DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Findings of Scientific Misconduct

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Office of Research Integrity (ORI) has made a final finding of scientific misconduct in the following case:

David N. Shapiro, M.D., St. Jude Children's Research Hospital: Based upon a report from St. Jude Children's Research Hospital as well as information obtained by the Office of Research Integrity (ORI) during its oversight review, ORI found that Dr. Shapiro, former faculty member, St. Jude Children's Research Hospital, engaged in scientific misconduct by falsifying the authorship of five publications listed in his biographical sketches in several National Institutes of Health (NIH) grant applications, including applications submitted to the National Institute of Arthritis and Musculoskeletal and Skin Diseases (NIAMS), the National Institute of General Medical Sciences (NIGMS), the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and the National Cancer Institute (NCI).

Specifically, Dr. Shapiro listed himself as an author when he was not. Dr. Shapiro also fabricated data for Figures 5 and 7 in the following publication: Sublett, J.E., Jeon, I.S., & Shapiro, D.N. ''The aveolar rhabdomyosarcoma *PAX3/FKHR* fusion protein is a transcriptional activator.'' *Oncogene* 11:545–552, 1995. Dr. Shapiro has submitted a letter to *Oncogene* requesting retraction of these figures.

Dr. Shapiro has accepted the ORI finding and has entered into a Voluntary Exclusion Agreement with ORI in which he has voluntarily agreed:

(1) To exclude himself from serving in any advisory capacity to the Public Health Service (PHS), including but not limited to service on any PHS advisory committee, board, and/or peer review committee, or as a consultant for a period of three (3) years, beginning on July 29, 1997;

(2) To exclude himself from any contracting or subcontracting with any agency of the United States Government and from eligibility for, or involvement in, nonprocurement transactions (e.g., grants and cooperative agreements) of the United States Government as defined in 45 CFR part 76 (Debarment Regulations) for a period of two (2) years, beginning on July 29, 1997;

(3) That any institution that submits an application for PHS support for a research project on which Dr. Shapiro's participation is proposed or that uses him in any capacity on PHS supported research must concurrently submit a plan for supervision of his duties to the funding agency for approval for a period of one (1) year following the two (2) year exclusion. The supervisory plan must be designed to ensure the scientific integrity of Dr. Shapiro's research contribution. The institution also must submit a copy of the supervisory plan to ORI.

FOR FURTHER INFORMATION CONTACT: Acting Director, Division of Research Investigations, Office of Research Integrity, 5515 Security Lane, Suite 700, Rockville, MD 20852, (301) 443–5330.

Chris B. Pascal,

Acting Director, Office of Research Integrity.

[FR Doc. 97–20816 Filed 8–6–97; 8:45 am]

BILLING CODE 4160–17–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

Notice of Meeting

The Agency for Toxic Substances and Disease Registry announces the following meeting.

Name: Expert Workshop Regarding Medical Monitoring in Bunker Hill, Idaho.

Times and Dates: 8:30 a.m.–5 p.m., August 19, 1997. 8:30 a.m.–5 p.m., August 20, 1997.

Place: Kellogg Middle School Library, 800 Bunker Avenue, Kellogg, Idaho 83837, telephone 208/784–1348.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 100 people.

Purpose: Target population(s) of residents and workers in and surrounding the former Bunker Hill lead and zinc smelting facility in Idaho have received past exposures to lead (and possibly other heavy metals).

The exposures have decreased markedly, but studies show adverse health outcomes in these populations, most probably as a result of the past exposures. The literature supports an association between known adverse health outcomes and lead exposure.

ATSDR wants to determine if there is a definable population at significantly increased risk of disease who may benefit from a medical monitoring program. ATSDR will judge the appropriateness of such a program by applying its medical monitoring criteria. If a program is deemed appropriate, the agency will develop a medical monitoring plan for the target population(s). ATSDR is planning three workshops consisting of external experts to provide individual input and guidance about applying the medical monitoring criteria to Bunker Hill. This announcement is for the first workshop; all three workshops will be open to the public.

Matters To Be Considered: The objective of the first workshop is to use all available information from ATSDR and other relevant data to make individual recommendations and answer questions related to the application of the first four ATSDR medical monitoring criteria at Bunker Hill, definition of the target populations, and specific outcomes as candidates for monitoring. Community and local health representatives and nationally recognized lead experts will convene to consider the first four ATSDR Medical Monitoring Criteria as they apply to Bunker Hill.

Agenda items are subject to change as priorities dictate.

Contact Person for More Information: Vivian Rush, M.D., Medical Officer, ATSDR-Division of Health Education and Promotion, 1600 Clifton Road, NE, M/S E–33, Atlanta, Georgia 30333; telephone 404/639–5080.

Dated: August 1, 1997.

Carolyn J. Russell,

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

[FR Doc. 97–20785 Filed 8–6–97; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Toxic Substances and Disease Registry

[ATSDR–123]

ATSDR's Interim Policy Guideline and Technical Support Document on Dioxin and Dioxin-Like Compounds in Soil

AGENCY: Agency for Toxic Substances and Disease Registry (ATSDR), Department of Health and Human Services (HHS).

ACTION: Notice of availability.

