from both regulatory and industry representatives. FDA also seeks input from consumer representatives and others. ICH is concerned with harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labour, and Welfare; the Japanese Pharmaceutical Manufacturers Association; CDER, CBER, and FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA).

The ICH Steering Committee includes representatives from each of the ICH sponsors and the IFPMA, as well as observers from the World Health Organization, Health Canada, and the European Free Trade Area.

In the **Federal Register** of February 17, 2009 (74 FR 7449), FDA published a notice announcing the availability of a draft guidance entitled ''Q4B Evaluation and Recommendation of Pharmacopoeial Texts for Use in the ICH Regions; Annex 6: Uniformity of Dosage Units General Chapter.'' The notice gave interested persons an opportunity to submit comments by April 20, 2009.

After consideration of the comments received and revisions to the guidance, a final draft of the guidance was submitted to the ICH Steering Committee and endorsed by the three participating regulatory agencies in November 2013.

The guidance provides the specific evaluation results from the ICH Q4B process for the Uniformity of Dosage Units General Chapter harmonized text originating from the three-party PDG. This guidance is in the form of an annex to the core ICH Q4B guidance (*http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM073405.pdf*) made available in the **Federal Register** of February 21, 2008 (73 FR 9575). The annex will provide guidance to assist industry and regulators in the implementation of the specific topic evaluated by the ICH Q4B process.

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 this topic. 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 submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm, http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/default.htm,* or *http://www.regulations.gov.*

Dated: June 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13908 Filed 6–13–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0731]

Methodological Considerations in Evaluation of Cancer as an Adverse Outcome Associated With Use of Non-Oncological Drugs and Biological Products in the Postapproval Setting; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

The Food and Drug Administration (FDA), in collaboration with the National Cancer Institute (NCI), is announcing a public meeting entitled ''Methodological Considerations in Evaluation of Cancer as an Adverse Outcome Associated With Use of Non-Oncological Drugs and Biological Products in the Postapproval Setting.'' The purpose of the public meeting is to engage in constructive dialogue and information sharing among regulators, researchers, the pharmaceutical industry, public health agencies, health care providers, and the general public concerning challenges in designing and implementing postapproval studies to evaluate the risk of cancer associated with use of non-oncological drugs and biological products. The input from this meeting and public docket will be used to inform the Agency on best study design and methodological options to consider when evaluating cancer risk in the postapproval setting.

Dates and Time: The public meeting will be held on September 10, 2014, from 8 a.m. to 5 p.m., and September 11, 2014, from 8 a.m. to 5 p.m.

Location: The public meeting will be held at The DoubleTree by Hilton Hotel Washington DC—Silver Spring, The Maryland Ballroom, 8727 Colesville Rd., Silver Spring, MD 20910 (Metro: Silver Spring Station on the Red Line).

Contact Person: Paul Tran, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–9029, FAX: 301–796–9832, *Paul.Tran@fda.hhs.gov.*

Registration and Requests for Oral Presentations: Registration is free and available on a first-come, first-served basis. You must register online by August 27, 2014. Seating is limited, so register early. FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the meeting will be available. To register for this meeting, please visit FDA's Drugs News & Events—Meetings, Conferences, & Workshops calendar at *http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm* and select this meeting from the events list. If you need special accommodations due to a disability, please contact Paul Tran (see *Contact Person*) by September 3, 2014. Those without Internet access should contact Paul Tran to register.

This meeting includes a public comment session. If you would like to present at the meeting on topics related to challenges in designing and implementing postapproval studies to evaluate the risk of cancer associated with use of non-oncological drugs and biological products, please identify during registration the topic(s) you will address (see section II).

FDA will do its best to accommodate requests to speak. FDA urges individuals and organizations with common interests to coordinate and give a joint, consolidated presentation. Following the close of registration, FDA will allot time for each presentation and notify presenters by September 3, 2014.

Do not present or distribute commercial or promotional material during the meeting. Registered presenters should check in before the meeting.

Comments: FDA is holding this meeting to seek input on the study design and methodological options for conducting postapproval studies to evaluate cancer as an adverse outcome associated with use of non-oncological drugs and biological products. FDA is soliciting from interested persons electronic or written comments on all aspects of the meeting topics through October 9, 2014.

Attendees and non-attendees may submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Send only one set of comments. When sending comments, please include the docket number from the heading of this notice. In addition, when addressing specific topics (see section II), please identify the topic. Received comments may be viewed in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Transcripts: After the meeting, FDA will post a transcript at *http://www.regulations.gov.* The transcript may be viewed at the Division of Dockets Management (see *Comments*). A transcript will also be available in either hardcopy or on CD–ROM upon submission of a Freedom of Information request. Send requests to the Division of Freedom of Information (ELEM–1029), Food and Drug Administration, 12420 Parklawn Dr., Element Bldg., Rockville, MD 20857.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is holding this meeting to seek input from industry, academia, public health agencies, the clinical community, and other stakeholders regarding the study design and methodological options for conducting studies to evaluate cancer as an adverse outcome associated with use of non-oncological drugs and biological products in the postapproval setting.

