Request for OMB Review

Supporting Statement

Survey of Food Safety and Nutrition Information Provided to Pregnant Women by Health Care Providers and WIC Educators

Submitted by:

Division of Social Sciences
Office of Regulations, Policy, and Social Sciences
Center for Food Safety and Applied Nutrition
Food and Drug Administration
Department of Health and Human Services

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A. JUSTIFICATION

A.1 Necessity for the Information Collection

The proposed Survey of Food Safety and Nutrition Information Provided to Pregnant Women by Health Care Providers and WIC Educators is designed to provide information on what health care providers and educators from the Special Supplemental Nutrition Program for Women, Infants, and Children (WIC) are discussing with their patients about topics of interest to the Center for Food Safety and Applied Nutrition (CFSAN), within the Food and Drug Administration (FDA). CFSAN has oversight authority with respect to food safety and nutrition and dietary supplements. The topics addressed in the survey include: (1) nutrition advice, (2) methyl mercury and seafood consumption, and (3) food related illnesses.

FDA is interested in determining whether health care providers and WIC educators counseling pregnant women are aware of advice from FDA regarding the consumption of certain foods by pregnant women[1] and whether they are educating patients and clients about information in FDA advisories for pregnant women, such as the advisory about methyl mercury in fish and shellfish[2]. FDA is also interested in determining the preferences of health care providers and WIC educators use for materials and resources that could assist them in staying abreast of food safety and nutrition advice for pregnant women. This information will be used to improve FDA's effectiveness at reaching those who provide health care and education to pregnant women.

The authority for FDA to collect the information for this survey derives from the FDA Commissioner's authority, as specified in section 903(d)(2) of the Food, Drug, and Cosmetic Act (the act) (21 USC § 393(d)(2)).

A.2 How, By Whom, and the Purpose for Collecting This Information.

The proposed study will be conducted via a mailed questionnaire. A sample of 400

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1 See *Food Safety for Moms-to-Be*, 2005 available http://www.cfsan.fda.gov/~pregnant/pregnant.html.

2 In 2001, the Food and Drug Administration (FDA) issued an advisory for women who are pregnant, nursing, or of child bearing age, recommending that these women limit their consumption of large, predatory fish because they may contain elevated levels of methyl mercury. Consumption of fish with elevated levels of methylmercury has been associated with an increased risk of neurological problems in the developing fetus and young children. (See *An Important Message for Pregnant Women and Women Of Childbearing Age who May Become Pregnant About the Risk of Mercury in Fish*, 2001, available at http://www.cfsan.fda.gov/~acrobat/hgadv1.pdf). In March, 2004, the advisory was updated and jointly issued by the Environmental Protection Agency (EPA) and FDA. The new advisory also included recommendations for young children and provided updated consumption guidelines for various categories of fish. It urged the target audiences not to eat shark, king mackerel, swordfish, and tilefish; and provided specific advice for consuming light canned tuna, white albacore canned tuna, and tuna steaks. (See *What you Need to Know about Mercury in Fish and Shellfish* available at http://www.cfsan.fda.gov/~dms/admehg3.html).

obstetrician/gynecologists (OB/GYNs), 200 nurse practitioners, 200 certified nurse midwives, 200 physician assistants, and 200 WIC educators will be included in this survey. The sample of nurse practitioners, nurse midwives, and physician assistants will be drawn from those specializing in obstetrics/gynecology. The health care provider samples will be randomly selected from lists obtained from national professional associations and state registries. The sample of WIC educators will be drawn from a list of all WIC local agencies provided by the U.S Department of Agriculture (USDA). Cognitive interviews and a pretest will be conducted prior to fielding the survey.

The survey data will be collected by Synovate, an independent contractor. Synovate has extensive experience conducting physician surveys. The cognitive interviews will be conducted by experienced FDA staff members.

A.3 Use of Information Technology to Reduce the Burden on the Public

The study does not use electronic collection of information. The most efficient means of reaching the population of interest, i.e., health care providers and WIC educators, is through a mailed questionnaire.

A.4 Identification and Use of Duplicative Information

A search of the literature has revealed that there are no national surveys that ask about the discussions health care providers are having with their pregnant patients concerning the topics of interest in this survey. Nor are there studies that address how best to disseminate FDA's food safety and nutrition information to these groups. FDA plans to use data obtained from the Infant Feeding Practices Study II and the 2006 Food Safety Survey to understand how the advice on methyl mercury in seafood, listeriosis, and other food safety risks are being interpreted by pregnant women and the general population, but these information collections are not duplicative of the proposed collection.

One study has been identified concerning health care provider advice to pregnant women about food safety. Morales et al conducted a qualitative study on the attitudes of health care providers about food safety recommendations for pregnant women. Results suggest that few health care providers include food safety education as part of their work with pregnant women, due in part to a lack of time and information. Doctors, midwives, nurses, and WIC professionals did, however, consider food safety education to be part of their role. However, the study sample was small (23) and collected using non-random methods. The results from the Morales study provided important context for the development of the questionnaire to be used in the proposed FDA study.

There is no likelihood of Federal duplication of effort across agencies. FDA is working closely with EPA and USDA on this study. EPA has contributed both expertise in reviewing the draft survey questionnaire and has provided significant funding for the survey. The work on this survey highlights FDA and EPA's continuing close collaboration on the methyl mercury seafood advisory. USDA is the federal agency that oversees WIC. USDA has provided expertise in both reviewing the questionnaire for appropriateness for WIC educators, and provided a comprehensive list of all WIC local agencies from which the WIC sample will be drawn.

