Guidance for Industry

Disclosing Information Provided to Advisory Committees in Connection with Open Advisory Committee Meetings Related to the Testing or Approval of New Drugs and Convened by the Center for Drug Evaluation and Research, Beginning on January 1, 2000

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit comments to Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions on the content of the draft document contact Murray M. Lumpkin at 301-594-5400.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)

December 1999
Procedural

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Additional copies are available from:
Drug Information Branch (HFD-210),
Center for Drug Evaluation and Research (CDER),
5600 Fishers Lane, Rockville, MD 20857 (Tel) 301-827-4573
http://www.fda.gov/cder/guidance/index.htm

U.S. Department of Health and Human Services
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Draft -- Not for Implementation

Guidance for Industry[1]

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I. PURPOSE

This document is intended to provide guidance to the sponsors of applications that are the subjects of open advisory committee meetings convened by the Center for Drug Evaluation and Research (CDER), beginning January 1, 2000.[2] It describes the procedures CDER intends to follow when making publicly available the information provided to advisory committee members in connection with such meetings. The guidance also describes how a sponsor should prepare its submissions to an advisory committee.

The procedures described in this guidance are intended to make the process of complying with the disclosure requirements of the Federal Advisory Committee Act (the FACA) (5 U.S.C. App. 2) as efficient as possible. These procedures address (1) the content and organization of a sponsor submission for an advisory committee, (2) the timing of the sponsor submission to CDER, (3) the process by which CDER will review and redact the sponsor submission and the related CDER submission, and (4) the effect this process may have on the time allotted to a review cycle in which an advisory committee meeting occurs.

II. BACKGROUND

On November 30, 1999 (64 FR 66920), CDER issued a guidance document on the public disclosure

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[1] This guidance document represents the Agency's current thinking on the implementation by the Center for Drug Evaluation and Research (CDER) of the disclosure provisions of the FACA. 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 and regulations.

[2] This guidance covers the following advisory committees: Anesthetic and Life Support Drugs, Anti-Infective Drugs, Antiviral Drugs, Arthritis, Cardiovascular and Renal Drugs, Compounding, Dermatologic and Ophthalmic Drugs, Drug Abuse, Endocrinologic and Metabolic Drugs, Reproductive Health Drugs, Gastrointestinal Drugs, Generic Drugs, Medical Imaging Drugs, Nonprescription Drugs, Oncologic Drugs, Peripheral and Central Nervous System Drugs, Pharmaceutical Science, Psychopharmacologic Drugs, Pulmonary-Allergy Drugs. CDER advisory committees that are chartered in the future will also be covered by this guidance.

of materials provided to advisory committees in connection with open advisory committee meetings convened by CDER on or after January 1, 2000 (*Disclosure of Information 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*[3]) (the disclosure policy guidance). In that document, CDER provided the following interpretation of the Agency's responsibilities under the FACA and of FDA's regulations governing disclosure of information concerning new drug applications in 21 CFR 314.430:

> 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 (the 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.

CDER will make advisory committee materials available consistent with these principles. CDER has developed procedures for ensuring that materials that are provided to advisory committees in connection with open advisory committee meetings convened by CDER beginning January 1, 2000, will be made publicly available before or at the meeting, whenever practicable. These procedures should also ensure that those materials that are exempt from disclosure under the FOIA will not be made publicly available. These procedures are designed to minimize the time and resources spent reviewing the materials in an advisory committee submission, determining which materials are exempt from disclosure under the FOIA, and redacting such materials.

It is necessary to minimize CDER consultation and redaction time because the more time the Agency needs to redact materials in advance of an advisory committee meeting, the earlier in the application review process the sponsor must prepare its background package for the advisory committee. If the preparation of the advisory committee package occurs too early in the review process, the package may not adequately address the issues that will be the subject of the advisory committee meeting, because those issues will not yet have crystallized.

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[3] This document is available from the Drug Information Branch (HFD-210), CDER, 5600 Fishers Lane, Rockville, MD 20857, (Tel) (301) 827-4573, http://www.fda.gov/cder/guidance/index.htm.

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