Dated: April 15, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–9927 Filed 4–20–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

The National Center for Environmental Health (NCEH) of the Centers for Disease Control and Prevention (CDC) Announces the Following Public Meetings

Name: Update on Hanford Thyroid Disease Study Draft Final Report.

Dates: Wednesday, May 5, 1999, Thursday, May 6, 1999

Times: 7 p.m.–9 p.m., 7 p.m.–9 p.m.

Place: WestCoast Ridpath Hotel, West 515 Spraque, Spokane, Washington 99201,

*Tel: (*509) 838–2711, Doubletree Hotel Seattle Airport, 18740 Pacific Highway South, Seattle, Washington 98188, (206) 246–8600.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 200 people.

Purpose

The CDC and investigators from Seattle's Fred Hutchinson Cancer Research Center (FHCRC) will discuss findings on the Hanford Thyroid Disease Study Draft Final Report. The purpose of the study was to determine if there was an increased risk for thyroid disease among a randomly selected study population exposed to atmospheric releases of radioactive iodine-131 (I–131) from the Hanford Nuclear Site in eastern Washington State during the 1940s and 1950s. The study, mandated by Congress, was conducted by a team of scientists at the FHCRC under contract from the CDC.

Background

In 1986, Freedom of Information Act requests led the Department of Energy to make public thousands of pages of documentation indicating that large quantities of radioactive materials were released into the atmosphere from the Hanford Nuclear Site. The radioactivity was a byproduct of nuclear weapons production from December 1944 through 1957. Most of the radioactivity was released in the form of I–131, which concentrates in the thyroid glands of those who eat food contaminated by it. The amount of I–131 released during this period was more than half a million curies, prompting concern regarding thyroid health effects. The government convened a special Hanford Health Effects Review Panel to review the documents and recommend steps to evaluate possible health consequences among those who live near the Hanford Site.

Two studies were undertaken as a result of these recommendations. The first was the Hanford Environmental Dose Reconstruction Project which estimated potential radiation doses to the thyroid among persons exposed to Hanford I–131 releases. The second was the Hanford Thyroid Disease Study. This study was designed to determine whether the exposures from Hanford resulted in an increased risk of thyroid disease in a randomly selected study population. In late 1989, a contract to perform this study was awarded to the FHCRC.

CONTACT PERSONS FOR ADDITIONAL INFORMATION: General information may be obtained from Mr. Mike Donnelly, Project Officer, Radiation Studies Branch (RSB), Division of Environmental Hazards and Health Effects (DEHHE), NCEH, CDC, 4770 Buford Highway, NE, M/S (F–35), Atlanta, Georgia 30341–3724, telephone 770–488–7040, fax 770–488–7044. Technical information may be obtained from Dr. Paul Garbe, RSB, DEHHE, NCEH, CDC, 4770 Buford Highway, NE, (F–35), Atlanta, Georgia 30341–3724, telephone 770–488–7040, fax 770–488–7044.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities, for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: April 15, 1999.

Carolyn J. Russell,

Director, Management Analysis and Services Office Centers for Disease Control and Prevention (CDC).

[FR Doc. 99–9926 Filed 4–20–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 99D–0674]

Draft Guidance for Industry on IND's for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format; 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 ''INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format.'' This draft guidance is intended to provide recommendations to sponsors of investigational new drug applications (IND's) on the chemistry, manufacturing, and controls documentation (CMC), including microbiology documentation, that should be submitted for phase 2 and 3 of IND's. This draft guidance applies to human drugs and specified-biotechnology derived products.

DATES: Written comments on the draft guidance document may be submitted by July 20, 1999. General comments on agency guidance documents are welcome at any time.

ADDRESSES: Submit written requests for single copies of the draft guidance for industry to the Drug Information Branch (HFD–210), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, or the Office of Communication, Training, and Manufacturers Assistance (HFM–40), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448. Send one self-addressed adhesive label to assist the office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft. Submit written comments on the draft guidance to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Charles P. Hoiberg, Center for Drug Evaluation and Research (HFD–810), Food and Drug

Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–2570, or

Robert A. Yetter, Center for Biologics Evaluation and Research (HFM–10), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852, 301–827–0373.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''INDs for Phase 2 and 3 Studies of Drugs, Including Specified Therapeutic Biotechnology-Derived Products; Chemistry, Manufacturing, and Controls Content and Format.'' This draft guidance is intended to: (1) Facilitate drug discovery and development, (2) ensure that sufficient data will be submitted for the agency to assess the safety as well as the quality of the proposed clinical studies from the CMC and microbiology perspectives, and (3) expedite the entry of new drugs into the marketplace.

This level 1 draft guidance is being issued consistent with FDA's good guidance practices (62 FR 8961, February 27, 1997). This draft guidance represents the agency's current thinking on CMC content and format of IND's for phase 2 and 3 studies of drugs, including specified therapeutic biotechnology-derived products. 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 statute, regulations, or both.

II. Comments

Interested persons may submit written comments on the draft guidance to the Dockets Management Branch (address above). 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. The draft guidance and received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Copies of this draft guidance are available on the Internet at ''http://www.fda.gov/cder/guidance/index.htm'' or ''http://www.fda.gov/cber/guidelines.htm''.

Dated: April 13, 1999.

William K. Hubbard,

Acting Deputy Commissioner for Policy.

[FR Doc. 99–9769 Filed 4–20–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–1728 and HCFA–R–0266]

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

AGENCY: Health Care Financing Administration; HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Home Health Agency Cost Report and Supporting Regulations in 42 CFR 413.20, 413.24 and 413.106; *Form No.:* HCFA–1728 (OMB No. 0938–0022); *Use:* Participating providers are required to submit annual information to HCFA in order to achieve settlement of costs for health care services rendered to Medicare beneficiaries. The HCFA–1728 is the form used by Home Health Agencies to report their health care costs to determine the amount reimbursable for services furnished to Medicare beneficiaries. *Frequency:* Annually; *Affected Public:* Business or other for profit, Not for profit institutions, and State, Local or Tribal Gov.; *Number of Respondents:* 8,950; *Total Annual Responses:* 8,950; *Total Annual Hours Requested:* 1,575,200.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Disproportionate Share Hospital Payments—Institutions for Mental Disease; *Form No.:* HCFA–R–0266 (OMB# 0938–0746); *Use:* This PRA package announces the Federal share of disproportionate share hospital (DSH) allotments for Federal fiscal years (FFYs) 1998 through 2002. It also describes the methodology for calculating the Federal share DSH allotments for FFY 2003 and thereafter, and announces the FFY 1998 and FFY 1999 limitations on aggregate DSH payments States may make to institutions for mental disease (IMD) and other mental health facilities.; *Frequency:* Annually; *Affected Public:* State, Local, or Tribal Government; *Number of Respondents:* 54; *Total Annual Responses:* 54; *Total Annual Hours:* 2,160.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access HCFA's Web Site address at http://www.hcfa.gov/regs/prdact95.htm, or E-mail your request, including your address, phone number, OMB number, and HCFA document identifier, to Paperwork@hcfa.gov, or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Allison Eydt, New Executive Office Building, Room 10235, Washington, D.C. 20503.

Dated: April 13, 1999.

John P. Burke III,

HCFA Reports Clearance Officer, HCFA Office of Information Services, Security and Standards Group, Division of HCFA Enterprise Standards.

[FR Doc. 99–9969 Filed 4–20–99; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Care Financing Administration

[Document Identifier: HCFA–R–0268, R–0271, and R–0274]

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

AGENCY: Health Care Financing Administration, HHS.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send