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Draft Guidance on Current Good Manufacturing Practice for Positron Emission Tomography Drug Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''PET Drug Products—Current Good Manufacturing Practice (CGMP).''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 We are making the draft guidance available so that producers of PET drugs can better understand FDA's thinking on CGMP compliance if the proposed regulations become final after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DATES: Submit written or electronic comments on the draft guidance by December 19, 2005.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ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 Submit written comments on the draft guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.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