

presentations from the public will be scheduled between approximately 9 a.m. and 9:15 a.m., and between approximately 3:30 p.m. and 3:45 p.m., on May 26, 1998, and between approximately 9 a.m. and 9:15 a.m., and between approximately 1:30 p.m. and 1:45 p.m., and between approximately 3:30 p.m. and 3:45 p.m., on May 27, 1998. Time allotted for each presentation may be limited. Those desiring to make formal oral presentations should notify the contact person before May 19, 1998, and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation.

Closed Committee Deliberations: On May 26 and 27, 1998, from 8 a.m. to 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential information (5 U.S.C. 552b(c)(4)). These portions of the meeting will be closed to discuss pending investigational new drug applications or pending product licensing applications.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 28, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98-11806 Filed 5-4-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 98D-0149]

Guidance for Industry on National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs; Availability; Clarification

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; clarification.

SUMMARY: The Food and Drug Administration (FDA) is clarifying an administrative error relating to a notice that appeared in the **Federal Register** of April 9, 1998 (63 FR 17429). The notice announced the availability of a guidance for industry entitled "National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs." The agency displayed the incorrect draft of the guidance. This document clarifies that error.

FOR FURTHER INFORMATION CONTACT: Thomas C. Kuchenberg, Center for Drug

Evaluation and Research (HFD-7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-594-2041.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of April 9, 1998 (63 FR 17429), FDA published a notice announcing the availability of a guidance for industry entitled "National Uniformity for Nonprescription Drugs—Ingredient Listing for OTC Drugs." The agency, however, inadvertently put on display a working draft of the guidance dated February 1998, rather than the version the agency intends to implement, which is dated April 1998. This notice clarifies that error by announcing the availability of the April 1998 version of the guidance document and by withdrawing the February 1998 draft. Additionally, on February 19, 1998, FDA inadvertently put the working draft dated February 1998 on the Internet at <http://www.fda.gov/cder/guidance/index.htm>. The agency intends to replace the working draft that is on the Internet with the April 1998 version in the near future.

Dated: April 27, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-11841 Filed 5-4-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding is Sought

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the Office of the Director (OD), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Responsibility of Applicants for Promoting Objectivity in Research for Which Public Health Service (PHS) Funding is Sought: 42 CFR Part 50; 45 CFR Part 94. **Type of Information Collection Request:** Extension of OMB No. 0925-0417, expiration date 09/30/98. **Need and Use of Information Collection:** This is a request for OMB

approval for the information collection and recordkeeping requirements contained in the final rule 42 CFR Part 50 and 45 CFR Part 94. The purpose of the regulations is to protect the objectivity with which PHS-funded research is conducted. The regulations require disclosure of financial interests related to PHS-funded research by personnel who have decision-making responsibilities that could affect the outcome of the research. **Frequency of Response:** On occasion. **Affected Public:** Individuals or households; Business or other for-profit; Not-for-profit institutions; State, Local or Tribal Government. **Type of Respondents:** Any public or private entity or organization. The annual reporting burden is as follows: **Estimated Number of Respondents:** 57,235; **Estimated Number of Responses per Respondent:** 10; **Average Burden Hours per Response:** 20; and **Estimated Total Annual Burden Hours Requested:** 171,110. The annualized costs to respondents is estimated at: \$5,068,850. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

Request For Comments

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION CONTACT:

To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Thomas F. McCormack, Ph.D., Assistant Grant's Policy Officer, Office of Extramural Research, Office of Policy for Extramural Research Administration, 6701 Rockledge Drive, Bethesda, MD 20892, or call non-toll-free number (301) 435-0935 or E-mail your request,

including your address to:
TM102d@NIH.gov

Comments Due Date

Comments regarding this information collection are best assured of having their full effect if received on or before July 8, 1998.

Dated: April 28, 1998.

