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Appearance Issues and Granting Authorizations for Participation in Food and Drug Administration Advisory Committees; Draft Guidance for the Public, Food and Drug Administration Advisory Committee Members, and Food and Drug Administration Staff; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA) is extending the comment period for the notice that appeared in the Federal Register of June 29, 2016. In the notice, FDA requested comments on "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" and on whether FDA should request that each advisory committee member, who receives an authorization from FDA on an appearance issue so that they may participate in an advisory committee meeting, voluntarily publicly disclose the authorization. The Agency is taking this action due to errors displayed on the FDA Web site pertaining to this guidance.

DATES: FDA is extending the comment period for the notice that published on June 29, 2016 (81 FR 42363) by an additional 60 days. 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before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by November 26, 2016.

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 FDA Advisory Committees; Guidance for the Public, FDA Advisory Committee Members, and FDA Staff." 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. See the SUPPLEMENTARY INFORMATION section for electronic access to the draft guidance document.

FOR FURTHER INFORMATION CONTACT: Janine M. Morris, Office of Special Medical Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5114, Silver Spring, MD 20993-0002, 301-796-5706.

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of June 29, 2016, FDA published a notice with a 90-day comment period to request comments on the draft guidance and public disclosure of authorizations described in this guidance.

The Agency has decided to allow for a 60-day extension of the comment period for the notice. The FDA Web site that displayed the posting of this guidance indicated, in error, that the guidance was not open for comment. The Agency was concerned that individuals visiting the FDA Web site and interested in providing comments may not have known that the document was available for comment under the docket found at http://www.regulations.gov.

FDA is therefore extending the comment period for the notice for an additional 60 days, until November 26, 2016. The Agency believes that a 60-day extension allows adequate time for interested persons to submit comments without compromising timely publication of the final guidance.

II. 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/ucm122045.htm or http://www.regulations.gov.

Dated: September 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

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