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 Meeting

Name: Advisory Committee to the Director, National Center for Environmental Health.

Times and Dates: 10 a.m.–5:15 p.m., May 3, 1999. 8:30 a.m.–3:30 p.m., May 4, 1999.

Place: Swissotel, 3391 Peachtree Street, NE, Atlanta, Georgia, 30326 (next to Lenox Square), in the ''Zermatt'' room, telephone 404/365–0065.

Status: Open to the public, limited only by the space available. The meeting room will accommodate approximately 20 committee members and presenters, plus 20 observers.

Matters to be Discussed

The Committee will provide advice on the following: environmental public health problems that potentially pose the greatest risks to human health and may not be receiving adequate attention; the primary prevention of birth defects and developmental and other disabilities; the prevention of secondary conditions in persons with a primary disability; and the research agenda needed to improve the science base relative to human health effects and environmental exposures and that will ultimately provide sound human health data for policy and decision-making. Particular attention will be paid to the matters of NCEH surveillance systems and the relationship between genetics and public health.

Persons wishing to make written or oral comments at the meeting should notify the contact person in writing or by telephone no later than close of business April 26, 1999.

Requests to make oral comments should contain the name, address, telephone number, and organizational affiliation of the presenter. Depending on the time available and the number of requests to make oral comments, it may be necessary to limit the time of each presenter.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Anne Wilson, Program Analyst, Office of the Director, NCEH, CDC, 4770 Buford Highway, NE, M/S F49, Atlanta, Georgia 30341–3724, telephone 770/488–7321, fax 770/488–7024, e-mail: amw6@cdc.gov

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. 99–9925 Filed 4–20–99; 8:45 am]

BILLING CODE 4163–18–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Hanford Thyroid Morbidity Study Advisory Committee: Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following meeting.

Name: Hanford Thyroid Morbidity Study Advisory Committee.

Times and Date: 1 p.m.–5 p.m., May 6, 1999; 7 p.m.–9 p.m., May 6, 1999.

Place: Doubletree Hotel Seattle Airport, 18740 Pacific Highway South, Seattle, Washington 98188, telephone 206/246–8600, fax 206/431–8687.

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 present and discuss findings of the Hanford Thyroid Disease Study and appropriate activities to follow-up study results to the Hanford Thyroid Morbidity Study Advisory Committee. The Committee will continue in evening session at 7 p.m., with a presentation by CDC, and/or its contractor, on the findings of the Hanford Thyroid Disease Study Draft Final Report and to allow more time for public input and comment. 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), National Center for Environmental Health (NCEH), CDC, 4770 Buford Highway, NE, (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.

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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]

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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.

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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]

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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