adverse events, drug use data, healthcare administrative data, epidemiologic and observational studies, clinical trials, and active surveillance systems. Considerations will include the advantages and disadvantages of the current system for safety signal detection, and proposals for short-term and long-term ways to improve the current system. The background materials for this meeting will be posted 1 business day before the meeting on the FDA Web site at *http://www.fda.gov/ohrms/dockets/ac/acmenu.htm*. (Click on the year 2005 and scroll down to the Drug Safety and Risk Management Advisory Committee.)

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person by May 9, 2005. Oral presentations from the public will be scheduled between approximately 11 a.m. and 12 noon on May 18, 2005, and between approximately 11:10 a.m. and 11:40 a.m. on May 19, 2005. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 9, 2005, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Persons attending FDA's advisory committee meetings are advised that the agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact Shalini Jain at least 7 days in advance of the meeting.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 7, 2005.

Sheila Dearybury Walcoff,

Associate Commissioner for External Relations.

[FR Doc. 05–7458 Filed 4–13–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2005D–0122]

Draft Guidance for Industry on Exploratory Investigational New Drugs Studies; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance for industry entitled ''Exploratory IND Studies.'' This draft guidance clarifies what preclinical and clinical issues (including chemistry, manufacturing, and controls issues) should be considered when planning exploratory studies in humans, including studies of closely related drugs or biologics, under an investigational new drug (IND) application. This draft guidance emphasizes the concept that limited investigations in humans can be initiated with more limited preclinical support because such studies present fewer potential risks than do traditional phase 1 studies that look for dose-limiting toxicities.

DATES: Submit written or electronic comments on the draft guidance by July 13, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the 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 draft guidance to the Division of Dockets Management (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 draft guidance document.

FOR FURTHER INFORMATION CONTACT: David Jacobson-Kram, Center for Drug Evaluation and Research (HFD–24), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–5346.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Exploratory IND Studies.'' In its March 2004 Critical Path Report, the agency explained that to reduce the time and resources expended during early drug development on candidates that are unlikely to succeed, tools are needed to allow developers to distinguish earlier in the process those candidates that hold promise from those that do not. This guidance describes some exploratory approaches that will protect human subjects while providing early information about candidate performance in humans.

Exploratory IND studies have a number of different goals. In some cases, an exploratory study can help developers gain an understanding of the relationship between a specific mechanism of action and the treatment of a disease. In other cases, a study can provide important information on pharmacokinetics, including, for example, biodistribution of a candidate drug. Whatever the goal of the study, exploratory IND studies can help sponsors identify, early in the process, promising candidates for continued development.

Existing regulations allow a great deal of flexibility in terms of the amount of data that need to be submitted in an IND application, depending on the goals of an investigation, the specific human testing being proposed, and the expected risks. Nevertheless, sponsors have not always taken advantage of that flexibility and limited, early phase 1 studies, such as those described in this document, are often supported by a more extensive preclinical database than is needed. In many cases, a more extensive workup is done because sponsors intend to move immediately into a more traditional phase 1 trial if the screening results are favorable. Because exploratory studies will typically involve administering either subtherapeutic doses of a product, or doses expected to produce a pharmacological, but not a toxic effect, the potential risk to human subjects is less than for a traditional phase 1 study that, for example, seeks to establish a maximally tolerated dose.

This guidance applies to exploratory studies (i.e., early phase 1 clinical studies), involving investigational new drug and biological products, that assess feasibility for further development of a drug or biological product. For the purposes of this guidance the phrase ''exploratory study'' is intended to describe clinical trials that occur very early in phase 1, involve very limited human exposure, and often have no therapeutic intent.

Typically, these exploratory studies are conducted prior to the traditional

dose evaluation, safety, and tolerance studies that ordinarily initiate a clinical drug development program. Thus, FDA believes that, typically, the duration of dosing would be limited (e.g., 7 days). The agency is, however, interested in soliciting comment from the public on the appropriate duration of dosing for such exploratory studies.

