

**ACTION:** Correction notice.

**SUMMARY:** This notice amends the statement of Organization, Functions and Delegations of Authority for the Department of Health and Human Services, Administration for Children and Families, published in the Federal Register August 9, 1995 (60 FR 40586).

**FOR FURTHER INFORMATION CONTACT:** Howard Rolston (202) 401-9220.

**SUPPLEMENTARY INFORMATION:** The notice published in the Federal Register on August 9, 1995, amended Part K of the Statement of Organization, Functions and Delegations of Authority of the Department of Health and Human Services as it applies to certain offices within the Administration for Children and Families. One of those offices is the Office of Planning, Research and Evaluation, Chapter KM.

As published, the functional statement of the Office of Planning, Research and Evaluation, Division of Child and Family Development, included extraneous and misplaced words (60 FR 40591). For clarity, the functional statement for this Division is published in its entirety below:

#### KM.10 Organization

The Office of Planning, Research and Evaluation is headed by a Director who reports to the Deputy Assistant Secretary for Policy and External Affairs. The Office is organized as follows:

- Office of the Director (KMA).
- Division of Economic Independence (KMB).
- Division of Child and Family Development (KMC).

#### KM.20 Functions

A. \* \* \* \* \*

B. \* \* \* \* \*

#### C. The Division of Child and Family Development

The Division of Child and Family Development, in cooperation with ACF programs and others, works with Federal counterparts, states, community agencies, and the private sector to: improve the effectiveness and efficiency of programs; assure the protection of children and other vulnerable populations; strengthen and promote family stability; and foster sound growth and development of children and their families.

The Division provides guidance, analysis, technical assistance and oversight in ACF on: Strategic planning and performance measurement for child and family development; statistical, policy and program analysis; surveys, research and evaluation methodologies; demonstration testing and model

development; synthesis and dissemination of research and demonstration findings; and application of emerging technologies to improve the effectiveness of programs and service delivery.

The Division: Manages the section 1110 social service research budget; develops policy-relevant priorities; conducts, manages and coordinates major cross-program, leading-edge research, demonstration, and evaluation studies; manages and conducts statistical, policy and program analyses on social trends and behaviors which impact child and family well-being; and works in partnership with states, local communities, and the private sector to promote the well-being of children and families.

Dated: November 3, 1995.

Mary Jo Bane,

*Assistant Secretary for Children and Families.*

[FR Doc. 95-27774 Filed 11-8-95; 8:45 am]

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### Agency for Toxic Substances and Disease Registry

#### Public Meeting of the Inter-tribal Council on Hanford Health Projects (ICHHP)

The Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

*Name:* Public Meeting of the Inter-tribal Council on Hanford Health Projects (ICHHP), in association with the meeting of the Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Hanford Health Effects Subcommittee (HHES).

*Time and Date:* 9 a.m.-4:30 p.m., November 29, 1995.

*Location:* Edgewater Inn, 2411 Alaskan Way-Pier 67, Seattle, Washington 98121, telephone 206/728-7000, FAX 206/441-4119.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 50 people.

*Background:* A Memorandum of Understanding (MOU) was signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund"). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health

surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

In addition, under an MOU signed in December 1990 with DOE, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production and use. HHS delegated program responsibility to CDC.

Community involvement is a critical part of ATSDR's and CDC's energy-related research and activities and input from members of the ICHHP is part of these efforts. The ICHHP will work with the HHES to provide input on Native American health effects at the Hanford, Washington, site.

*Purpose:* The purpose of this meeting is to address issues that are unique to tribal involvement with the HHES including considerations regarding a proposed medical monitoring program and explorations of options and alternatives to providing support for tribal involvement in the HHES.

*Matters to be Discussed:* Agenda items will include a dialogue pertaining to issues unique to tribal involvement with HHES. This will include an update on the status of ATSDR's draft policy on establishing government-to-government relations with the nine affected tribes as sovereign nations, and exploring options and alternatives to providing support for tribal participation in HHES.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Linda A. Carnes, Health Council Advisor, ATSDR, E-28, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639-0730, FAX 404/639-0759.

Dated: November 3, 1995.

Carolyn J. Russell,

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

[FR Doc. 95-27770 Filed 11-8-95; 8:45 am]

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### Public Health Service, Activities and Research at Department of Energy Sites, Citizens Advisory Committee

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Agency for Toxic Substances and Disease Registry (ATSDR) and the Centers for Disease Control and Prevention (CDC) announce the following meeting.

*Name:* Citizens Advisory Committee on Public Health Service Activities and Research at DOE Sites: Hanford Health Effects Subcommittee (HHES).

*Times and Dates:* 9 a.m.-9 p.m., November 30, 1995. 9:15 a.m.-4 p.m., December 1, 1995.

*Place:* Edgewater Inn, 2411 Alaskan Way-Pier 67, Seattle, Washington 98121, telephone 206/728-7000, FAX 206/441-4119.

*Status:* Open to the public, limited only by the space available. The meeting room accommodates approximately 150 people.

