DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0038]

Agency Information Collection Activities; Proposed Collection; Comment Request; Irradiation in the Production, Processing, and Handling of Food

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 the reporting and recordkeeping requirements for food irradiation processors.

DATES: Submit written or electronic comments on the collection of information by April 7, 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.

Irradiation in the Production, Processing, and Handling of Food—21 CFR Part 179 (OMB Control Number 0910–0186)—Extension

Under sections 201(s) and 409 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321(s) and 348), food irradiation is subject to regulation under the food additive premarket approval provisions of the act. The regulations providing for uses of irradiation in the production, processing, and handling of food are found in part 179 (21 CFR part 179). To ensure safe use of a radiation source, § 179.21(b)(1) requires that the label of sources bear appropriate and accurate information identifying the source of radiation and the maximum energy of radiation emitted by x ray tube sources. Section 179.21(b)(2)(i) requires that the label or accompanying labeling bear adequate directions for installation and use. Section 179.25(e) requires that food processors who treat food with radiation make and retain, for 1 year past the expected shelf life of the products up to a maximum of 3 years, specified records relating to the irradiation process (e.g., the food treated, lot identification, scheduled process, etc.). The records required by § 179.25(e) are used by FDA inspectors to assess compliance with the regulation that establishes limits within which radiation may be safely used to treat food. The agency cannot ensure safe use without a method to assess compliance with the dose limits, and there are no practicable methods for analyzing most foods to determine whether they have been treated with ionizing radiation and are within the limitations set forth in part 179. Records inspection is the only way to determine whether firms are complying with the regulations for treatment of foods with ionizing radiation.

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

TABLE 1.—ESTIMATED ANNUAL RECORDKEEPING BURDEN[1]

21 CFR Section	No. of recordkeepers	Annual frequency per recordkeeping	Total annual records	Hours per record	Total hours
179.25(e)	6	120	720	1	720

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

The number of firms who process food using irradiation is extremely limited. FDA estimates that there are two irradiation plants whose business is devoted primarily (i.e., approximately 100 percent) to irradiation of food and other agricultural products. Four other firms also irradiate small quantities of food. FDA estimates that this irradiation accounts for no more than 10 percent of the business for each of these firms. Therefore, the average estimated burden is based on: Two facilities devoting 100 percent of their business (or 600 hours for recordkeeping annually) to food irradiation; four facilities devoting 10 percent of their business or 120 hours (4 x 30 hours) for recordkeeping annually to food irradiation.

No burden has been estimated for the labeling requirements in §§ 179.21(b)(2)(i) and (b)(2)(ii) and 179.26(c) because the information to be disclosed is information that has been supplied by FDA. Under 5 CFR 1320.3(c)(2), the public disclosure of

information originally supplied by the Federal Government to the recipient for the purpose of disclosure to the public is not a collection of information.

Dated: January 30, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0037]

Agency Information Collection Activities; Proposed Collection; Comment Request; Proposed Experimental Study of Trans Fat Claims on Foods

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 reinstatement of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on a proposed experimental study of *trans* fat claims on foods to evaluate the effects of various possible disclosure requirements intended to help consumers understand and apply *trans* fat claims they might see on food products. The proposed experimental study will estimate the communication effectiveness of these disclosure requirements in realistic label usage situations for a range of products that may bear *trans* fat claims.

DATES: Submit written or electronic comments on the collection of information by April 7, 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 reinstatement 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.

Proposed Experimental Study of Trans Fat Claims on Foods (OMB Control Number 0910–0533)—Reinstatement

FDA is requesting OMB approval of a proposed experimental study of *trans* fat claims on food products intended to help FDA's Center for Food Safety and Applied Nutrition formulate decisions and policies affecting labeling requirements for *trans* fat claims on foods.

In the **Federal Register** of July 11, 2003 (68 FR 41507), FDA issued an advance notice of proposed rulemaking entitled ''Food Labeling: Trans Fatty Acids in Nutrition Labeling; Consumer Research to Consider Nutrient Content and Health Claims and Possible Footnote or Disclosure Statements,'' which requested comments about possible disclosure requirements to accompany nutrient content claims about *trans* fatty acids that could help consumers make heart-healthy food choices. The proposed experimental study will evaluate the ability of several such disclosure requirements to help consumers make heart-healthy food choices. The results of the proposed experimental study will provide empirical support for possible policy decisions about the need for such disclosures and the appropriate form they should take.

FDA or its contractor will collect and use information gathered from Internet panel samples to evaluate how consumers understand and respond to possible disclosure requirements for *trans* fat content claims. The distinctive features of Internet panel and shopping mall methodologies for the purpose of the proposed experimental study are that they allow for controlled visual presentation of study materials, experimental manipulation of study materials, and the random assignment of subjects to condition. Experimental manipulation of labels and random assignment to condition makes it possible to estimate the effects of the various possible disclosure requirements while controlling for individual differences. Random assignment ensures that mean differences between conditions can be tested using well-known techniques such as analysis of variance or regression analysis to yield statistically valid estimates of treatment effect size. The proposed study will be conducted from a sample drawn from a large, nationally representative consumer panel with 800,000 households. The sample size and population pool are adequate to ensure that results can be generalized.

Participants will be adults, age 18 and older, who are recruited for a study about foods and food labels. Each participant will be randomly assigned to one of the 144 experimental conditions consisting of fully crossing 8 disclosure conditions, 3 product types, 3 fatty acid profiles and 2 prior knowledge conditions.

FDA will use the information from the proposed experimental study to evaluate regulatory policy options. The agency often lacks empirical data about how consumers understand and respond to statements they might see in product labeling. The information gathered from this proposed experimental study will be used by the agency to assess likely consumer responses to various disclosure