several comments on the draft guidance and have modified the final guidance entitled ''Guidance for Industry: Distinguishing Liquid Dietary Supplements From Beverages'' where appropriate. The modifications to the final guidance entitled ''Guidance for Industry: Distinguishing Liquid Dietary Supplements From Beverages'' include a modified version of the ingredients section, which refers to the separate guidance that is the subject of this document.

The guidance that is the subject of this document derives from the ingredients section of the draft guidance. It is intended to remind manufacturers and distributors of conventional foods about the requirements of the FD&C Act regarding substances added to conventional foods, including beverages. This guidance also is intended to remind dietary supplement manufacturers and distributors that the same requirements apply to certain substances that are added to dietary supplements; namely, those that are not dietary ingredients as defined in section 201(ff)(1) of the FD&C Act (21 U.S.C. 321(ff)(1)). We are issuing this separate guidance, in addition to referring to it within the guidance entitled ''Guidance for Industry: Distinguishing Liquid Dietary Supplements From Beverages,'' to make it more prominent and improve its accessibility to manufacturers and distributors who look for guidance on the requirements of the FD&C Act regarding substances added to conventional foods, including beverages. Although we met the procedural requirements for issuing Level 1 final guidance by making the draft guidance available for comment, we are issuing this final guidance as Level 2 guidance under 21 CFR 10.115(g)(4) because it merely summarizes long-established requirements in the FD&C Act and regulations without setting forth any new interpretations of those requirements (see 21 CFR 10.115(c)(1) to (c)(2)).

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. 2014–00500 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–2009–D–0542]

Guidance for Industry: Distinguishing Liquid Dietary Supplements From Beverages; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a guidance for industry entitled ''Distinguishing Liquid Dietary Supplements From Beverages.'' This 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. This guidance describes the factors that distinguish liquid products that are dietary supplements from those that are conventional foods. Further, this guidance reminds manufacturers and distributors of dietary supplements and beverages about the requirements of the Federal Food, Drug, and Cosmetic

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