comments regarding this document. 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. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

Dated: September 9, 2005.

Linda S. Kahan,

Deputy Director, Center for Devices and Radiological Health.

[FR Doc. 05–18655 Filed 9–19–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0266]

Draft Guidance on Current Good Manufacturing Practice for Positron Emission Tomography Drug Products; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''PET Drug Products—Current Good Manufacturing Practice (CGMP).'' Elsewhere in this issue of the **Federal Register**, we are issuing proposed regulations on CGMPs for positron emission tomography (PET) drug products. We are making the draft guidance available so that producers of PET drugs can better understand FDA's thinking on CGMP compliance if the proposed regulations become final after notice-and-comment rulemaking.

DATES: Submit written or electronic comments on the draft guidance by December 19, 2005. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.

FOR FURTHER INFORMATION CONTACT: Brenda Uratani, Center for Drug Evaluation and Research (HFD–320), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–8941.

SUPPLEMENTARY INFORMATION:

I. Background

On November 21, 1997, the President signed the Food and Drug Administration Modernization Act of 1997 (Modernization Act) (Public Law 105–115) into law. Section 121(c)(1)(A) of the Modernization Act directs us to establish appropriate approval procedures and CGMP requirements for PET drugs. Section 121(c)(1)(B) states that, in adopting such requirements, we must take due account of any relevant differences between not-for-profit institutions that compound PET drugs for their patients and commercial manufacturers of the drugs. Section 121(c)(1)(B) also directs us to consult with patient advocacy groups, professional associations, manufacturers, and physicians and scientists who make or use PET drugs as we develop PET drug CGMP requirements and approval procedures.

We presented our initial tentative approach to PET drug CGMP requirements and responded to numerous questions and comments about that approach at a public meeting on February 19, 1999. In the **Federal Register** of September 22, 1999 (64 FR 51274), FDA published preliminary draft regulations on CGMP for PET drug products. FDA received comments on the preliminary draft regulations at another public meeting on the same subject on September 28, 1999. FDA made changes in the working draft in response to the public comments. In the **Federal Register** of April 1, 2002 (67 FR 15344), FDA published a preliminary draft proposed rule, in conjunction with the first draft guidance (67 FR 15404, April 1, 2002). FDA received written and oral comments on the preliminary draft proposed rule and the first draft guidance at a public meeting on May 21, 2002, and written comments after the May 2002 meeting, FDA has taken all comments into consideration in revising the preliminary draft proposed rule and the draft guidance. The draft guidance provides more details for discussion purposes on acceptable approaches to complying with the proposed regulations should they be published in final form.

Elsewhere in this issue of the **Federal Register**, we are publishing a proposed rule on CGMP for PET drug products. We are making this draft guidance available so that PET drug producers can better understand FDA's thinking on compliance with the proposed CGMP regulations if they become final after notice-and-comment rulemaking. We invite comments on whether the draft guidance would be a useful accompaniment to the proposed rule.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments on the draft guidance. Two paper copies of mailed comments are to be submitted, 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.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm*, *http://www.fda.gov/ohrms/dockets/default.htm*, or *http://www.fda.gov/cder/fdama* under ''Section 121—PET (Positron Emission Tomography).''

Dated: September 1, 2005.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 05–18509 Filed 9–15–05; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

National Indian Health Board

AGENCY: Indian Health Service, HHS.

ACTION: Notice to supplement the single-source cooperative agreement with the National Indian Health Board.

SUMMARY: The Indian Health Service (IHS) announces a supplement to the single-source cooperative agreement award to the National Indian Health Board (NIHB) for costs in providing advice and technical assistance to the IHS on behalf of federally recognized Tribes in the area of health care policy analysis and program development. The

NIHB is a non-profit organization as described in section 501(c)(3) of the Internal Revenue Code. The mission of the IHS is to work in partnership with American Indian and Alaska Native people to raise their health to the highest level. Under the original cooperative agreement published in the **Federal Register**, 69 FR 11447, on March 10, 2004, the NIHB assists the IHS in carrying out its mission through access to a broad based consumer network involving the Areas Health Boards or Health Board representatives from each of the 12 IHS Areas. The NIHB communicates with these boards and with Tribes and Tribal organizations in order to raise health of AI/AN people to the highest level. NIHB also disseminates health care information which serves to improve and expand access for American Indians and Alaska Natives (AI/AN) Tribal Governments to all available health programs in the Department of Health and Human Services (HHS). The NIHB assists in the coordination of the Tribal consultation activities associated with formulating the IHS annual budget request.

