GENERAL SERVICES ADMINISTRATION

Proposed Collection: Submission for OMB Review; Comment Request Entitled Questionnaire: CD–ROM of the Catalog of Federal Domestic Assistance and Federal Assistance Award Data System

AGENCY: Office of Acquisition Policy, GSA

ACTION: Notice of request for approval of a new information collection entitled Questionnaire: CD–ROM of the Catalog of Federal Domestic Assistance and Federal Assistance Award Data System.

SUMMARY: Under the provisions of the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35), GSA has submitted to the Office of Management and Budget (OMB) a request to review and approve a new information collection concerning Questionnaire: CD–ROM of the Catalog of Federal Domestic Assistance and Federal Assistance Award Data System.

The Federal Domestic Assistance Catalog Staff, General Services Administration is requesting that users of the CD–ROM version of the Catalog of Federal Domestic Assistance and Federal Assistance Award Data System reply, on a voluntary basis to a survey designed to determine user satisfaction and solicit comments that will help them understand users' needs. The Federal Domestic Assistance Catalog Staff will use information solicited from users to improve its usefulness to customers. Without this information, CD–ROM users' needs may go unrecognized. This is a voluntary survey that will take approximately 5 minutes to complete

DATES: Submit comments on or before January 28, 2000.

ADDRESSES: Comments concerning this notice should be submitted to: Jacqueline Garrett, Governmentwide Information Systems Division, Room 101–Reporters Building, 300 7th Street, SW., Washington, DC 20407, or e-mail to Jackie.Garrett@gsa.gov.

FOR FURTHER INFORMATION CONTACT: Jacqueline Garrett, Governmentwide Information Systems Division, Room 101–Reporters Building, 300 7th Street, SW., Washington, DC 20407, or e-mail to Jackie.Garrett@gas.gov.

SUPPLEMENTARY INFORMATION:

A. Purpose

The purpose of this Notice is to solicit comments from users of the CD–ROM version of the Catalog of Federal Domestic Assistance (CFDA) and Federal Assistance Award Data System (FAADS) to improve its usefulness to customers.

B. Annual Reporting Burden

Respondents: 1,000; annual responses: 1,000; average hours per response: .10; burden hours: 100.

Copy of Proposal: A copy of this proposal may be obtained by contacting Jacqueline Garrett at the above address.

Dated: November 22, 1999.

J. Les Davison,

Acting Deputy Associate Administrator for Acquisition Policy.

[FR Doc. 99–30863 Filed 11–26–99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–4808]

Guidance for Industry on Drug Master Files for Bulk Antibiotic Drug Substances; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Drug Master Files for Bulk Antibiotic Drug Substances.'' This guidance is intended to assist those in industry whose approved applications for bulk antibiotic drug substances were converted to Type II drug master files (DMF's) as a result of the repeal of the statutory provision in the Federal Food, Drug, and Cosmetic Act (the act) under which the agency certified antibiotic drugs.

DATES: Written comments may be submitted at any time.

ADDRESSES: Copies of this guidance are available on the Internet at http://www.fda.gov/cder/guidance/index.htm. Submit written requests for single copies of this guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist the office in processing your requests. Submit written comments on the guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Susan M. Rosencrance, Center for Drug Evaluation and Research (HFD–643), Food and Drug Administration, Office of Generic Drugs, 7500 Standish Pl., Rockville, MD 20855, 301–827–5779.

SUPPLEMENTARY INFORMATION: FDA is announcing the availability of a guidance for industry entitled ''Drug Master Files for Bulk Antibiotic Drug Substances.'' The purpose of this guidance is to provide recommendations to those in industry whose approved applications for bulk antibiotic drug substances were administratively converted, by FDA, to Type II DMF's as a result of the repeal of section 507 of the act (see section 125(b) of the Food and Drug Administration Modernization Act of 1997). This guidance describes the purpose of DMF's, discusses the type of information expected in a Type II DMF, explains the administrative procedures governing review of DMF's, and clarifies the responsibilities of a DMF holder. FDA is issuing this guidance because of a possible misunderstanding by some DMF holders about the need to inform FDA of manufacturing changes to bulk antibiotic drug substances that are covered under a DMF. The information included in the guidance is a compilation of previously published information.

This Level 2 guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). FDA is issuing a notice of availability for this Level 2 guidance to ensure that industry is aware of the importance of updating DMF's when changes are made.

The guidance represents the agency's current thinking on DMF's for bulk antibiotic drug substances. 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: November 17, 1999.

Margaret M. Dotzel,

Acting Associate Commissioner for Policy.

[FR Doc. 99–30819 Filed 11–26–99; 8:45 am]

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