Geoffrey Grant,

Director, Office of Policy for Extramural Research Administration

[FR Doc. 98-11931 Filed 5-4-98; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Hazardous Waste Worker Training

SUMMARY: In compliance with the requirement of Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, for opportunity for public comment on proposed data collection projects, the National Institute of Environmental Health Sciences (NIEHS), the National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

Title: Hazardous Waste Worker Training—42 CFR part 65. **Type of Information Collection Request:** Revision of OMB No. 0925-0348, expiration date 09/30/98. **Need and Use of Information Collection:** This request for OMB review and approval of the information collection is required by regulation 42 CFR part 65(a)(6). The National Institute of Environmental Health Sciences (NIEHS) has been given major responsibility for initiating a worker safety and health training program under Section 126 of the Superfund Amendments and Reauthorization Act of 1986 (SARA) for hazardous waste workers and emergency responders. A network of non-profit organizations that are committed to protecting workers and their communities by delivering high-quality, peer-reviewed safety and health curricula to target populations of hazardous waste workers and emergency responders has been developed.

During the first ten years of the NIEHS Worker Training program (FY 1987-97), the NIEHS has successfully supported 20 primary grantees who have trained

over 1,140,000 workers across the country and presented nearly 60,000 classroom and hands-on training courses, which have accounted for almost 20 million contact hours of actual training. Generally, the grant will initially be for one year, and subsequent continuation awards are also for one year at a time.

Grantees must submit a separate application to have the support continued for each subsequent year. Grantees are to provide information in accordance with S65.4 (a), (b), (c), and 65.6(a) on the nature, duration, and purpose of the training, selection criteria for trainees' qualifications, and competency of the project director and staff, cooperative arrangements in the case of joint applications, the adequacy of training plans and resources, including budget and response to meeting training criteria in OSHA's Hazardous Waste Operations and Emergency Response Regulations (29 CFR 1910.120 and 29 CFR 1910.121). The information collection is used by the Director through officers, employees, experts, and consultants to evaluate applications based on technical merit to determine whether to make awards. **Frequency of Response:** Biannual. **Affected Public:** Non-profit organizations. **Type of Respondents:** Grantees. The annual reporting burden is as follows: **Estimated Number of Responses per Respondent:** 2; **Average Burden Hours per Response:** 8; and **Estimated Total Annual Burden Hours Requested:** 320. The annualized costs to respondents is estimated at: \$7,000. There are no Capital Costs, Operating Costs and/or Maintenance Costs to report.

Request for Comments

Written comments and/or suggestions from the public and affected agencies should address one or more of the following points: (1) Evaluate whether the proposed collection of information is necessary for the proper performance of the function of the agency, including whether the information will have practical utility; (2) Evaluate the accuracy of the agency's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) Enhance the quality, utility, and clarity of the information to be collected; and (4) Minimize the burden of the collection of information on those who are to respond, including the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology.

FOR FURTHER INFORMATION: To request more information on the proposed project or to obtain a copy of the data collection plans and instruments, contact: Joseph T. Hughes, Jr., Director, Worker Education and Training Program, Division of Extramural Research and Training, NIEHS, P.O. Box 12233, Research Triangle Park, NC 27709 or call non-toll-free number (919) 541-0217 or E-mail your request, including your address to hughes3@niehs.nih.gov.

COMMENTS DUE DATE: Comments regarding this information collection are best assured of having their full effect if received on or before July 6, 1998.

Dated: April 22, 1998.

Samuel Wilson,

Deputy Director, NIEHS.

[FR Doc. 98-11932 Filed 5-4-98; 8:45 am]

BILLING CODE 4140-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Proposed Collection; Comment Request; Human Research Subjects Payment Survey

SUMMARY: In compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, which provides for an opportunity for public comment on proposed data collection projects, the Department of Clinical Bioethics (DCB), National Institutes of Health (NIH) will publish periodic summaries of proposed projects to be submitted to the Office of Management and Budget (OMB) for review and approval.

Proposed Collection

The Department of Clinical Bioethics, Warren Grant Magnuson Clinical Center (CC), National Institutes of Health (NIH), intends to seek approval to conduct a survey aimed at payers of human research subjects, including drug companies, medical device manufacturers and academic research institutions, concerning the amount they pay to subjects of human medical research and what factors they consider in determining how much to pay subjects. Data collected will be used to assess methods for the determination of payments to research subjects. Results of the survey will be reported confidentially, in the aggregate and stripped of individual identifiers.

Estimate of burden: Public reporting burden for this collection of information is estimated to average 30 minutes per respondent.