DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 01D–0297]

Medical Devices; Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled ''Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff.'' This document provides guidance to the Center for Devices and Radiological Health (CDRH) staff and to industry whose device is the subject of an open advisory committee meeting. The Federal Advisory Committee Act (FACA) generally requires FDA to make available to the public the information given to panel members, except for material that is exempt under the Freedom of Information Act (FOIA). This draft guidance describes the process CDRH intends to follow when making this information publicly available. This draft guidance also describes how these materials should be assembled and timeframes for their availability. This draft guidance is neither final nor is it in effect at this time.

DATES: Submit written or electronic comments concerning this guidance by October 16, 2001.

ADDRESSES: Submit written requests for single copies on a 3.5″ diskette of the draft guidance document entitled ''Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff'' to the Division of Small Manufacturers Assistance (HFZ–220), Center for Devices and Radiological Health, Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850. Send two self-addressed adhesive labels to assist that office in processing your request, or fax your request to 301–443–8818. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance.

Submit written comments on the document to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments.

FOR FURTHER INFORMATION CONTACT: Nancy J. Pluhowski, Center for Devices and Radiological Health (HFZ–400), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2022.

SUPPLEMENTARY INFORMATION:

I. Background

FACA provides at section 10(b) that materials that are made available to an advisory committee in connection with an open advisory committee meeting shall also be made available to the public, if the materials are not exempt from disclosure under FOIA. This FACA provision is intended to facilitate meaningful public participation at such meetings. CDRH has now developed a process to make materials provided to advisory committee members in connection with open public meetings available for public disclosure, whenever practicable before or at the time of the meeting. This process also ensures that those materials exempt from disclosure under FOIA are protected. This draft guidance is designed to minimize the amount of time and resources spent in reviewing, redacting (the deletion of nondisclosable information), and publishing this information so that panel meetings can proceed when they are scheduled and in compliance with the requirements of FACA.

II. Significance of Guidance

This draft guidance document represents the agency's current thinking on the availability of information given to advisory committee members in connection with CDRH open public panel 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 applicable statutes and regulations.

The agency has adopted good guidance practices (GGPs), and published the final rule, which set forth the agency's regulations for the development, issuance, and use of guidance documents (21 CFR 10.115; 65 FR 56468, September 19, 2000). This draft guidance document is issued as a level 1 guidance in accordance with the GGP regulations.

III. Electronic Access

In order to receive ''Availability of Information Given to Advisory Committee Members in Connection with CDRH Open Public Panel Meetings; Draft Guidance for Industry and FDA Staff'' via your fax machine, call the CDRH Facts-On-Demand system at 800–899–0381 or 301–827–0111 from a touch-tone telephone. Press 1 to enter the system. At the second voice prompt press 1 to order a document. Enter the document number 1341 followed by the pound sign (#). Follow the remaining voice prompts to complete your request.

Persons interested in obtaining a copy of the draft guidance may also do so using the Internet. CDRH maintains an entry on the Internet for easy access to information including text, graphics, and files that may be downloaded to a personal computer with Internet access. Updated on a regular basis, the CDRH home page includes the civil money penalty guidance documents package, device safety alerts, **Federal Register** reprints, information on premarket submissions (including lists of approved applications and manufacturers' addresses), small manufacturers' assistance, information on video conferencing and electronic submissions, Mammography Matters, and other device-oriented information. The CDRH home page may be accessed at http://www.fda.gov/cdrh.

IV. Comments

Interested persons may submit to Dockets Management Branch (address above) written or electronic comments regarding this draft guidance by October 16, 2001. Submit two copies of any comments, 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 draft guidance document and any received comment may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

Dated: July 12, 2001.

Linda S. Kahan,

Deputy Director for Regulations Policy, Center for Devices and Radiological Health.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–312 and HCFA–R–263]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

In compliance with the requirement of section 3506(c)(2)(A) of the