4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-D-1399]

Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in Food and Drug Administration Advisory Committees; Draft Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees; Guidance for the Public, FDA Advisory Committee Members, and FDA Staff." This draft guidance addresses FDA's process, under Government-wide Federal regulations, for evaluating whether an advisory committee member has an appearance issue that raises concerns about the member's participation in an advisory committee meeting and describes FDA's process for determining whether to authorize a member with an appearance issue to participate in the advisory committee meeting. This draft guidance is not final nor is it in effect at this time.

FDA is also requesting comment on whether FDA should request that each advisory committee member who has an appearance issue and who has received an authorization from FDA to participate in an advisory committee meeting voluntarily publicly disclose the authorization.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comments on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: http://www.regulations.gov. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to http://www.regulations.gov will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on http://www.regulations.gov.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-D-1399 for "Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in Food and Drug Administration Advisory Committees; Draft Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff; Availability." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at http://www.regulations.gov or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on http://www.regulations.gov. Submit both copies to the Division of

Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: http://www.fda.gov/regulatoryinformation/dockets/default.htm.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to http://www.regulations.gov and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

Submit written requests for a single hard copy of the draft guidance entitled "Procedures for Evaluating Appearance Issues and Granting Authorizations for Participation in FDA Advisory Committees; Guidance for the Public, FDA Advisory Committee Members, and FDA Staff" to the Advisory Committee Oversight and Management Staff, Office of Special Medical Programs, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Michael Ortwerth, Advisory Committee Oversight and Management Staff, Office of Special Medical Programs, Food and Drug

Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993-0002, 301-796-8220.

SUPPLEMENTARY INFORMATION:

I. Background

Advisory committees provide independent, expert advice to FDA on a range of issues affecting the public health. To protect the credibility and integrity of advisory committee advice, FDA screens advisory committee members carefully for two categories of potentially disqualifying interests or relationships: (1) Current financial interests that may create a recusal obligation under Federal conflict of interest laws (18 U.S.C. 208) and (2) other interests and relationships that do not create a recusal obligation under financial conflict of interest laws but may create the appearance that the member lacks impartiality (5 CFR 2635.502). This draft guidance addresses FDA's process for evaluating whether an advisory committee member has potentially disqualifying interests or relationships that fall into the second category of interests, which are known as appearance issues, under 5 CFR 2635.502. It also describes FDA's process for determining whether to authorize a member with an appearance issue to participate in an advisory committee meeting under 5 CFR 2635.502.

In addition, FDA is seeking comment regarding public disclosure of such authorizations. Under Federal laws protecting the confidentiality of information, FDA may not itself disclose confidential information provided by advisory committee members related to appearance issues. FDA is soliciting comment on whether the agency should ask members with appearance issues who are authorized to participate in an advisory committee meeting to voluntarily publicly disclose authorization. The Agency will consider these comments in developing the final guidance document.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the processes for evaluating appearance issues and granting an authorization. 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 statute and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet at either http://www.fda.gov/RegulatoryInformation/Guidances/ucm122044.htm or http://www.regulations.gov.

Dated: June 23, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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