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 (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 dietary supplements on a separate line immediately under the line for the declaration of saturated fat.

Description of Respondents: Persons and businesses, including small businesses.

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 Response	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
Totals					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: April 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5219 Filed 4–10–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0136]

Agency Information Collection Activities; Proposed Collection; Comment Request; Interstate Shellfish Dealers Certificate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on Form FDA 3038, Interstate Shellfish Dealers Certificate.

DATES: Submit written or electronic comments on the collection of information by June 12, 2006.

ADDRESSES: Submit electronic comments on the collection of information to: *http://www.fda.gov/dockets/ecomments*. Submit written comments on the collection of information to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

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: Under the PRA (44 U.S.C. 3501–3520), Federal agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party.

Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Interstate Shellfish Dealers Certificate (OMB Control Number 0910–0021)—Extension

Under 42 U.S.C. 243, FDA is required to cooperate with and aid State and local authorities in the enforcement of their health regulations and is authorized to assist States in the prevention and suppression of communicable diseases. Under this authority, FDA participates with State regulatory agencies, some foreign nations, and the molluscan shellfish industry in the National Shellfish Sanitation Program (NSSP).

NSSP is a voluntary, cooperative program to promote the safety of molluscan shellfish by providing for the classification and patrol of shellfish growing waters and for the inspection and certification of shellfish processors. Each participating State and foreign nation monitors its molluscan shellfish processors and issues certificates for those that meet the State or foreign shellfish control authority's criteria. Each participating State and nation provides a certificate of its certified shellfish processors to FDA on Form FDA 3038, ''Interstate Shellfish Dealer's Certificate.'' FDA uses this information to publish the ''Interstate Certified Shellfish Shippers List,'' a monthly comprehensive listing of all molluscan shellfish processors certified under the cooperative program. If FDA did not collect the information necessary to compile this list, participating States would not be able to identify and keep out shellfish processed by uncertified processors in other States and foreign nations. Consequently, NSSP would not be able to control the distribution of uncertified and possibly unsafe shellfish in interstate commerce, and its effectiveness would be nullified.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

FDA Form No.	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
3038	39	62	2,418	.10	242

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

This estimate is based on FDA's experience and the number of certificates received in the past 3 years.

Dated: April 3, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. E6–5222 Filed 4–10–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0408]

Regulatory Site Visit Training Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration's (FDA's) Center for Biologics Evaluation and Research (CBER) is reannouncing the invitation for participation in its Regulatory Site Visit Training Program (RSVP). This training program is intended to give CBER's regulatory review, compliance, and other relevant staff an opportunity to visit biologics facilities. These visits are intended to allow CBER staff to directly observe routine manufacturing practices and to give staff a better understanding of the biologics industry, including its challenges and operations. This notice invites biologics facilities interested in participating in this program to contact CBER for more information.

DATES: Submit written or electronic requests for participation in this program by May 11, 2006.

ADDRESSES: If your biologics facility is interested in offering a site visit or learning more about this training opportunity for CBER staff, you should submit a request to participate in the program to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Submit electronic requests to *http://www.fda.gov/dockets/ecomments*.

If your biologics facility has previously responded to the notice announced in the **Federal Register** of September 23, 2004 (69 FR 57033), and you wish to continue to be considered for this year's program, you should notify CBER of your continued interest by sending an e-mail to *matt@cber.fda.hhs.gov*.

FOR FURTHER INFORMATION CONTACT: Lonnie Warren-Myers, Division of Manufacturers Assistance and Training, Center for Biologics Evaluation and Research (HFM–49), Food and Drug Administration, 1401 Rockville Pike, suite 200N, Rockville, MD 20852–1448, 301–827–2000, FAX: 301–827–3079, e-mail: *matt@cber.fda.hhs.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

CBER regulates biological products including blood and blood products, vaccines, and cellular, tissue, and gene therapies. CBER is committed to advancing the public health through innovative activities that help ensure the safety, effectiveness, and timely delivery of biological products to patients. To support this primary goal, CBER has initiated various training and development programs to promote high performance of its regulatory review, compliance, and other relevant staff. CBER seeks to continuously enhance and update review efficiency and quality, and the quality of its regulatory efforts and interactions, by providing