medications during pregnancy and lactation at the time they are marketed. Nevertheless, many women inadvertently use medications early in gestation before realizing they are pregnant, and many maternal conditions require treatment during pregnancy and breastfeeding to safeguard the health of both mother and infant. Currently, the United States does not have a comprehensive early warning system for major adverse pregnancy or infant outcomes related to medication exposures.

Teratology Information Services (TIS) utilize trained specialists to provide free phone consultation, risk assessment, and counseling about exposures during pregnancy and breastfeeding—including medications—to women and healthcare providers. Altogether, they respond to approximately 70,000–100,000 inquiries each year in the United States and Canada. Because they have direct contact with pregnant and breastfeeding women, TIS are in a unique position to monitor the adverse effects of medication exposures during pregnancy and lactation. The objective of this project is to conduct a pilot study to assess whether TIS in the United States can serve as an effective monitoring and early warning system for major adverse effects on (1) pregnancy outcomes (e.g., live birth, stillbirth, premature birth, low birth weight, etc.) and (2) maternal and infant health. The project will assess the willingness of pregnant and breastfeeding women who contact a TIS about medication exposure to participate in and complete a follow-up study; whether these women are similar in demographic characteristics to the U.S. population of child-bearing age women; the specificity and completeness of the information obtained from such a study about adverse pregnancy outcomes, and maternal and infant health; and the amount of time required to conduct the follow-up.

Within a continuous six-month period, three individual TIS will recruit all women who contact their service (approximately 250 enrollees per TIS) who have used any prescription or over-the-counter medication during pregnancy or while breastfeeding to participate in a follow-up study. Informed consent to participate will be obtained from each woman by telephone. For each pregnant woman who agrees to participate, the TIS will conduct 4 telephone interviews:(1) At enrollment; (2) during the third trimester of pregnancy; (3) approximately one month after delivery; and (4) when the infant is about 3 months old. For each breastfeeding woman who agrees to participate, the TIS will conduct 3 telephone interviews:(1) At enrollment; (2) approximately one month after enrollment; and (3) 3 months after enrollment, if the woman is still taking medication and still breastfeeding. The interviews will assess maternal and fetal health throughout pregnancy, and maternal and infant health at delivery, during the newborn and early infancy period, and while breastfeeding, and correlate these outcomes with medication exposure during pregnancy and while breastfeeding. There is no cost to respondents other than their time.

ESTIMATE OF ANNUALIZED BURDEN HOURS

Respondent	Number of respondents	Number of responses per respondent	Avg. burden per response (in hours)	Total burden (in hours)
Prenatal exposure group alone	338	4	20/60	451
Lactation exposure group alone	74	3	20/60	74
Prenatal exposure group and lactation exposure group (pregnant women who subsequently breastfeed)	338	4	30/60	676
Total	750			1,201

Dated: December 12, 2006.

Joan F. Karr,

Acting Reports Clearance Officer, Centers for Disease Control and Prevention.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006D–0246]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Manufactured Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 January 17, 2007.

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: Elizabeth Berbakos, Office of the Chief Information Officer (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1482.

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.

Manufactured Food Regulatory Program Standards

The Food and Drug Administration (FDA) is announcing the availability of a draft document entitled ''Manufactured Food Regulatory Program Standards: (draft program standards). The draft program standards, which establish a uniform foundation for the design and management of State programs responsible for regulation of plants that manufacture, process, pack, or hold foods in the United States, are being distributed for comment purposed only. This document is neither final nor is it intended for implementation.

The elements of the draft program standards are intended to ensure that the States have the best practices of a high-quality regulatory program to use for self-assessment and continuous improvement and innovation. The ten standards describe the critical elements

of a regulatory program designed to protect the public from foodborne illness and injury. These elements include the State program's regulatory foundation, staff training, inspection, quality assurance, food defense preparedness and response, foodborne illness and incident investigation, enforcement, education and outreach, resource management, laboratory resources, and program assessment. Each standard has corresponding self-assessment worksheets, and certain standards have supplemental worksheets and forms that will assist State programs in determining their level of conformance with the standard.

The State program is not required to use the forms and worksheets contained herein; however, alternate forms should be equivalent to the forms and worksheets in the draft program standards. These draft program standards do not address the performance appraisal processes that a State agency may use to evaluate individual employee performance. When finalized, FDA will use the program standards as a tool to improve contracts with State agencies. The program standards will assist both FDA and the States in fulfilling their regulatory obligations.

The implementation of the program standards will be negotiated as an option for payment under the State contract. States that are awarded this option will receive up to $5,000 to perform the self assessment and to maintain an operational plan for self improvement. FDA recognizes that full use and implementation of the program standards by those States will take several years. Such States will, however, be expected to implement improvement plans to demonstrate that their programs are moving toward full implementation. Those self assessments and improvement plans will be audited as a part of the program oversight of the FDA state contracts.

The goal is to enhance food safety by establishing a uniform basis for measuring and improving the performance of manufactured food regulatory programs in the United States. The development and implementation of these program standards will help Federal and State programs better direct their regulatory activities at reducing foodborne illness hazards in plants that manufacture, process, pack, or hold foods. Consequently, the safety and security of the food supply in the United States will improve.

