DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D–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Draft Guidance on Current Good Manufacturing Practice for Positron Emission Tomography Drug Products; Availability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SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled ''PET Drug Products—Current Good Manufacturing Practice (CGMP).'' We are announcing the availability of preliminary draft proposed regulations elsewhere in this issue of the **Federal Register**. We are making the draft guidance available so that producers of positron emission tomography (PET) drugs will better understand FDA's thinking concerning CGMP compliance if the preliminary draft proposed regulations were to become final after notice and comment rulemaking.

DATES: A public meeting on the draft guidance will be held on May 21, 2002.

Submit written or electronic comments on the draft guidance by June 5, 2002.

ADDRESSES: Submit written requests for single copies of the draft guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.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 See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft guidance.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

FOR FURTHER INFORMATION CONTACT: Brenda Uratani, Center for Drug Evaluation and Research (HFD–325), Food and Drug Administration, 7520 Standish Pl., Rockville, MD 20855, 301–594–0098.

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), we published a notice of availability of preliminary draft regulations on CGMP for PET drug products. Those preliminary draft regulations were discussed at a subsequent public meeting on September 28, 1999.

After considering the comments on the preliminary draft regulations, we have decided to make several revisions to those regulations. Elsewhere in this issue of the **Federal Register**, we are announcing the availability of a preliminary draft proposed rule on CGMP for PET drug products. We are making this draft guidance available now so that PET drug producers will better understand FDA's thinking concerning compliance with the preliminary draft proposed CGMP regulations if they were to become final after notice and comment rulemaking. We invite comments on whether the guidance would be a useful accompaniment to the proposed rule. The preliminary draft proposed rule and the draft guidance will be discussed at a public meeting to be held on May 21, 2002, from 9 a.m. to 4:30 p.m., at 5630 Fishers Lane, rm. 1066, Rockville, MD 20852.

II. Comments

Interested persons may submit to the Dockets Management Branch (address above) written or electronic comments on the draft guidance. 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. Electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. The draft guidance and the comments submitted to the docket may be seen 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, http://www.fda.gov/ohrms/dockets/default.htm, or http://www.fda.gov/cder/fdama under ''Section 121—PET (Positron Emission Tomography).''

Dated: March 25, 2002.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–7729 Filed 3–29–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Indian Health Service

Proposed Collection; Comment Request

AGENCY: Indian Health Service.

ACTION: Request for public comment: 30-day proposed information collection; Hoz'ho'nii: An intervention to increase breast and cervical cancer screening among Navajo women.

SUMMARY: In compliance with section 3507(a)(1)(D) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed information collection projects, the Indian Health Service (IHS) has submitted to the Office of Management and Budget (OMB) a request to review and approve the information collection listed below. This proposed information collection project was previously published in the **Federal Register** (66 FR 66912) on December 27, 2001 and allowed 60 days for public comment. No public comment was received in response to the notice. The purpose of this notice is to allow 30 days for public comment to be submitted directly to OMB.

Proposed Collection: Title: Hoz'ho'nii: An Intervention To Increase Breast and Cervical Cancer Screening Among Navajo Women. *Type of Information Collection Request:* New. *Form Number:* None. *Need and Use of the Information Collection:* The information is needed to evaluate a culturally appropriate educational outreach program designed to increase breast and cervical cancer screening among Navajo women ages 20 and older. The purpose is to identify barriers that may prevent Navajo women from participating in breast and cervical cancer screening by comparing changes

in knowledge, attitudes, and behaviors of three study groups; educational outreach only, education outreach plus chapter-based clinic, and a control group. Results will be used to assess the impact of the impact of the educational outreach program, improve breast and cervical cancer screening, and to guide the IHS and Tribal health programs in the delivery of culturally appropriate intervention to reduce mortality rates from breast and cervical cancer among Navajo women. *Affected Public:* Individuals. *Type of Respondents:* Individuals. The table below provides the estimated burden response for this information collection:

ESTIMATED BURDEN RESPONSE TABLE

Data collection instrument	Estimated No. of respondents	Responses per respondent	Average burden hour per response	Total annual burden hrs
KAB Pretest	450	1	0.42 hr (25 minutes)	188.0
KAB Post test	450	1	0.42 hr (25 minutes)	188.0
Interviews	30	1	0.25 hr (15 minutes)	8.0
Total	930	1		384.0

[1] For ease of understanding, burden hours are also provided in actual minutes.

