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Certifier	J. M. Windsor

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-2405]

Draft "Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act;" Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled "Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act." This draft guidance is intended to provide guidance to industry on the use of certain types of letters by the Center for Drug Evaluation and Research (CDER) and the Center for Biologics Evaluation and Research (CBER) as part of the review of marketing applications for certain drug and biological products.

DATES: Written comments may be submitted at any time, however, comments should be submitted by (*insert date 90 days after date of publication in the Federal Register*), to ensure their adequate consideration in preparation of the final document.

ADDRESSES: Submit written requests for single copies of the draft guidance entitled "Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act" to the Drug Information Branch (HFD-210), Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self addressed adhesive label to assist the office in processing your request. The document may also be obtained by mail by calling the CBER Voice Information System at 1-800-835-4709 or

301—827—1800, or by fax by calling the FAX Information System at 1—888—CBER—FAX or 301—827—3844. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance document. 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.

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—1448, 301—827—0373.

SUPPLEMENTARY INFORMATION:

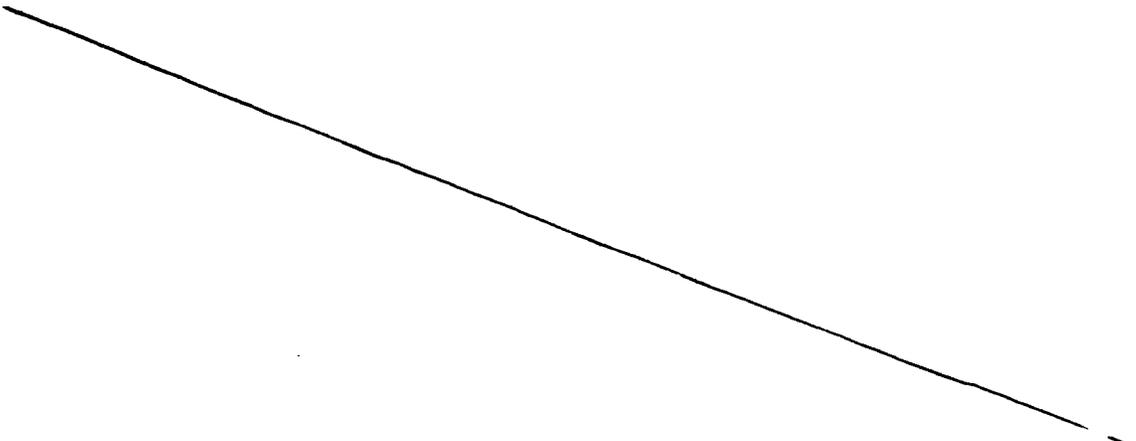
I. Background

FDA is announcing the availability of a draft document entitled “Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act.” In a November 1997 letter to Congress regarding the reauthorization of the Prescription Drug User Fee Act (PDUFA) as part of the Food and Drug Administration Modernization Act of 1997 (Public Law 105—115), the Secretary of Health and Human Services (the Secretary) committed FDA to certain user fee performance goals and additional procedures related to the review of products in human drug applications as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)) (PDUFA products). As one of the additional procedures intended to help expedite the development of drugs and biologics, the Secretary specified that FDA intends to provide early agency thoughts on possible deficiencies to applicants in a letter as each discipline finishes its initial review of its portion of the pending application. The procedures and policies described in this draft guidance are intended to explain how the agency will issue and use information request letters and discipline review letters during the review of PDUFA products.

This draft guidance document represents the agency's current thinking on information request letters and discipline review letters under PDUFA. 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. As with other guidance documents, FDA does not intend this document to be all-inclusive and cautions that not all information may be applicable to all situations. The document is intended to provide information and does not set forth requirements.

II. Comments

This draft document is being distributed for comment purposes only, and is not intended for implementation at this time. Interested persons may submit to the Dockets Management Branch (address above) written comments regarding this guidance document. Written comments may be submitted at any time, however, comments should be submitted by (*insert date 90 days after date of publication in the Federal Register*), to ensure adequate consideration in preparation of the final document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments are to be identified with the docket number found in the brackets in the heading of this document. The draft 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.



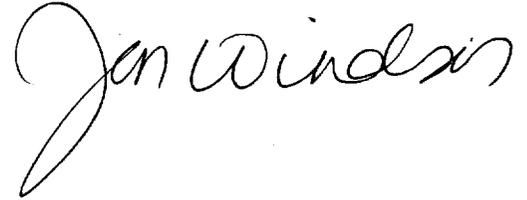
III. Electronic Access

Persons with access to the Internet may obtain the draft guidance document using the World Wide Web (WWW). For WWW access, connect to CDER at “<http://www.fda.gov/cder/guidance/index.htm>”, or CBER at “<http://www.fda.gov/cber/guidelines.htm>”.

Dated: Aug 9, 1999
August 9, 1999

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL





Margaret M. Dotzel,
Acting Associate Commissioner for Policy.

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