In the **Federal Register** of July 20, 2006 (FR 71 41221), FDA published a 60-day notice requesting public comment on the information collection provisions in the draft program standards. FDA received a number of comments on the draft program standards; however, only two letters of comment included comments regarding the information collection provisions. An additional letter supported the comments provided in one of the two letters of comment.

Two comments stated that the record collection required to meet the standards is cumbersome and voluminous. FDA does not agree with the comments about the record collection. The record collection requested by the program standards is not outside the information collected and reported by an efficient and effective regulatory program. The program standards capture the State program's accomplishments in standardized forms.

FDA reminds you that in the draft program standards FDA anticipates full implementation of the program standards will take several years so that State programs can integrate the program standards into its own quality assurance programs. FDA estimates that the majority of the State agencies have quality assurance programs and only a minimum amount of time would be necessary to revise or update them to comply with the program standards. Ultimately, the program standards will assist both FDA and the States in fulfilling their regulatory obligations and developing strategies that will continuously improve the State programs.

Furthermore, the total estimated burden under the draft program standards did not consider the use of forms in Portable Document Format (PDF) that will be filled and submitted electronically. The PDF fill-in forms will reduce the estimated burden for both the reporting and recordkeeping burdens and should be accessible when the program standards are negotiated as an option for payment under the State contracts.

One comment requested that alternative mechanisms to document compliance with the standards be permitted. FDA further reminds you that in the draft program standards we provide for using alternate forms.

In revising the draft program standards, FDA will consider the general comments on draft program standards.

Because State agencies already keep records of the usual and customary activities required by their inspection programs, the burden from compiling these records is not included in the burden chart.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
40	0.5	20	40	800

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

TABLE 2.—ESTIMATED FIVE-YEAR SELF ASSESSMENT BURDEN[1]

Number of Respondents	Five-Year Frequency per Response	Total Five-year Responses	Hours per Response[2]	Total Hours[2]
40	1	40	100/40	4,000/1,600

[1]The initial self assessment is estimated at 100 hours per respondent. Subsequent updates of the self assessments will be conducted every five years and should be completed in 40 hours or less.

TABLE 3.—ESTIMATED ANNUAL IMPROVEMENT PLAN BURDEN

No. of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours per Response	Total Hours
40	1	40	5	200

Dated: December 11, 2006.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2006N–0036]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Experimental Study of Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative *Trans* Fat Disclosure on the Nutrition Facts Panel

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

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 December 18, 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 the Chief Information Officer (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.

Experimental Study of Possible Footnotes and Cueing Schemes to Help Consumers Interpret Quantitative *Trans* Fat Disclosure on the Nutrition Facts Panel—(OMB Control Number 0910–0532—Reinstatement)

FDA is requesting OMB approval of an experimental study of possible footnotes and cueing schemes intended to help consumers interpret quantitative *trans* fat information on the Nutrition Facts Panel (NFP) of a food product. The purpose of the experimental study is to help FDA's Center for Food Safety and Applied Nutrition formulate decisions and policies affecting labeling requirements for *trans* fat disclosure.

In the **Federal Register** of July 11, 2003 (68 FR 41434), FDA issued a final rule requiring disclosure on the Nutrition Facts Panel of quantitative *trans* fat information on a separate line without any accompanying footnote. At the same time, the agency 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'' (68 FR 41507) which requested comments about possible footnotes to help consumers better understand *trans* fat declarations on the product label. The agency sought comments about whether it should consider requiring statements about *trans* fat, either alone or in combination with saturated fat and cholesterol, as a footnote on the Nutrition Facts Panel to enhance consumers' understanding about such cholesterol-raising lipids and how to use information on the label to make healthy food choices. Comments received in response to the notice contained suggested footnotes and cueing schemes. The proposed experimental study will evaluate the ability of several possible footnotes and cueing schemes to help consumers make heart-healthy food choices. The results of the experimental study will provide empirical support for possible policy decisions about the need for such requirements and the appropriate form they should take.

FDA or its contractor will use information gathered from Internet panel samples to evaluate how consumers understand and respond to possible footnote and cueing schemes. The distinctive features of Internet panels for the purpose of the 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 footnotes and cueing schemes while controlling for individual differences between subjects. 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 effect size. The study will be conducted using a convenience sample drawn from a large, national consumer panel of about one million households.

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 1 of the 54 experimental conditions derived from fully crossing 8 possible footnotes/cueing schemes, 3 product types, and 2 prior knowledge conditions.

FDA will use the information from the experimental study to evaluate regulatory and 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 experimental study will be used to estimate consumer comprehension and the behavioral impact of various footnotes and cueing schemes intended to help consumers better understand quantitative *trans* fat information.

The experimental study data will be collected using participants of an Internet panel of approximately one million people. Participation in the experimental study is voluntary.

In the **Federal Register** of February 6, 2006 (71 FR 6079), FDA published a 60-day notice requesting public comment on the information collection that will take place as part of the experimental study. FDA received two letters in response to the notice, each containing multiple comments.