There are no Capital Costs, Operating Costs and/or Maintenance Costs to report for this information collection.

Request for Comments: Your written comments and/or suggestions are invited on one or more of the following points: (a) Whether the information collection activity is necessary to carry out an agency function; (b) whether the IHS processes the information collected in a useful and timely fashion; (c) the accuracy of the public burden estimate (the estimated amount of time needed for individual respondents to provide the requested information); (d) whether methodology and assumptions used to determine the estimate are logical; (e) ways to enhance the quality, utility, and clarity of the information being collection; and (f) was to minimize the public burden through the use of automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

Direct Comments to OMB: Send your written comments and suggestions regarding the proposed information collection contained in this notice, especially regarding the estimated public burden and associated response time, to: Office of Management and Budget, Office of Regulatory Affairs, New Executive Office Building, Room 10235, Washington, DC 20503, Attention: Desk Officer for IHS.

To request more information on the proposed collection or to obtain a copy of the data collection plan(s) and/or instruction(s), contact: Mr. Lance Hodahkwen, Sr., M.P.H., IHS Reports Clearance Officer, 12300 Twinbrook Parkway, Suite 450, Rockville, MD 20852–1601, or call non-toll free (301) 443–5938, or send via facsimile to (301) 443–2613, or send your e-mail requests, comments, and return address to: *lhodahkwen@hqe.ihs.gov.*

Comment Due Date: Comments regarding this information collection are best assured of having their full effect if received within 30-days of the date of this publication.

Dated: March 3, 2002.

Michael H. Trujillo,

Assistant Surgeon General, Director, Indian Health Service.

[FR Doc. 02–7763 Filed 3–29–02; 8:45 am]

BILLING CODE 4160–16

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Consensus Development Conference on Management of Hepatitis C: 2002

Notice is hereby given of the National Institutes of Health (NIH) Consensus Development Conference on ''Management of Hepatitis C: 2002'' to be held June 10–12, 2002, in the NIH Natcher Conference Center, 45 Center Drive, Bethesda, Maryland 20892. The conference will begin at 8 a.m. on June 10 and 11, and at 9 a.m. on June 12 and will be open to the public.

The hepatitis C virus (HCV) is the leading cause of liver disease in the United States and certainly the most common cause of cirrhosis and hepatocellular carcinoma; it is also the most common reason for liver transplantation. Almost 4 million people in this country are believed to be infected with this virus. A Consensus Development Conference on hepatitis C was held at the National Institutes of Health in March 1997. This led to an important, widely distributed NIH Consensus Statement that, for several years, was broadly accepted as the standard of care.

In the five years since that time, there has been a dramatic increase in knowledge of the condition, indicating the need to re-examine the approaches to management and treatment. This conference is convened with the aim of reviewing the most recent developments regarding management, treatment options, and the widening spectrum of potential candidates for treatment.

During the first day-and-a-half of the conference, experts will present the latest hepatitis C research findings to an independent, non-Federal panel. After weighing all of the scientific evidence, the panel will draft a statement, addressing the following key questions:

- What is the natural history of hepatitis C?
- What is the most appropriate approach to diagnose and monitor patients?
- What is the most effective therapy for hepatitis C?
- Which patients with hepatitis C should be treated?
- What recommendations can be made to patients to prevent transmission of hepatitis C?
- What are the most important areas for future research?

On the final day of the conference, the panel chairperson will read the draft statement to the conference audience and invite comments and questions. A press conference will follow, to allow the panel and chairperson to respond to questions from the media.

The primary sponsors of this meeting are the National Institute of Diabetes and Digestive and Kidney Diseases and the NIH Office of Medical Applications of Research. Cosponsors of the meeting are: Centers for Disease Control and Prevention (CDC), the U.S. Food and Drug Administration (FDA), the U.S. Department of Veterans Affairs (VA), the National Institute of Child Health and Human Development (NICHD), the National Cancer Institute (NCI), the National Center for Complementary and Alternative Medicine (NCCAM), the National Institute on Alcohol Abuse and Alcoholism (NIAAA), the National Institute of Allergy and Infectious Diseases (NIAID), and the National