Questions about whether a drug causes or influences cancer development and how this cancer risk can be evaluated are frequent concerns posed to FDA. Cancer signals can arise from premarket non-clinical and clinical trial data, and also from spontaneous adverse event reports or other studies conducted following a drug's approval. Unfortunately, further evaluation of these cancer signals is hindered by methodological limitations of tools and data available in the postapproval setting, particularly in light of the often complex exposure patterns and expected long latency of certain cancer outcomes. In the preapproval setting, randomized controlled trials (RCTs) are considered the gold standard in evaluating drug efficacy, and can evaluate frequently occurring and short-latency adverse events. However, due to certain limitations, RCTs are not best suited to identify the occurrence of cancer as an adverse outcome associated with drug treatment, although cancer events observed in trials raise concerns. Preapproval RCTs have important limitations, such as use of restricted populations, limited number of participants, as well as short duration and followup time. Postapproval studies, frequently observational, better reflect real-world-use patterns and capture the clinical experience for a larger number of individuals over time. In theory, these studies are better positioned to evaluate rare and longer-latency drug safety signals, including cancer signals. In practice, however, evaluating drug-related cancer outcomes using observational data is hampered by important methodological limitations, including difficulties in determining the timing of the outcome occurrence accurately, difficulties in identifying the biologically relevant period of risk, and challenges in handling complex exposure patterns over time, among others.

Given the many methodological challenges in the postmarketing evaluation of adverse cancer outcomes associated with use of non-oncological products and current gaps in knowledge, FDA, in collaboration with NCI, is sponsoring a public meeting to seek input from industry, academia, public health agencies, the clinical community, and other stakeholders.

The meeting will include multiple sessions over 2 days.

II. Scope of the Meeting

The objective of the meeting is to engage researchers, industry, public health agencies, health care providers, and the public through presentations and panel discussions on the following topics:

Topic 1: Determination of exposure and identification of relevant risk window. The ability to accurately capture complex drug-use patterns over a period of time, to determine the most appropriate exposure metric(s), and to identify the most biologically relevant risk periods are essential elements in the appropriate postapproval evaluation of cancer-related outcomes associated with use of non-oncological drugs and biological products. There is currently no consensus on how these elements should be considered in postapproval studies that evaluate cancer outcomes. Discussions will explore methodologies for determining informative exposure metric(s), thresholds, latency period, and length of followup. These discussions will be based on current knowledge of carcinogenesis, potential underlying biological mechanisms, and particular types of cancers (according to site or histology). Given uncertainties around defining some of these metrics, discussions may consider strategies beyond testing of hypotheses, including the use of exploratory hypotheses and sensitivity analyses, as well as consideration of scenarios under which postapproval studies are unlikely to be informative.

Topic 2: Identification of cancer-related outcome(s). The insidious nature of cancer events makes identification and timing-of-event occurrence challenging. Discussions will focus on relevant methodologies to identify cancer-related outcomes, as well as considerations regarding the challenges involved in identifying the sequence of symptoms that eventually lead to an accurate cancer diagnosis, a sequence that may be initiated before or during drug exposure.

Topic 3: Identification of population/data source. Identifying the relevant characteristics of the data or population source is crucial in conducting and interpreting postapproval evaluations of cancer signals. Discussions will focus on the essential characteristics of population/data source (e.g. administrative databases, registries, clinical encounters, surveys/interviews); the ability to appropriately capture medical history over time; and other information relevant to the evaluation of cancer outcomes, sample size, and participant followup.

Topic 4: Current thinking on cancer biology to inform epidemiology study design. It is noteworthy that recommendations for postapproval study designs to date have been based on the concept that cancer develops over a period of time, long after initiating drug treatment (long latency period). Nonetheless, several cancer-related signals have been observed during preapproval RCTs of non-oncological therapies, trials which typically have short duration of followup. Discussions will focus on the current thinking of potential biological mechanism(s) underlying purported drug-related increase in initiating, promoting, or detecting cancerous

tumors, with particular consideration given to scenarios where cancer signals arise at any time following drug exposure. Discussions will also focus on cancer biology (and the different types of tumors) to inform postapproval evaluation of cancer signals and to better identify the most relevant exposure metric and risk windows.

