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

DATES: Fax written comments on the collection of information by November 13, 2006.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–6974.

FOR FURTHER INFORMATION CONTACT: Jonna Capezzuto, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–4659.

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

Food Labeling; Trans Fatty Acids in Nutrition Labeling—21 CFR 101.9(C)(2)(ii) and 101.36(b)(2) (OMB Control Number 0910–0515)—Extension

Section 403(q) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 343(q)) establishes the requirements for nutrition labeling of foods. In particular, section 403(q)(1)(A) and 403(q)(1)(B) require that the label or labeling of a food bear nutrition information on the amount of nutrients present in a product. Section 403(q)(2) of the act permits FDA to require information about nutrients not specified in section 403(q)(1) if that additional information will assist consumers in maintaining healthy dietary practices. Section 403(q)(5)(F) of the act specifies the nutrition information that must be on the label or labeling of dietary supplements. Under these provisions of the act, FDA issued regulations in § 101.9(c)(2) (21 CFR 101.9(c)(2)) that require information on the amounts of fat and certain fatty acids in food products to be disclosed in the Nutrition Facts panel. Similarly, FDA issued regulations in § 101.36(b) (21 CFR 101.36(b)) that specify the nutrition information that must be on the label or labeling of dietary supplements. In particular, §§ 101.9(c)(2)(ii) and 101.36(b)(2) require that the amount of trans fatty acids present in a food, including dietary supplements, must be declared on the nutrition label of conventional foods, and for dietary supplements, on a separate line immediately under the line for the declaration of saturated fat.

Respondents are expected to be persons and businesses, including small businesses.

In the **Federal Register** of April 11, 2006 (71 FR 18338), FDA published a 60-day notice requesting public comment on the information collection provisions. One comment was received but unrelated to the information collection.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Respondent	Total Hours	Total Operating Costs
101.9(c)(2)(ii)	10,490	27	278,100	2	556,200	$155,200
101.36(b)(2)	910	32	29,500	2	59,000	$16,500
Total					615,200	$171,700

[1]There are no capital costs or maintenance costs associated with this collection of information.

FDA believes that the burden associated with the disclosure of trans fatty acid information on labels or in labeling food and dietary supplement products is largely a one-time burden created by the need for firms to revise the labels for those existing products that contain trans fatty acids.

FDA estimated that there were approximately 10,490 firms producing food products and 910 firms producing dietary supplement products that, because they contain trans fatty acids, were affected by §§ 101.9 and 101.36. The agency estimated that these firms needed to revise approximately 278,100 food labels and 29,500 dietary supplement labels, although only about 25 percent of these label changes would have to be made earlier than the firms planned. Because these firms were already disclosing information on total fat, saturated fat, and other significant nutrients on their product labels, based upon its knowledge of food and dietary supplement labeling, FDA estimated that firms would require less than 2 hours per product to comply with the nutrition labeling requirements of §§ 101.9 and 101.36.

Multiplying the total number of responses by the hours per response gives the total hours. FDA estimated operating costs by combining testing and relabeling costs ($44.9 million + $126.8 million). This total was then apportioned between §§ 101.9 and 101.36 according to the proportion of responses for each section. Based on the labeling cost model, FDA expected that, with a compliance period of over 2 years, 75 percent of firms will coordinate labeling revisions required by the trans fat final rule with other planned labeling changes for their products.

Dated: October 5, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–16840 Filed 10–11–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 1998D–0777] (formerly Docket No. 98D–0777)

Guidance for Industry on Investigating Out-of-Specification Test Results for Pharmaceutical Production; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a guidance for industry entitled ''Investigating Out-of-Specification (OOS) Test Results for Pharmaceutical Production.'' This guidance provides information for the pharmaceutical industry on how to evaluate laboratory test results that fall outside of specification limits. The guidance is intended to provide clear and consistent communication of

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).