regulatory expectations and to promote voluntary compliance with current FDA requirements.

DATES: Submit written or electronic comments on agency guidances at any time.

ADDRESSES: Submit written requests for single copies of this guidance to the Division of Drug Information (HFD–240), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your requests. Submit written comments on the guidance to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic comments to *http://www.fda.gov/dockets/ecomments*. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Paul W. Haynie, Center for Drug Evaluation and Research (HFD–327), Food and Drug Administration, 11919 Rockville Pike, Rockville, MD 20852, 301–827–9020.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production.'' This guidance document provides guidance to the pharmaceutical industry on investigation of laboratory results that fall outside of specification limits. The guidance addresses investigations of OOS results in the laboratory phase, including responsibilities of the analyst and supervisor, and when indicated, the expansion of an investigation outside of the laboratory to include production processes, and raw materials as appropriate. This guidance is intended to apply to traditional methods of drug product testing and release, based on testing of discrete samples of in-process materials and finished products. The guidance is not intended to address process analytical technology, as routine in-process use of these methods might include other considerations. The agency, in accordance with its August 2002 ''Pharmaceutical CGMPs for the 21st Century'' initiative, encourages modern approaches to manufacturing, monitoring, and control to enhance process predictability and efficiency. The use of continuous on-line testing technologies will be addressed in other agency guidance.

In the **Federal Register** of September 30, 1998 (63 FR 52276), FDA announced the availability of a draft guidance of the same title and gave interested persons an opportunity to submit comments by November 30, 1998. The agency received public comments from a broad spectrum of the pharmaceutical industry. In response to comments received on the draft guidance, the agency made the following changes: (1) Revised the scope and background sections to clarify the applicability of the document, (2) reorganized the sections on investigating OOS results, averaging, and concluding the investigation, and (3) clarified or added more specific guidance on certain issues.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the agency's current thinking on investigating OOS test results for pharmaceutical production. 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 statutes and regulations.

II. Comments

Interested persons may submit to the Division of Dockets Management (see **ADDRESSES**) written or electronic comments regarding this document. Submit a single copy of electronic comments or two paper copies of any mailed comments, except that individuals may submit one paper copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/cder/guidance/index.htm* or *http://www.fda.gov/ohrms/dockets/default.htm*.

Dated: October 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–16838 Filed 10–11–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Genes and Environment Initiative (GEI)—Exposure Biology Program; GEI—Exposure Biology RFA Application Information Meeting

AGENCY: National Institute of Environmental Health Sciences (NIEHS), National Institutes of Health (NIH), DHHS.

ACTION: Notice.

SUMMARY: An Application Information Meeting, hosted by the National Institute of Environmental Health Sciences (NIEHS), the National Cancer Institute (NCI), the National Heart, Lung, and Blood Institute (NHLBI), and the National Institute on Drug Abuse (NIDA), will be held on October 20, 2006, on the NIEHS campus in Research Triangle Park, North Carolina. The meeting will include an overview of the Exposure Biology Program, presentations on the five funding opportunities, an overview of the cooperative agreement mechanism and Grants Management and Review issues, and a question and answer session addressing RFA-related questions.

DATES: October 20, 2006.

ADDRESSES: The GEI-Exposure Biology Program RFA Application Information meeting will be held at the National Institute of Environmental Health Sciences, 111 TW Alexander Drive, Research Triangle Park, North Carolina [Rall Building (Building 101), Rodbell B]. Information on the meeting will be posted on the GEI-Exposure Biology Web site at *http://www.gei.nih.gov/exposurebiology/index.asp.*

FOR FURTHER INFORMATION CONTACT: Anne Thompson, NIEHS, P.O. Box 12233, MD B2–01, Research Triangle Park, NC 27709; telephone: 919–316–4517, or e-mail: *thomps13@niehs.nih.gov.*

SUPPLEMENTARY INFORMATION:

Preliminary Agenda

GEI-Exposure Biology RFA Application Information Meeting, October 20, 2006, National Institute of Environmental Health Sciences, Rall Building (Bldg. 101), Rodbell B, 111 TW Alexander Drive, Research Triangle Park, NC 27709.

1–1:20 p.m. Exposure Biology Program Overview—Brenda Weis (NIEHS).

1:20–1:50 p.m. Biological Response Indicators of Environmental Stress RFAs (U01 and U54)—Sally Tinkle (NIEHS).

1:50–2:10 p.m. Environmental Sensors for Personal Exposure Assessment RFA (U01)—David Balshaw (NIEHS).
2:10–2:30 p.m. Improved Measures of Diet and Physical Activity RFA (U01)—Amy Subar/Cay Loria (NCI/NHLBI).
2:30–2:50 p.m. Field-Deployable Tools for Quantifying Exposures to Psychosocial Stress and to Addictive Substances for Studies of Health and Disease RFA (U01)—Kay Wanke/Kevin Conway (NIDA).
2:50–3:10 p.m. Overview of the ''U'' Mechanism and the Review and Grants Management Process—Gwen Collman (NIEHS).
3:10–3:25 p.m. General Open Discussion and Questions—Everyone.
3:25–3:35 p.m. Break to One-on-One Sessions.
3:35–4 p.m. One-on-One Session—General Q&A.
4–5:30 p.m. One-on-One Session—Individual Q&A.

