4160-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2002-D-0094]

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; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (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." 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 03/28/2014 at 8:45 am; Publication Date: 03/31/2014]