The amount and type of preclinical information necessary to support an exploratory study will depend on the planned nature and extent of human exposure relative to the toxicity (or lack thereof) at the planned dose. Thus, this guidance emphasizes the concept that limited investigations in humans can be initiated with more limited preclinical support because such studies present fewer potential risks than do traditional phase 1 studies that look for dose-limiting toxicities. The studies discussed here ordinarily do not have therapeutic intent. They are designed to evaluate whether a particular candidate should be entered into a drug development program.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the agency's current thinking on exploratory IND studies. 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. Paperwork Reduction Act of 1995

This draft guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collection of information in this guidance has been approved under OMB control number 0910–0014 and expires on January 31, 2006.

III. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. The draft guidance and received comments are available for public examination in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

IV. Electronic Access

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

Dated: April 8, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–7485 Filed 4–13–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Injury Prevention Program Announcement Type: New

Funding Opportunity Number: HHS–2005–IHS–IPP–0001.

CFDA Number: 93.284.

Key Dates:

Application Deadline: May 20, 2005.

Application Review: June 27–28, 2005.

Anticipated Award Start Date: September 1, 2005.

Application Notification: September 30, 2005.

I. Funding Opportunity Description

Legislative Authority

The Indian Health Service (IHS) announces competitive cooperative agreement applications for Injury Prevention Program for American Indians and Alaska Natives (AI/AN):

(A) Part I Basic Five-year projects (minimum population required 2,500)

(B) Part I Advanced Five-year projects (minimum population required 2,500)

Part I Advanced applicants include Tribes and organizations who are current recipients of the 2000–2005 IHS Injury Prevention Cooperative Agreements (applies only to 2000–2005 Tribal Injury Prevention Cooperative Agreement recipients).

(C) Part II Intervention Three-year projects (no population requirement)

These cooperative agreements are established under the authority of section 301(a), Public Health Service Act, as amended. This program is described at 93.284 in the Catalog of Federal Domestic Assistance, the Indian Health Care Improvement Act, U.S.C. 1602 (b)(17); and Urbans (25 U.S.C. 1652).

II. Award Information

Type of Instrument: Cooperative Agreement (CA)

A cooperative agreement will have substantial oversight to ensure best practices and high quality performance in sustaining capacity of the Injury Prevention projects. The estimated amount of funds available is $1.475 million for Fiscal Year 2005 to fund up to approximately 33 awards.

Types of Cooperative Agreement (CA) covered under this announcement:

Part I—Basic: Approximately 47% of funds are available to fund up to 14 new awards for the Basic Injury Prevention Program. Individual awards will range from $25,000 up to $50,000.

Part I—Advanced: Approximately 46% of funds are available to fund up to 9 Injury Prevention Program considered ''experienced'' in Injury Prevention. Part I Advanced applicants are Tribes and organizations who are current recipients of the 2000–2005 IHS Injury Prevention Cooperative Agreements (applies only to 2000–2005 Tribal Injury Prevention Cooperative Agreement recipients). Individual awards will range from $25,000 up to $75,000.

Part II—Intervention: Approximately 7% of funds are available to fund up to 10 awards to implement proven or promising injury intervention projects that are based on addressing local injury problems. Individual awards will be $10,000. Injury Prevention applicants may apply for new funding under Part I Basic or Part I Advanced or Part II—Intervention, but only one award will be funded to each applicant. A separate application is required for each type of project.

Project Period: The Cooperative Agreement (CA) will be a 12-month budget period within a project year:

- Part I—Basic—5 years beginning on or about Sept 1, 2005.
- Part I—Advanced—5 years beginning on or about Sept 1, 2005.
- Part II—Intervention—3 years beginning on or about Sept 1, 2005.

Future continuation awards within the project period will be based on satisfactory performance, availability of funding, and continuing needs of the Indian Health Service.

Estimated Range of Awards: $10,000 to $75,000.

Substantial Involvement Description for Cooperative Agreement Activities for Part I

The cooperative agreement Part I awardee (Tribe or Tribal/urban/non-profit Indian organization) will be responsible for activities listed under A. IHS will be responsible for activities listed under B. A contractor will be hired to assist in the oversight in the Part I CA projects. Oversight includes assurances to promote best practices and high quality performance in