Attendance, Registration, and Remote Access

The meeting is being held on October 20, 2006, from 1–5:30 p.m. Individuals who plan on attending either in person or by videocast should register on the GEI-Exposure Biology Web site at *http://fmp-8.cit.nih.gov/gei/register.html.* A map of the NIEHS campus, including visitor parking, is available at *http://www.niehs.nih.gov/external/contact.htm.* Please note that a photo ID is required to access the NIEHS campus. Individuals with disabilities, who need Sign Language Interpreters and/or reasonable accommodation to participate in this event, should contact 919–541–2475 voice, 919–541–4644 TTY, through the Federal TTY Relay System at 800–877–8339, or by e-mail: *niehsoeeo@niehs.nih.gov.* Requests should be made at least 5 days in advance of the event.

Availability of Meeting Materials

Meeting details will be posted on the GEI-Exposure Biology Web site at *http://www.gei.nih.gov/exposurebiology/meetings/appinfo06/.* Following the meeting, a recorded videocast of the meeting will be made available on the Web site.

Background Information on the Exposure Biology Program

The Genes and Environment Initiative (GEI) is a four-year, NIH-wide program, which aims to accelerate understanding of genetic and environmental contributions to health and disease. The GEI is comprised of two components—the Genetics Program being led by NHGRI and the Exposure Biology Program being led by NIEHS. The Exposure Biology Program will focus on the development of innovative technologies to measure environmental exposures, diet, physical activity, psychosocial stress, and addictive substances that contribute to the development of disease. The program will support: (1) Development of environmental sensors for measurement of chemicals, dietary intake, physical activity, and psychosocial stressors and addictive substances; (2) development of markers of biological response via common pathogenic mechanisms such as oxidative stress, epigenetic modifications, and DNA damage; (3) integration of biological responses with the development of biosensors; and (4) application of novel assays and biomarkers to GWA studies of gene-environment interaction. This will be accomplished through the use of five cooperative agreements (RFAs) led by three NIH Institutes (NIEHS, NIDA, and NCI/NHLBI). Further information on the GEI-Exposure Biology Program can be found on the GEI-Exposure Biology Web site at: *http://www.gei.nih.gov/exposurebiology/index.asp.*

Dated: October 4, 2006.

David A. Schwartz,

Director, National Institute of Environmental Health Sciences, National Institutes of Health.

[FR Doc. E6–16858 Filed 10–11–06; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HOMELAND SECURITY

Preparedness Directorate; Proposed Collection; Comment Request; FY03 Domestic Preparedness Program—State and Local Survey

AGENCY: Preparedness Directorate, National Preparedness Task Force (NPTF), Department of Homeland Security (DHS).

ACTION: 60-day notice and request for comments.

SUMMARY: The Preparedness Directorate invites the general public and other Federal agencies the opportunity to comment on the reinstatement of a previously approved information collection request (ICR) OMB 1651–0101 FY03 Domestic Preparedness Program, State and Local Survey. This request for comment is being made pursuant to the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106).

DATES: Written comments should be received on or before December 11, 2006 to be assured consideration.

ADDRESSES: Direct all written comments to the Preparedness Directorate, NPTF, Attn. Sharon Kushnir, 3801 Nebraska Avenue Complex, Building 3, Washington, DC 20528.

FOR FURTHER INFORMATION CONTACT: Requests for additional information should be directed to the Preparedness Directorate, NPTF, Attn.: Sharon Kushnir, 3801 Nebraska Avenue Complex, Building 3, Washington, DC 20528, Tel. (202) 282–9680 or by electronic mail (e-mail) to: *Sharon.kushnir@dhs.gov.*

SUPPLEMENTARY INFORMATION: The Preparedness Directorate invites the general public and other Federal Agencies to comment on proposed and/or continuing information collections pursuant to the Paperwork Reduction Act of 1995, (Pub. L. 104–13, 44 U.S.C. chapter 35) as amended by the Clinger-Cohen Act (Pub. L. 104–106). Written comments and suggestions from the public and affected agencies concerning the proposed collection of information should address one or more of the following four points:

(1) Evaluate whether the proposed collection of information is necessary for the proper performance of the functions 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 through the use of appropriate automated, electronic, mechanical, or other technological collection techniques or other forms of information technology, *e.g.*, permitting electronic submissions of responses.

The comments that are submitted will be summarized and included in the request for Office of Management and Budget (OMB) approval. All comments will become a matter of public record. In this document the Preparedness Directorate is soliciting comments concerning the following information collection:

Analysis

Agency: Preparedness Directorate, National Preparedness Task Force