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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-4959]

Guidance for Industry on the Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000." This document provides guidance for industry on how FDA interprets the Federal Advisory Committee Act (FACA) with respect to the disclosure of materials provided to advisory committees convened by the Center for Drug Evaluation and Research (CDER).

DATES: Written comments may be submitted on the guidance document by (insert **date 90 days after date of publication in Federal Register**). General comments on the agency guidance documents are welcome at any time.

ADDRESSES: Copies of this guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. Submit written requests for single copies of this guidance to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research, 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 written comments on this guidance

to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Murray M. Lumpkin, Center for Drug Evaluation and Research (HFD-2), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-5400.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled “Disclosure of Materials Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Convened by the Center for Drug Evaluation and Research Beginning on January 1, 2000.” The document provides guidance on how FDA interprets the FACA (5 U.S.C. App. 2) and § 314.430 (21 CFR 314.430) with respect to the disclosure of materials provided to advisory committees and how FDA will exercise its discretion under § 314.430(d)(1) in connection with open advisory committee meetings convened by CDER beginning on January 1, 2000.

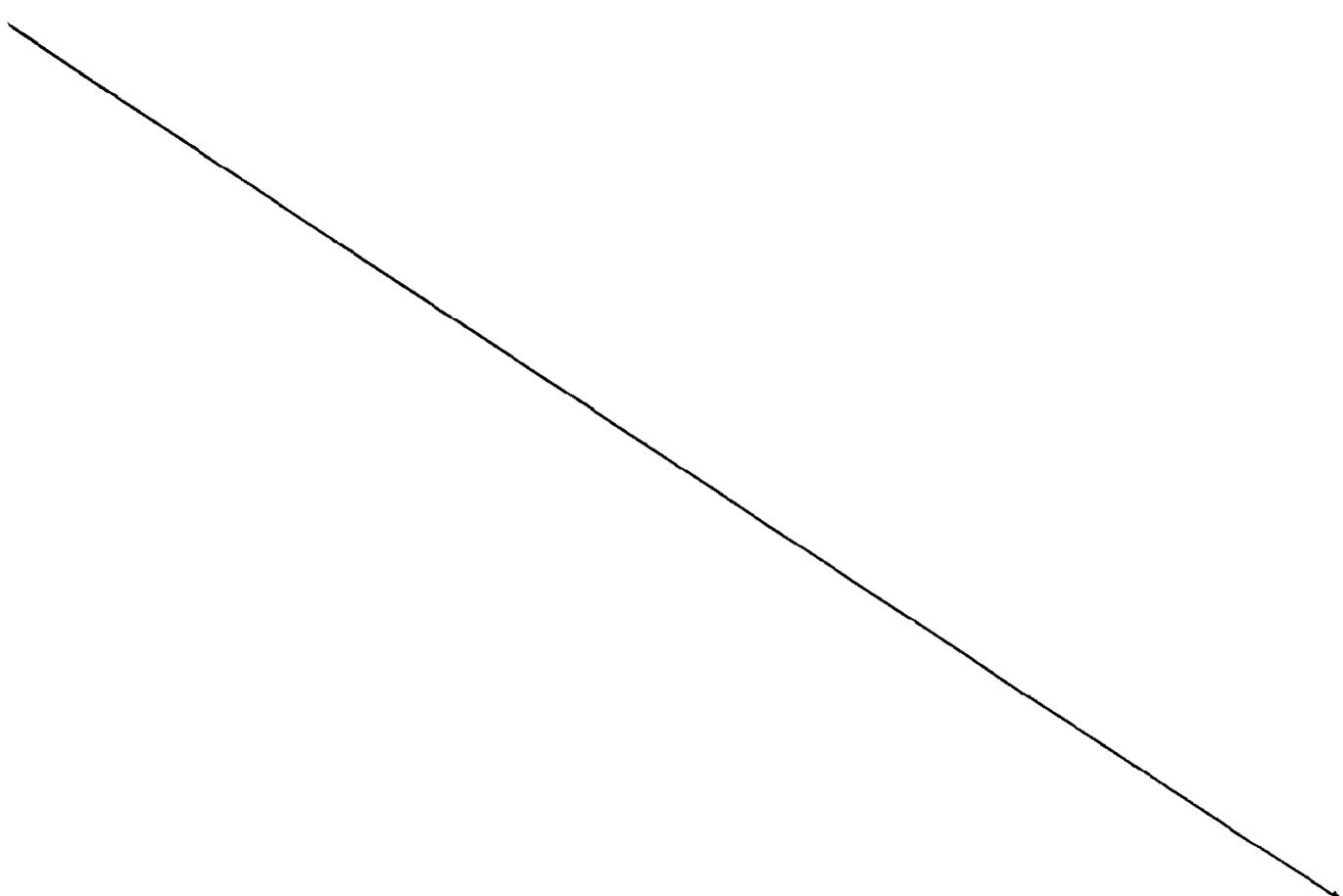
FDA construes the FACA to require that, with respect to any open advisory committee meeting convened pursuant to the FACA, whenever practicable and subject to any applicable exemptions of the Freedom of Information Act (FOIA) (5 U.S.C. 552), those materials that are provided to the members of an advisory committee in connection with that meeting must be made available for public inspection and copying before or at the time of the advisory committee meeting. FDA interprets § 314.430 to be consistent with the FACA and therefore will exercise its discretion under § 314.430(d)(1) in a manner consistent with the FACA and the FOIA as described in the previous sentence to make available for public inspection and copying materials provided to the members of an advisory committee in connection with open advisory committee meetings convened by CDER, beginning on January 1, 2000.

FDA will issue further guidance on what sponsors may expect concerning the disclosure of the materials they submit to advisory committees in connection with open advisory committee meetings convened by CDER beginning on January 1, 2000.

This level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). It is being implemented immediately without prior public comment because the guidance is needed to implement a court-approved settlement agreement. However, the agency wishes to solicit comment from the public and is providing a 90-day comment period and establishing a docket for the receipt of comments.

The guidance represents the agency's current thinking on the disclosure of materials provided to advisory committees in connection with open advisory committee meetings convened by CDER beginning on January 1, 2000. 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, regulations, or both.

Interested persons may submit written comments on the guidance to the Dockets Management Branch (address above). Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets



in the heading of this document. The guidance and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: 11/22/99
November 22, 1999



Margaret M. Dotzel
Acting Associate Commissioner for Policy

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