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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-D-0417]

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Draft Guidance for the Public and the Food and Drug Administration Staff on Convening Advisory Committee Meetings; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document entitled "Guidance for the Public and FDA Staff on Convening Advisory Committee Meetings." This draft guidance is intended to provide guidance on when FDA should consider referring a matter to an advisory committee. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of four guidances intended to improve FDA's advisory committee procedures.

DATES: Although you can comment on any guidance at any time (see § 10.115(g)(5) (21 CFR 10.115(g)(5))), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comments on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*.

ADDRESSES: Submit written requests for single copies of the guidance to the Office of Policy (HF-11), Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests.

Submit phone requests to 800-835-4709 or 301-827-1800. Submit written

FDA-2008-D-0417

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comments on the guidance to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to <http://www.regulations.gov>. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Jill Hartzler Warner, Office of Policy and Planning (HF-11), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-3370.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance entitled “Guidance for the Public and FDA Staff on Convening Advisory Committee Meetings,” dated July 2008. Advisory committees provide FDA with independent, expert advice on a range of complex scientific and technical issues related to the products it regulates. These issues typically focus on a specific food or medical product, a class of foods or medical products, the development and implementation of a specific regulatory program, or the development and implementation of a regulatory policy. Advisory committee meetings also facilitate public discussion of important topics and provide a means for the public to provide comments to the agency.

To enhance the transparency of FDA’s advisory committee program, the agency is publishing this draft guidance to provide its current thinking on when to bring a matter to an advisory committee. In some instances, FDA refers a matter to an advisory committee because it is required to do so by law. In others, FDA convenes an advisory committee meeting at its own discretion. Regardless, FDA recognizes that advisory committee meetings demand

significant resource commitments by advisory committee members, sponsors, and other public participants, as well as for FDA itself, and should be used for important matters. The draft guidance is intended to clarify how the agency identifies which matters should be referred.

In developing this draft guidance, FDA has been mindful of the legal requirements of the Federal Advisory Committee Act (FACA), other relevant statutes, regulations, guidance, and policies, and the goals of FDA's of advisory committee program.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (§ 10.115). The draft guidance represents the agency's current thinking on when FDA convenes an advisory committee meeting. 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 to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified 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.

Please note that on January 15, 2008, the FDA Division of Dockets Management Web site transitioned to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system.

Electronic comments or submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

III. Electronic Access

Persons with access to the Internet may obtain the document at either <http://www.fda.gov/ohrms/dockets/default.htm> or <http://www.regulations.gov>.

Dated: 8/1/08
August 1, 2008.



Randall W. Lutter,
Deputy Commissioner for Policy.

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