FDA staff, entitled ''Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers.'' We are issuing the guidance to help the public, FDA advisory committee members, and FDA staff to understand and implement FDA procedures regarding public availability of information regarding certain financial interests and waivers granted by FDA to permit individuals to participate in an advisory committee meeting. This guidance replaces the guidance of the same title dated March 2012.

DATES: Submit either electronic or written comments on Agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to Advisory Committee Oversight and Management Staff, Office of Special Medical Programs, Office of Medical Products and Tobacco, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993. 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: Michael Ortwerth, Office of Special Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993, 301–796–8220, email: *Michael.Ortwerth@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for the public, FDA advisory committee members, and FDA staff, entitled ''Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff: Public Availability of Advisory Committee Members' Financial Interest Information and Waivers.''

FDA's advisory committees provide independent expert advice and recommendations to the Agency on scientific, technical, and policy matters related to FDA-regulated products. In March 2012, FDA published a guidance for the public, FDA advisory committee members, and FDA staff concerning the implementation of Agency-wide procedures regarding disclosure of financial interest information that apply to all special Government employees and regular Government employees invited to participate in FDA advisory committee meetings subject to the Federal Advisory Committee Act.

Effective October 1, 2012, the Food and Drug Administration Safety and Innovation Act amended the statutory provision related to this guidance. The amendments were relatively minor. FDA is revising the March 2012 guidance to reflect these amendments and to make other non-substantive editorial changes.

This level 2 guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the Agency's thinking on the public availability of waivers relating to the disclosure of conflicts of interest for advisory committee members participating in FDA advisory committee meetings. 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 either electronic comments regarding this document 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 document at either *http://www.fda.gov/RegulatoryInformation/Guidances/ucm122045.htm* or *http://www.regulations.gov.*

Dated: March 25, 2014.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–06997 Filed 3–28–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

The Food and Drug Administration and Global Engagement: Progress on the Pathway to Global Product Safety

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public workshop.

SUMMARY: The Food and Drug Administration (FDA) Denver District Office, in cosponsorship with the Association of Food and Drug Officials (AFDO), will be hosting the 118th AFDO Annual Educational Conference. During the conference, a 2-day public workshop will be held entitled ''FDA and Global Engagement: Progress on the Pathway to Global Product Safety,'' This 2-day public workshop is intended to provide information about FDA drug and device regulation to the regulated industry.

DATES: *Dates and Times:* The conference will be held from June 21 through June 25. The public workshop, ''FDA and Global Engagement: Progress on the Pathway to Global Product Safety,'' will be held on June 23 and 24, 2014, from 10:30 a.m. to 5 p.m.

Location: The public workshop will be held at the Grand Hyatt Denver, 1750 Welton St., Denver, CO 80202, 1–303–295–1234 or toll free 800–233–1234; *http://granddenver.hyatt.com.* Attendees are responsible for their own accommodations. To make reservations at the Grand Hyatt Denver at the reduced conference rate, please go to *https://resweb.passkey.com/go/afdo2014* or call 1–303–295–1234 and mention ''AFDO Conference'' before May 21, 2014.

AFDO Contact Information: Randy Young, Association of Food and Drug Officials, 2550 Kingston Rd., Suite 311, York, PA 17402, 1–717–757–2888, FAX: 717–650–3650, *ryoung@afdo.org.*

Registration: You are encouraged to register by May 23, 2014. The AFDO registration fees cover the cost of facilities, materials, and breaks. Seats are limited; therefore, please submit your registration as soon as possible. Public workshop space will be filled in order of receipt of registration. Those accepted into the public workshop will receive confirmation. Registration will close after the public workshop is filled. Registration at the site is not guaranteed but may be possible on a space-available basis on the day of the public workshop beginning at 7:30 a.m. The cost of registration follows:

COST OF REGISTRATION *	
ADFO Member	$475.00
Non-ADFO Member	575.00

*A $100 registration fee will be added if payment is postmarked after June 1, 2014.

If you need special accommodations due to a disability, please contact Randy Young (see AFDO Contact information) at least 21 days in advance of the workshop.

Registration instructions: To register, please complete and submit an AFDO Conference Registration Form, along with a check or money order payable to ''AFDO.'' Please mail your completed registration form and payment to: AFDO, 2550 Kingston Rd., Suite 311, York, PA 17402. To register online, please visit *http://www.afdo.org/conference.* (FDA has verified the Web site address, but is not responsible for subsequent changes to the Web site after this document publishes in the **Federal Register**.)

The registrar will also accept payment through Visa and MasterCard credit cards. For more information on the public workshop, or for questions about registration, please contact AFDO at 1–717–757–2888, FAX: 717–650–3650, or email: *afdo@afdo.org.*

SUPPLEMENTARY INFORMATION: The public workshop helps fulfill the Department of Health and Human Services' and FDA's important mission to protect the public health. The workshop will provide FDA-regulated drug and device entities with information on a number of topics concerning FDA requirements related to the production and marketing of drugs and/or devices. Topics for discussion include, but are not limited to the following:

- Medical Device Single Audit Program;
- Contract Manufacturing Arrangements for Drugs: Quality Agreements;
- Compliance Question and Answer Panel;
- Draft Guidance: Distinguishing Medical Device Recalls from Product Enhancements and Associated Reporting Requirements;
- Compounding Pharmacies;
- Overview of Global Device/Drug Requirements vs. U.S. System;
- Case for Quality Initiative Update;
- Unique Device Identifier Implementation Update;
- Metric, Data, and Analysis; Biometrics;
- Pharmaceutical Inspection Cooperation Scheme; and
- Biosimilar Regulations.

FDA has made education of the food, feed, drug, and device manufacturing community a high priority to help ensure the quality of FDA-regulated products. The public workshop helps to achieve objectives set forth in section 406 of the Food and Drug Administration Modernization Act of 1997 (21 U.S.C. 393) which includes working closely with stakeholders and maximizing the availability and clarity of information to stakeholders and the public. The workshop also is consistent with the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), as outreach activities by government agencies to small businesses.

Dated: March 25, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–07059 Filed 3–28–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–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 April 21, 2014, from 8 a.m. to 5 p.m. This is a reschedule of a postponed meeting announced in the **Federal Register** of January 14, 2014 (79 FR 2452), originally scheduled for March 3, 2014.

Location: Bethesda Marriott, 5151 Pooks Hill Rd., 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, 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 April 21, 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), PERZISTA (darunavir), REYATAZ (atazanavir), SKLICE (ivermectin), TISSEEL (fibrin sealant), TORISEL (temsirolimus), ULTRESA (pancrelipase), Vertical Expandable Prosthetic Titanium Rib (VEPTR), and 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 April 14, 2014. Oral presentations from the public will be scheduled on April 21, 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