SUMMARY: This notice announces the availability of ATSDR's ''Interim Policy Guideline: Dioxin and Dioxin-Like Compounds in Soil,'' and the ''Technical Support Document for ATSDR Interim Policy Guideline: Dioxin and Dioxin-Like Compounds in Soil.'' ATSDR has adopted this interim policy guideline to assess the public health implications of dioxin and dioxin-like compounds in residential soils near or on hazardous waste sites. These compounds include 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD), related chlorinated dibenzo-p-dioxins (CDDs), chlorinated dibenzofurans (CDFs), and other structurally related groups of chemicals from the family of halogenated aromatic hydrocarbons.

DATES: Comments concerning this notice and the interim guidelines must be received by October 6, 1997.

ADDRESSES: Requests for a copy of these documents should be sent to the attention of Ms. Kim E. Jenkins, Division of Toxicology, Agency for Toxic Substances and Disease Registry, Mailstop E–29, 1600 Clifton Road, NE Atlanta, Georgia 30333. Requests for the documents must be in writing.

Comments on this notice should bear the docket control number ATSDR–123 and should be sent to the attention of Dr. Jim Holler, Agency for Toxic Substances and Disease Registry, Division of Toxicology, Emergency Response and Scientific Assessment Branch, 1600 Clifton Road, NE Mailstop E–29, Atlanta, Georgia 30333. Comments on this notice will be available for public inspection at the Agency for Toxic Substances and Disease Registry, Building 4, Executive Park Drive, Atlanta, Georgia (not a mailing address), from 8 a.m. until 4:30 p.m., Monday through Friday, except for legal holidays. Because all public comments are available for public inspection, no confidential business information should be submitted in response to this notice.

FOR FURTHER INFORMATION CONTACT: Dr. Christopher T. De Rosa, Director, Division of Toxicology, Agency for Toxic Substances and Disease Registry, 1600 Clifton Road, NE Mailstop E–29, Atlanta, Georgia 30333, telephone (404) 639–6300.

SUPPLEMENTARY INFORMATION: This interim policy guideline provides a description of ATSDR's current approaches and judgments regarding hazards posed by the presence of TCDD and its less toxic dioxin-like congeners, the CDDs and CDFs, in residential soils. Likely users of this interim policy guideline include health assessors at ATSDR and in the States, and ATSDR partners including relevant Federal, State, and local health and environmental entities, and concerned community groups who may be involved in a range of health assessment and risk management decisions.

The technical support document is intended to serve as technical background and support for the agency interim policy guideline and, to the extent practicable, harmonize such efforts with those of other Federal agencies and relevant organizations. This document reflects an assessment of current practice within the agency and defines the appropriate roles of professional judgment and emerging scientific principles in ATSDR's public health assessments of exposures to dioxin and dioxin-like compounds.

These guidelines and procedures apply to human exposure by direct ingestion of soils contaminated with dioxin and dioxin-like compounds in residential areas and may not be appropriate for exposure by other routes or media. This guidance will be evaluated in the future in view of new data that may become available.

Dated: July 31, 1997.

Georgi Jones,

Director, Office of Policy and External Affairs, Agency for Toxic Substances and Disease Registry.

[FR Doc. 97–20740 Filed 8–6–97; 8:45 am]

BILLING CODE 4163–70–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 97N–0040]

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

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the proposed collection of information listed below has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (the PRA).

DATES: Submit written comments on the collection of information by September 8, 1997.

ADDRESSES: Submit written comments on the collection of information to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Desk Officer for FDA.

FOR FURTHER INFORMATION CONTACT: Margaret R. Wolff, Office of Information Resources Management (HFA–250), Food and Drug Administration, 5600 Fishers Lane, rm. 16B–19, Rockville, MD 20857, 301–827–1223.

SUPPLEMENTARY INFORMATION: In compliance with section 3507 of the PRA (44 U.S.C. 3507), FDA has submitted the following proposed collection of information to OMB for review and clearance.

Survey of Food Safety Practices of Food Processing Firms—New Collection

FDA is evaluating the marginal costs of requiring food processors to use Hazard Analysis and Critical Control Point (HACCP) systems. HACCP is already required for seafood processors, and FDA is considering whether to issue regulations requiring HACCP for processors of other foods under the agency's jurisdiction. The analysis of marginal costs requires information about the prevalence of specific HACCP systems and practices among food manufacturers and repackers. FDA will collect this information through an anonymous voluntary survey of a random sample of food processors. Additionally, through a series of onsite visits to selected processors, a contractor will collect information on the marginal cost of various procedures required to operate a HACCP system. The information will help the Center for Food Safety and Applied Nutrition determine the baseline level of HACCP use from which to estimate the economic costs to the industry of mandatory HACCP regulations for foods other than seafood. FDA will use this information in tailoring any HACCP regulations that may issue so that costs and benefits of such regulations are appropriately considered.

In the **Federal Register** of February 28, 1997 (62 FR 9194), the agency requested comments on the proposed collection of information. FDA received one comment that supported the implementation of HACCP but questioned several aspects associated with the proposed survey. First, the comment questioned whether the survey would yield ''reliable'' or ''practical'' data because it was difficult to interpret what ''critical control point'' means and what the term ''hazards'' includes. The comment stated ''it is difficult to identify costs attributable only to HACCP in facilities where the system has been implemented.'' This comment is not relevant to the survey because the survey does not ask processors about critical control points, hazards, or costs of HACCP but, instead, seeks information on the processes and controls currently in place.

The comment also stated that FDA should use other sources of data. In fact, FDA is already planning to used multiple sources of information to estimate the marginal costs of requiring HACCP. These sources include interviews with food processing firms and information taken from pilot plants that are already using HACCP, and comments received during other HACCP rulemakings.