

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D-2405]

DMB

Display Date	11-20-01
Publication Date	11-21-01
Order	<i>SKere</i>

“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 document entitled “Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act” dated November 2001. The guidance document provides 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. The guidance document announced in this notice finalizes the draft guidance document entitled “Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act” dated August 1999.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Office of Communication, Training, and Manufacturers Assistance (HFM-40), Center for Biologics Evaluation and Research (CBER), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Send one self-addressed adhesive label to assist the office in processing your requests. 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 guidance document.

Submit written comments on the guidance 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:

Michael Anderson, Center for **Biologics** Evaluation and Research (HFM-17), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-827-6210; or Paul Varki, Center for Drug Evaluation and Research (HFD-7), 5600 Fishers Lane, Rockville, MD 20852-1448, 301-594-2041.

SUPPLEMENTARY INFORMATION:

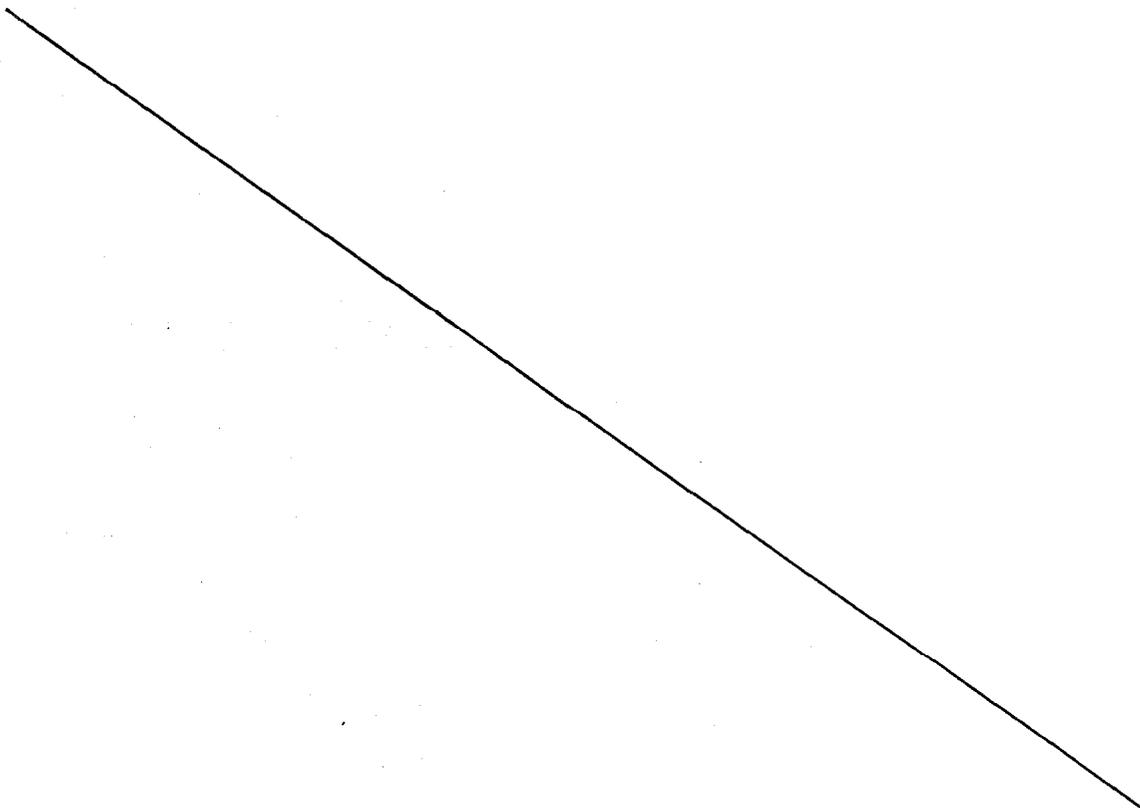
I. Background

FDA is announcing the availability of a document entitled “Guidance for Industry: Information Request and Discipline Review Letters Under the Prescription Drug User Fee Act” dated November 2001 . 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)). The guidance document explains how the agency will issue and use information request letters and discipline review letters during the review of PDUFA products. The guidance document announced in this notice finalizes the draft guidance document entitled “Guidance for Industry: Information Request and Discipline. Review Letters Under the Prescription Drug User Fee Act” dated August 1999 that was announced in the **Federal Register** of August 17, 1999 (64 FR 44741).

The guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). This guidance document represents the agency's current thinking on information request 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 requirement of the applicable statutes and regulations.

II. Comments

Interested persons may, at any time, **submit** written comments to the Dockets Management Branch (address above) regarding this guidance document. Two copies of any comments are to be submitted, except individuals may submit one copy. Comments should be identified with the docket number found in the brackets in the heading of this document. A copy of the document 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 document at <http://www.fda.gov/cber/guidelines.htm>.

Dated: 10/29/01
October 29, 2001.

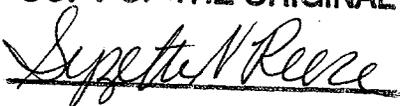


Margaret M. Dotzel,
Associate Commissioner for Policy.

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

BILLING CODE 4160-01-S

**CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL**



Supantha/Reese