A.5 Methods to Minimize Burden on Small Business

There is no impact on small business from this data collection.

A.6 Consequence of Not Conducting the Collection

This study is a one-time data collection. Without this data collection, FDA will not be able to assess the awareness of FDA advice among health care providers and WIC educators, nor assess the effectiveness of FDA communication about food safety and nutrition to those providers and educators.

A.7 Special Circumstances Explanation

This collection fully complies with 5 CFR 1320.5. There are no special circumstances associated with this information collection.

A.8 Public Comments and Consultation Outside the Agency

In accordance with 5 CFR 1320.8(d), in the FEDERAL REGISTER of June 2, 2006 (71 FR 32095), FDA published a 60-day notice requesting public comment on the information collection provisions. FDA received one comment responsive to the comment request.

(Comment) The comment suggests that FDA should expand the respondent universe of the survey to include all categories of health care providers that care for pregnant women.

(Response) FDA agrees that the survey universe should include samples drawn from all categories of health care providers that provide care for pregnant women. The current sampling plan calls for samples of 400 OB/GYNs, 200 nurse practitioners, 200 certified nurse midwives, 200 physician assistants, and 200 WIC nutrition educators.

This study was designed in collaboration with Cara Lalley, formerly of the Environmental Protection Agency.

The following individuals at the U.S. Department of Agriculture, Food and Nutrition Service, have been consulted with for input on the questionnaire and sampling plan with respect to the WIC sample.

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A.9 Payment or Gifts to Respondents

Numerous studies have looked at the effect of payment on increasing survey response rate among physicians (see, e.g., Kellerman and Herold, 2001). The Center for Drug Evaluation

and Research (CDER) at FDA recently conducted a study on the effect of incentives on physician participation in a survey of direct-to-consumer drug advertising. In this study, each physician was randomly assigned to receive an incentive of $50, $75, or $100 for their participation. The results indicated that the larger the incentive payment, the higher the response rate for the survey. The most significant effect on response rate was found between $75 and $100. We are planning on offering physicians $75 for their participation in this survey, a level found to be effective at increasing response rate that is also commensurate with the physicians' opportunity costs of time to complete the survey.

Other health care providers will be offered an incentive to increase the likelihood of participation. The amount of incentives will also be commensurate with the providers' opportunity costs of time to complete the survey. Based on past experience, the amount needed to ensure participation, which, in turn, reduces costs related to non-response to the survey, is $40 for nurse practitioners and physician assistants and $35 for nurse midwives and WIC educators.

A.10 Assurance of Confidentiality

All data will be collected with an assurance that the respondents' answers will remain confidential. A statement that responses will be kept confidential will be printed on the cover letter for the survey questionnaires. Confidentiality of the information provided will be discussed prior to any cognitive interview. Confidentiality will be assured by using an independent contractor to collect the information, by enacting procedures to prevent unauthorized access to respondent data, and by preventing the public disclosure of the responses of individual participants.

Identifying information will not be included on the data files delivered to FDA. The contractor, Synovate, has standard procedures for assuring the confidentiality of survey respondents. All of the contractor's employees sign a statement agreeing to maintain confidentiality of data. Access to the data files can only be gained through the use of a password which will be specific to this study. Names and mailing addresses for the sample will be retained only until validation and editing are complete; they will be stripped from the data base before the data are sent to FDA. All computer data will be maintained in a manner which is consistent with the Department of Health and Human Services ADP Systems Security Policy as described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

Confidentiality of the information submitted is protected from disclosure under the Freedom of Information Act (FOIA) under sections 552(a) and (b) (5 U.S.C. 552(a) and (b), and by part 20 of the agency's regulations (21 CFR part 20).

A.11 Sensitive Questions

The survey does not include any questions of a sensitive nature.

A.12 Hour Burden Estimates

FDA estimates the total annual burden for this one-time collection of information to be 225 hours. FDA estimates that respondents will take 10 minutes to complete the survey and that the variation in burden across respondents will be small. The proposed total number of respondents for all the surveys is 1,275. In addition, sixteen cognitive interviewees will be asked to discuss the survey questions. FDA estimates that each cognitive interview will take approximately 45 minutes to complete.

Table 1. -- Estimated Annual Reporting Burden[1]

Activity	No. of Respondents	Annual Frequency Per Response	Total Annual Responses	Hours Per Response	Total Hours
Survey	1,200	1	1,200	.167	200
Pretest	75	1	75	.167	13
Cognitive Interview	16	1	16	.75	12
	TOTAL	1	1291		225

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

A.13 Total Annual Cost Burden to Respondents Excluding Hours Burden Shown in Sections A.12 and A.14

There are no costs associated with this data collection outside the burden reflected in A12.

A.14 Annual Cost to the Federal Government

The total estimated cost of this research is $265,000. This includes fees paid to the contractor to program the study, draw the sample, collect the data, and create a database of the results.

A.15 Explanation of Program Changes or Adjustments

This is a new information collection.

A16. Statistical Reporting

FDA will disseminate the results of this study strictly following FDA's "Guidelines for Ensuring the Quality of Information Disseminated to the Public." In describing the data collected and results of the analysis, FDA will clearly acknowledge that the data do not provide nationally representative estimates of attitudes, knowledge, or behavior.

The Agency anticipates disseminating the results of the study after the final analyses of the data are completed, reviewed, and cleared. The exact timing and nature of any such dissemination has not been determined, but may include presentations and articles at trade and academic conferences, publications, and Internet posting.

A.17 Displaying the OMB Approval Expiration Date

No exemption is requested.

A.18 Exceptions to the Certification Statement of OMB Form 83.I

n/a