The program supplement to the single-source cooperative agreement is for $321,800 of non-recurring funding for use during the current budget period in effect from 01/01/2005 to 12/31/2005. The annual funding level of this single-source cooperative agreement is approximately $230,000, subject to the availability of appropriations.

Justification for Program Supplement

The program supplement is issued under the authority of the Public Health Service Act, section 301(a) and is included under the *Catalog of Federal Domestic Assistance* number 93.933. This supplement funding is related to the original goals of the cooperative agreement and does not represent an expansion of activities outside of the present scope of work. The **Federal Register** Notice for the sole-source cooperative agreement award can be found in 69 FR 11447, published on March 10, 2004. The specific objectives and justifications for this program supplement are as follows:

1. Outreach and Education Within the AI/AN Community Concerning the Programs of the Centers for Medicare and Medicaid Services (CMS)

We anticipate funding will be transferred through an inter-agency agreement between CMS and the IHS to supplement the NIHB cooperative agreement. the NIHB will inform and educated AI/AN beneficiaries on programs and opportunities that can be accessed in CMS. The NIHB will dedicate one full day of its upcoming annual health conference (*i.e.,* the 22nd Annual NIHB Consumer Conference in October 2005) to familiarize the anticipated 800 attendees with CMS and its programs. In addition the NIHB will provide expertise and assistance to he Tribal Technical Advisory Group (TTAG) with consultation efforts to ensure that Tribes have input in the development of both the CMS Tribal strategic plan and the CMS consultation policy for AI/AN's. This supplement will benefit AI/AN's by informing a AI/AN's of CMS programs established address health care needs of which they may not otherwise be aware. The benefit to the IHS is increased funding resources to the AI/AN beneficiaries. This effort is consistent with the NIHB's goals of expanding the access to other programs of the HHS for AI/AN.

2. Enumeration of the Public Health Infrastructure in AI/AN Communities

We anticipate funding will be transferred to the IHS from the CDC to conduct a study of the status of Tribal public health capacity in areas such as epidemiology disease surveillance, public health nursing, community environmental health, health education and promotion, and other preventative health capacities. A paucity of information exists about the prevention capacity available throughout the Tribal Public Health System (TPHS) which broadly includes Tribal health departments, health committees, service units, and services provided by Indian Health Boards. The study, which will be undertaken by the NIHB, will provide current and accurate date on the Tribal Public Health System and will serve as a foundation for public health workforce research, workforce development efforts and demonstration programs and discussions on the training needs of public health workers. This effort is consistent with the NIHB's goal of providing advice and assistance in the areas of health care policy analysis and program development.

3. Support of the Activities of the Tribal Leader's Diabetes Committee

Efforts to prevent and combat diabetes and its complications have been major activities for the IHS over the last several years that have resulted in numerous positive accomplishments. A major reason for this success had been the active involvement of AI/AN Tribal Leadership in determining, with the IHS, how resources should be targeted, and ''best practices'' that can be replicated throughout the Indian Country. Funding through the supplement will enable the NIHB to provide support to the Tribal Leaders Diabetes Committees (TLDC), which provide advice and recommendations to the NIHB on the public health effort to prevent and control diabetes. This effort is consistent with the NIHB goals of providing advice and assistance in the areas of policy analysis and program development and in ensuring that health care advocacy is based on input from Tribal Government.

Justification for Single Source: This project has been awarded on a non-competitive, single-source basis. The NIHB is the only national AI/AN organization with health expertise that represents the interest of all federally recognized Tribes.

Use of Cooperative Agreement: The program supplement to the original cooperative agreement has been awarded because of anticipated substantial programmatic involvement by IHS staff in the project. The substantial programmatic involvement includes the following:

1. The IHS staff will have approval over the hiring of key personnel as defined by regulation or provisions in the cooperative agreement.

2. The IHS will provide technical assistance to the NIHB as requested and attend and participate in all NIHB board meetings.

FOR FURTHER INFORMATION CONTACT: Mr. Douglas Black, Director, Office of Tribal Programs, Office of the Director, Indian Health Service, 801 Thompson Avenue, Reyes Building, Suite 220, Rockville, Maryland 20852, (301) 443–1104. For grants information, contact Ms. Sylvia Ryan, Grants Management Specialist, Division of Grants Policy, 12300 Twinbrook Parkway, Suite 100, Rockville, Maryland 20852, (301) 443–5204.

Dated: September 13, 2005.

Robert G. McSwain,

Deputy Director, Indian Health Service.

[FR Doc. 05–18653 Filed 9–19–05; 8:45 am]

BILLING CODE 4165–16–M

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Federal Emergency Management Agency, Emergency Preparedness and Response Directorate, U.S. Department of Homeland Security.