Guidance for Industry

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

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
November 1999

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This document provides guidance on how FDA interprets the Federal Advisory Committee Act (FACA) (5 U.S.C. App. 2) and 21 CFR 314.430 (§ 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)[2] in connection with open advisory committee meetings convened by the Center for Drug Evaluation and Research (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.

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[1] This guidance document represents the Agency's current thinking 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. 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, regulations, or both.

[2] FDA's regulation at 21 CFR 314.430(d)(1) states as follows:

> If the existence of an application or abbreviated application has been publicly disclosed or acknowledged before the agency sends an approval letter to the applicant, no data or information contained in the application or abbreviated application is available for public disclosure before the agency sends an approval letter, but the Commissioner may, in his or her discretion, disclose a summary of selected portions of the safety and effectiveness data that are appropriate for public consideration of a specific pending issue; for example, for consideration of an open session of an FDA advisory committee.

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.