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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

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**Food and Drug Administration**

[Docket No. 99D-0296]

**Guidance for Industry on Formal Meetings With Sponsors and Applicants for PDUFA Products; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled "Formal Meetings with Sponsors and Applicants for PDUFA Products." This guidance is intended to provide guidance to industry on procedures that will be adopted by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) for formal meetings between the agency and sponsors or applicants concerning certain drug products.

**DATES:** Submit written comments on agency guidances at any time.

**ADDRESSES:** Copies of the guidance for industry are available on the Internet at <http://www.fda.gov/cder/guidance/index.htm> or <http://www.fda.gov/cber/guidelines.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, or to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-3844, FAX 888-CBERFAX. Send two self-addressed adhesive labels 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.

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**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, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM-10), 1401 Rockville Pike, Rockville, MD 20852-448, 301-827-0373.

**SUPPLEMENTARY INFORMATION:** FDA is announcing the availability of a guidance for industry entitled "Formal Meetings with Sponsors and Applicants for PDUFA Products." This guidance is intended to provide guidance to industry on procedures that will be adopted by CDER and CBER for formal meetings between the agency and sponsors or applicants concerning certain drug products.

In the **Federal Register** of March 19, 1999 (64 FR 13591), FDA announced the availability of a draft version of this guidance. The agency has finalized that draft guidance after considering comments received on the draft version. Few comments were received, and only minor changes were made to the draft version in response to the comments in an effort to make the document clearer.

CDER and CBER participate in many meetings each year with sponsors of investigations and applicants for marketing who seek guidance relating to the development and review (including the initial launch) of products in human drug applications as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 379g(1)) (PDUFA products). These meetings often represent critical points in the regulatory process. It is essential that FDA maintain procedures for the timely and effective conduct of such meetings.

Section 119(a) of the Food and Drug Administration Modernization Act of 1997 (the Modernization Act) (Public Law 105-115) amends section 505(b) of the act (21 U.S.C. 355(b)) and directs FDA to meet with sponsors and applicants, provided certain conditions are met, for the purpose of reaching agreement on the design and size of clinical trials intended to form the primary basis of an effectiveness claim in a new drug application submitted under section 505(b)

of the act or in a biologics license application submitted under section 351 of the Public Health Service Act (21 U.S.C. 355(b)(4)(B)). Moreover, in conjunction with the reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA) in November 1997, FDA agreed to specific performance goals for the management of meetings with sponsors and applicants for PDUFA products. The performance goals are summarized in an enclosure to a letter dated November 12, 1997, from the Secretary of Health and Human Services, Donna E. Shalala, to Senator James M. Jeffords.

The procedures and policies described in this guidance are designed to promote efficient, well-managed meetings between sponsors, applicants, and CDER or CBER. These procedures will implement section 119(a) of the Modernization Act and are consistent with the timeframes described in the performance goals.

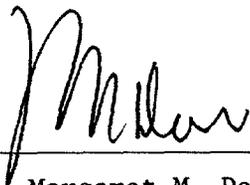
In the notice announcing the availability of the draft version of this guidance (64 FR 13591), FDA published notice of the proposed collection of information related to the draft guidance. The **Federal Register** notice also requested comments on the burden estimates for the guidance. In the **Federal Register** of August 26, 1999 (64 FR 46684), the agency announced that it was submitting the collection of information to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995. The information collection provisions related to this guidance have been approved under OMB control number 0910-0429. This approval expires December 31, 2002. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

This Level 1 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). The guidance represents the agency's current thinking on formal meetings with sponsors and applicants for PDUFA products. 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, at any time, 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: 2/29/00  
February 29, 2000



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Margaret M. Dotzel  
Acting Associate Commissioner for Policy

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