Information about this meeting, including registration and the agenda, will be posted at *http://www.fda.gov/Drugs/NewsEvents/ucm132703.htm* as it becomes available.

Dated: June 10, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–13907 Filed 6–13–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

American Indians Into Psychology

Announcement Type: New and Competing Continuation.

Funding Announcement Number: HHS–2014–IHS–INPSY–0001.

Catalog of Federal Domestic Assistance Number: 93.970.

Key Dates

Application Deadline Date: July 18, 2014.

Review Date: July 28, 2014.

Earliest Anticipated Start Date: September 01, 2014.

Proof of Non-Profit Status Due Date: July 18, 2014.

I. Funding Opportunity Description

Statutory Authority

The Indian Health Service (IHS) Office of Public Health Support (OPHS) is accepting competitive cooperative agreement applications for the American Indians into Psychology Program (Section 217). This program is authorized under Section 217 of the Indian Health Care Improvement Act, Public Law 94–437, as amended (IHCIA), codified at 25 U.S.C. 1621p(a–d). This program is described in the Catalog of Federal Domestic Assistance under 93.970.

Background

The IHS, an agency within the Department of Health and Human Services (HHS), is responsible for providing Federal health services to American Indians and Alaska Natives (AI/AN). The mission of the IHS is to raise the physical, mental, social, and spiritual health of AI/AN. The IHCIA authorizes the IHS to administer programs that are designed to attract and recruit qualified individuals into health professions needed at IHS facilities. The programs administered are designed to encourage AI/AN to enter health professions and to ensure the availability of health professionals to serve AI/AN populations. Section 217 of the IHCIA requires IHS to administer the American Indians into Psychology Scholarship Program. Within the Section 217 program, IHS provides grants to colleges, universities, and other entities to develop and maintain psychology education programs and recruit individuals to become Clinical Psychologists who will provide services to AI/AN people. Psychology program scholarship grants may be used by the educational institution to provide scholarships to students enrolled in clinical psychology education programs. According to the terms and conditions of the psychology program scholarship grant award, scholarship awards are for a 1-year period; additional scholarship support may be awarded to each eligible student for up to four years (maximum).

Purpose

The purpose of this IHS cooperative agreement is to augment the number of Clinical Psychologists who deliver health care services to AI/AN communities. The primary objectives of this cooperative agreement grant award are to: (1) Recruit and train individuals to be Clinical Psychologists; and (2) Provide scholarships to individuals enrolled in schools of clinical psychology to pay tuition, books, fees, and stipends for living expenses.

II. Award Information

Type of Award

Cooperative Agreement.

Estimated Funds Available

The total amount of funding identified for the current fiscal year 2014 is approximately $715,078. Individual award amounts are anticipated to be between $200,000 and $238,359. Awards issued under this announcement are subject to the availability of funds. In the absence of funding, the IHS is under no obligation to make awards that are selected for funding under this announcement.

Anticipated Number of Awards

Approximately three awards will be issued under this program announcement.

Project Period

The project period will be for five years and will run consecutively from September 1, 2014 to August 31, 2019.

In the HHS, a cooperative agreement is administered under the same policies as a grant. The funding agency (IHS) is required to have substantial programmatic involvement in the project during the entire award segment. Below is a detailed description of the level of involvement required for both IHS and the grantee. IHS will be responsible for activities listed under section A and the grantee will be responsible for activities listed under section B as stated:

Substantial Involvement Description for Cooperative Agreement

A. IHS Programmatic Involvement

(1) The IHS assigned program official will work closely with the project's Principal Investigator/Project Director to ensure timely receipt of the required semi-annual progress reports from each American Indians into Psychology grantee and review them for program compliance.

(2) The IHS assigned program official will provide programmatic technical assistance to the grantee as requested.

(3) The IHS assigned program official will coordinate and conduct site visits and semi-annual conference calls with grantees and students.

(4) The IHS assigned program official from the OPHS will work in partnership with the Division of Grants Management (DGM) to ensure all goals and objectives of the proposed project are met.

(5) The IHS assigned program official will provide an American Indians into Psychology scholarship handbook for student program review.

(6) The IHS assigned program official will initiate default proceedings within 90 days after receiving notification from the grantee that a student has been dismissed from the program, withdrawn from school, failed to graduate with a Ph.D. in Clinical Psychology, or failed to get licensed and begin obligated service time within 90 days.

B. Grantee Cooperative Agreement Award Activities

(1) The American Indians into Psychology grantee must designate a Principal Investigator/Project Director. The Project Director is the individual designated by the grant applicant to manage the project or activity being supported by the grant. He/she is responsible for the scientific or technical direction of the project, the day-to-day management of the program, and is accountable to the grantee for the