injection) may be approved by the agency.

Dated: May 15, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12874 Filed 5–22–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 00D–1563]

Guidance for Industry on Carcinogenicity Study Protocol Submissions; 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 ''Carcinogenicity Study Protocol Submissions.'' This document is intended to provide guidance on the types of information the Center for Drug Evaluation and Research (CDER) relies on when evaluating protocols for animal carcinogenicity studies.

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

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that 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. Submit electronic comments to http://www.fda.gov/dockets/ecomments. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Robert E. Osterberg, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5476.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Carcinogenicity Study Protocol Submissions.'' In conjunction with the reauthorization of the Prescription Drug User Fee Act of 1992 (PDUFA), FDA agreed to specific performance goals (PDUFA goals) for activities associated with the development and review of products in human drug applications. The PDUFA goals related to special protocol assessment and agreement provide that, upon request, FDA will evaluate within 45 calendar days certain protocols and issues relating to the protocols to assess whether they are adequate to meet scientific and regulatory requirements identified by the sponsor. Protocols for animal carcinogenicity studies are eligible for this special protocol assessment. This guidance is intended to facilitate the agency's review of protocols for animal carcinogenicity studies by informing sponsors of the types of information the agency relies on during its evaluation of such protocols. A draft guidance of the same name was made available for public comment in a notice published in the **Federal Register** of November 7, 2000 (65 FR 66757). This guidance contains only minor changes for clarification.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on carcinogenicity study protocol submissions. 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 and regulations.

II. Comments

Interested persons may, at any time, submit written or electronic 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at http://www.fda.gov/cder/guidance/index.htm or http://www.fda.gov/ohrms/dockets/default.htm.

Dated: May 15, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–12872 Filed 5–22–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Availability of Funds

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: General Notice.

SUMMARY: The Health Resources and Services Administration (HRSA) announces that applications will be accepted for fiscal year 2002 competitive Cooperative Agreements for health workforce research.

Purpose

The purpose of these Cooperative Agreements is to conduct research that will contribute to: (1) The development of information describing the current status of the health professions workforce and (2) the analysis of fundamental health workforce related issues. These Cooperative Agreements will support a wide range of projects designed to address health workforce issues at the National, Regional and State levels.

Authorizing Legislation

These Cooperative Agreements are governed by section 761 of Title VII of the Public Health Service Act, as amended, which authorizes the development of information describing the health professions workforce and analysis of workforce related issues and necessary information for decision-making regarding future direction in health professions and nursing programs in response to societal and professional needs. Section 761 also authorizes the development of a non-Federal analytic and research infrastructure for health workforce data collection and analysis.

Federal Role

The Federal role in the conduct of these cooperative agreements allow for substantial Federal programmatic involvement in the planning and development of and the reports resulting from these studies. The Bureau of Health Professions (BHPr) program officer may be assisted in this effort by program staff of the BHPr divisions. The Federal Government involvement will include: