

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. 2006N-0187]

#### **Agency Information Collection Activities: Proposed Collection; Comment Request; Survey of Health Care Professionals on the Food Safety and Nutrition Information That They Provide to Pregnant Women**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

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**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 and to allow 60 days for public comment in response to the notice. This notice solicits comments on a voluntary survey of health care professional on the food safety and nutrition information that they provide to pregnant women.

**DATES:** Submit written or electronic comments on the collection of information by *[insert date 60 days after date of publication in the **Federal Register**]*.

**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:** JonnaLynn 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 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.

**Survey of Health Care Professionals on the Food Safety and Nutrition Information that they Provide to Pregnant Women**

Under section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(b)(2)), FDA is authorized to conduct research relating to foods and to conduct educational and public information programs relating to the safety of the nation’s food supply. FDA is planning to conduct a survey of health care professionals to determine what information, advice, and recommendations they are offering to pregnant women about the following topics: (1) Methyl mercury and seafood consumption; (2) Listeriosis prevention; (3) weight control and nutrition; (4) dietary supplement usage; (5) food allergies; (6) Toxoplasmosis prevention; and (7) infant feeding practices. FDA is interested in obtaining this data since FDA has recently issued advice for pregnant women about food safety risks and diet risks such as mercury in seafood, Listeriosis, and Toxoplasmosis. (“Food Safety for Moms-to-Be”, 2005 and “What You Need to Know about Mercury in Fish and Shellfish”, 2004). Data from this survey will be used to evaluate whether health care professionals are aware of this advice and if they are educating their patients about information in the FDA advisories.

FDA will also use this survey to get a better understanding of what resources health care professionals use to stay abreast of current practices for caring for pregnant women. This will help FDA provide timely recommendations to health care professionals that will reach the largest audience.

A sample of 400 obstetrician/gynecologists, 200 nurse practitioners, 200 nurse midwives, 200 physician assistants, and 200 dietitians from the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) will be included in this survey. The sample of nurse practitioners, nurse midwives,

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and physician assistants will be drawn from those specializing in obstetrics. The samples will be randomly selected from lists obtained from national associations. The survey will be conducted using a mailed questionnaire. Cognitive interviews and a pretest will be conducted prior to fielding the survey.

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

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN<sup>1</sup>

| No. of Respondents       | Annual Frequency per Response | Total Annual Responses | Hours per Response | Total Hours |
|--------------------------|-------------------------------|------------------------|--------------------|-------------|
| 1,200 - Survey           | 1                             | 1,200                  | .167               | 200.4       |
| 75 - Pretest             | 1                             | 75                     | .167               | 12.5        |
| 16 - Cognitive Interview | 1                             | 16                     | .75                | 12          |
| Total                    | 1                             | 1,291                  |                    | 224.9       |

<sup>1</sup>There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden estimate is based on FDA's experience with previous surveys.

Dated: May 25, 2006.

**Jeffrey Shuren,**

*Assistant Commissioner for Policy.*

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