*Background:* A Memorandum of Understanding (MOU) was signed in October 1990 and renewed in November 1992 between ATSDR and DOE. The MOU delineates the responsibilities and procedures for ATSDR's public health activities at DOE sites required under sections 104, 105, 107, and 120 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA or "Superfund"). These activities include health consultations and public health assessments at DOE sites listed on, or proposed for, the Superfund National Priorities List and at sites that are the subject of petitions from the public; and other health-related activities such as epidemiologic studies, health surveillance, exposure and disease registries, health education, substance-specific applied research, emergency response, and preparation of toxicological profiles.

In addition, under an MOU signed in December 1990 with DOE, the Department of Health and Human Services (HHS) has been given the responsibility and resources for conducting analytic epidemiologic investigations of residents of communities in the vicinity of DOE facilities, workers at DOE facilities, and other persons potentially exposed to radiation or to potential hazards from non-nuclear energy production and use. HHS delegated program responsibility to CDC.

*Purpose:* The purpose of this meeting is to receive updates from the Inter-tribal Council on Hanford Health Projects; receive updates and clarification from ATSDR and CDC representatives on outstanding issues; discuss with Agency personnel, issues relevant to the Technical Steering Panel of the Hanford Environmental Dose Reconstruction Project; receive a report on the "Workshop on Radiation Health Risks for Hanford: Considerations for Medical Monitoring"; receive reports from the Outreach, Public Health Activities, and Health Studies Work Groups; and receive a presentation on "other contaminants of concern."

*Matters to be Discussed:* Agenda items will include ATSDR's and CDC's updates, a discussion of "Popular Epidemiology," and solicitation of concerns the Subcommittee wants ATSDR and CDC to address.

Agenda items are subject to change as priorities dictate.

*Contact Person for More Information:* Linda A. Carnes, Health Council Advisor, ATSDR, E-28, 1600 Clifton Road, NE, Atlanta, Georgia 30333, telephone 404/639-0730, FAX 404/639-0759.

Dated: November 3, 1995.

Carolyn J. Russell,

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

[FR Doc. 95-27771 Filed 11-8-95; 8:45 am]

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## Food and Drug Administration

[Docket No. 88N-0394]

### Generic Animal Drug and Patent Term Restoration Act; Ninth Policy Letter; Availability

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of a ninth policy letter, dated June 27, 1995, concerning implementation of the Generic Animal Drug and Patent Term Restoration Act (GADPTRA). The ninth policy letter states the revised policy of the Center for Veterinary Medicine (CVM) on the environmental information to be submitted by sponsors for generic animal drug products. The agency is soliciting comments on the policy letter.

**DATES:** Written comments may be submitted at any time regarding this or previous policy letters or implementation of GADPTRA in general.

**ADDRESSES:** Submit written requests for single copies of the ninth policy letter to the Industry Information Staff (HFV-12), Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855. Send two self-addressed adhesive labels to assist that office in processing your request. Submit written comments on the ninth policy letter to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Requests and comments should be identified with the docket number found in brackets in the heading of this document. The ninth policy letter and received comments are available for public examination in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

**FOR FURTHER INFORMATION CONTACT:** Charles E. Eirkson, Center for Veterinary Medicine (HFV-152), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1683.

**SUPPLEMENTARY INFORMATION:** On November 16, 1988, President Reagan signed GADPTRA into law (Pub. L. 100-670). GADPTRA amends the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 *et seq.*) by extending the generic approval system to copies of new animal drugs that were approved after October 10, 1962, and provides patent extension for certain animal drugs.

FDA has published notices of availability for eight policy letters concerning implementation of

GADPTRA. A list of the publication dates and topics of the first five letters was published in the Federal Register of June 18, 1990 (55 FR 24645). In the Federal Register of October 31, 1990 (55 FR 45860), FDA published a notice of availability of the sixth letter dated October 17, 1990. In the Federal Register of April 15, 1991 (56 FR 15083), FDA published a notice of availability of the seventh policy letter dated March 20, 1991. In the Federal Register of August 21, 1991 (56 FR 41561), FDA published a notice of availability of the eighth policy letter dated July 23, 1991.

FDA is now announcing the availability of a ninth policy letter dated June 27, 1995, which is a revision of the second policy letter, dated June 7, 1989. The second letter notified sponsors to submit an environmental assessment (EA) that addresses the environmental impact associated with the manufacture of the generic bulk drug and finished product. Based on the experience acquired from reviewing a considerable number of these EA's with no significant environmental impact identified, CVM has confirmed that there is no reason to believe the manufacture of generic animal drugs may significantly affect the environment and decided, in most cases, CVM will categorically exclude generic animal drug applications from preparation of an EA under 21 CFR 25.24(d)(1).

This policy does not create or confer any rights, privileges, or benefits for or on any person, nor does it operate to bind FDA in any way. The agency anticipates that changes in these policy statements may occur in the future. When and if changes are made, copies of the revised policy statements will be placed on display in the Dockets Management Branch (address above) and a notice of availability will be published in the Federal Register.

In addition, the subjects contained in these policy statements may be addressed in the regulations that will implement GADPTRA. Comments submitted in response to this notice will be considered in the drafting of the proposed regulations.

Dated: November 3, 1995.

William B. Schultz,

*Deputy Commissioner for Policy.*

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