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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2007D-0449]

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Certifier A. Corbin

Draft Guidance for Food and Drug Administration Advisory Committee Members and Food and Drug Administration Staff: Voting Procedures for Advisory Committee Meetings;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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance document for FDA advisory committee members and FDA staff entitled, "Voting Procedures for Advisory Committee Meetings." This draft document is intended to provide guidance on advisory committee voting procedures that can be used for the voting process when votes are taken during advisory committee meetings. It does not to define when votes should be taken.

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on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit written or electronic comment on the draft guidance by *[insert date 60 days after date of publication in the Federal Register]*.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

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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.fda.gov/dockets/ecomments> or <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, 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FDA is announcing the availability of a draft guidance for FDA advisory committee members and FDA staff entitled, “Voting Procedures for Advisory Committee Meetings,” dated November 2007.

FDA’s advisory committees provide independent, expert advice to the agency on a range of complex scientific, technical, and policy issues, including questions 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 decision-making processes. Although advisory committees provide recommendations to FDA, FDA makes the final decisions.

Advisory committees typically communicate advice or recommendations to the agency in two ways. First, committee members routinely share their individual thoughts and recommendations during the discussion of a particular matter at an 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 post-market safety data or pre-market assessment of a product's risk/benefit profile. Since 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 draft guidance recommends adopting uniform voting procedures to help maximize the integrity and meaning of voting results. In developing these recommendations, FDA is 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, and policies, and the goals of FDA's advisory committee program.

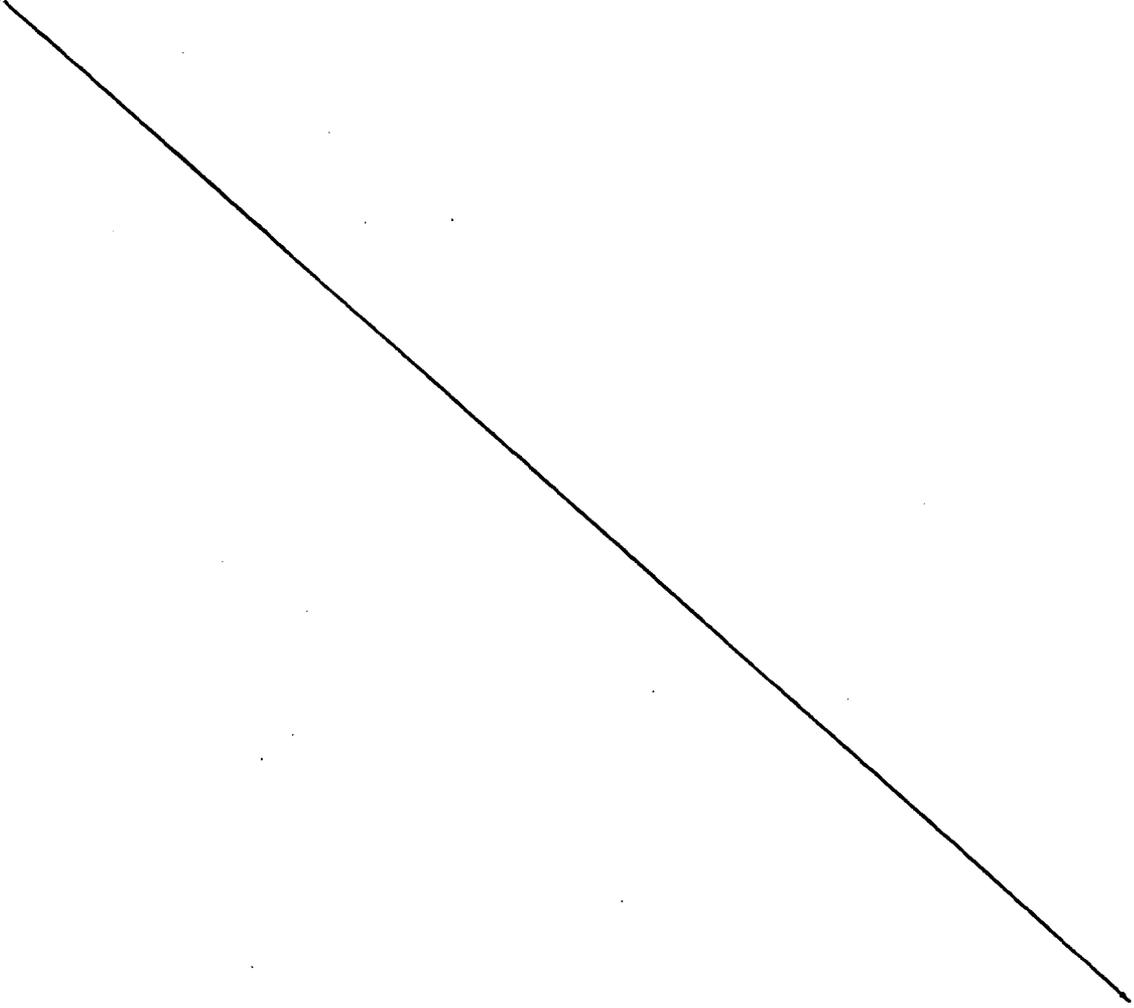
This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance represents the agency's current thinking on recommended uniform procedures that can be used for the voting process when votes are taken during advisory committee meetings.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

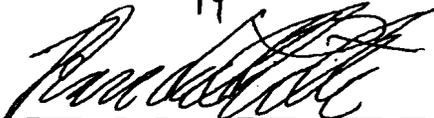
Please note that in January 2008, the FDA Web site is expected to transition to the Federal Dockets Management System (FDMS). FDMS is a Government-wide, electronic docket management system. After the transition date, electronic submissions will be accepted by FDA through the FDMS only.



When the exact date of the transition to FDMS is known, FDA will publish a **Federal Register** notice announcing that date.

Dated: NOV 15¹⁴ 2007
November 18¹⁴, 2007.

JD 11-14-07



Randall W. Lutter,
Deputy Commissioner for Policy.

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