

information to support applications for parametric release of human and veterinary drug products terminally sterilized by moist heat processes. 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. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information requested in the draft guidance is covered under FDA regulations at 21 CFR 314.50, 314.70, and 314.81(b)(2) for human drugs, 21 CFR 514.1, 514.8, 514.8(b)(4) and (c) for animal drugs, and 21 CFR 601.2 and 601.12 for biologics. The collection of information is approved under the following OMB control numbers: 0910–0001 for human drugs, 0910–0600 for animal drugs, and 0910–0338 for biologics.

III. 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 and submissions will be accepted by FDA only through FDMS at <http://www.regulations.gov>.

IV. Electronic Access

Persons with access to the Internet may obtain the document at <http://www.fda.gov/cder/guidance/index.htm>, <http://www.fda.gov/cber/guidelines.htm>, or <http://www.regulations.gov>.

Dated: July 29, 2008.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E8–17855 Filed 8–4–08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2008–D–0417]

Draft Guidance for the Public and the Food and Drug Administration Staff on Convening Advisory Committee Meetings; Availability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 October 6, 2008.

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 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: August 1, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8-18002 Filed 8-4-08; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2007-D-0196] (formerly Docket No. 2007D-0449)

Guidance for Food and Drug Administration Advisory Committee Members and Food and Drug Administration Staff: Voting Procedures for 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 guidance document for FDA advisory committee members and FDA staff entitled "Voting Procedures for Advisory Committee Meetings." This document is intended to provide guidance on advisory committee voting procedures that should be used when votes are taken during advisory committee meetings. It does not define when votes should be taken. Elsewhere in this issue of the **Federal Register**, FDA is announcing the availability of three additional guidances and one draft guidance, intended to improve FDA's advisory committee procedures.

DATES: The guidance is effective August 5, 2008. Submit written or electronic comments on agency guidances at any time.

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 telephone requests to 800-835-4709 or 301-827-1800. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit written 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>.

FOR FURTHER INFORMATION CONTACT: Jill Hartzler Warner, Office of Policy, Planning, and Preparedness (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 guidance for FDA advisory committee members and FDA staff entitled "Voting Procedures for Advisory Committee Meetings," dated August 2008. FDA's advisory committees provide independent and expert advice on scientific, technical, and policy matters related to the development and evaluation of products regulated by FDA. Advisory committees are a valuable resource to FDA, and they make an important contribution to the agency's decisionmaking processes. Although advisory committees provide recommendations to FDA, the agency makes the final decisions.

Advisory committees typically communicate advice or recommendations to the agency in two ways. First, FDA learns from the discussion and exchange that occurs among advisory committee members, and from individual recommendations and suggestions made during the discussion of any advisory committee meeting. Second, advisory committees often vote on a question or series of questions posed to the committee during a committee meeting.

Votes can be an effective means of communicating with FDA because they provide feedback on discrete questions. These questions are generally scientific in nature and can involve a range of

subjects, including evaluation of postmarket safety data or premarket assessment of a product's risk/benefit profile. Because all members vote on the same question, the results help FDA gauge a committee's collective view on complex, multi-faceted issues. This view helps inform the agency's own deliberations on scientific and regulatory matters.

This guidance recommends adopting uniform voting procedures to help maximize the integrity and meaning of voting results. In developing these recommendations, FDA was mindful of the legal requirements of the Federal Advisory Committee Act, other relevant statutes (e.g., the Federal Food, Drug, and Cosmetic Act), regulations (e.g., 21 CFR part 14), guidance, policies, and the goals of FDA's of advisory committee program.

FDA issued a draft of this guidance on November 19, 2007 (72 FR 65046), and gave interested persons an opportunity to comment on the agency's proposal. FDA carefully evaluated the comments submitted to that docket and considered them in preparation of the guidance.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on uniform procedures that should be used for the voting process when votes are taken during 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 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.

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