

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N-0166]

Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Feeding Practices Study II

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 a voluntary consumer survey about infant feeding and diet of pregnant women and new mothers.

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: Peggy Robbins, Office of Management Programs (HFA–250), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–1223.

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 a 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.

Infant Feeding Practices Study II

Under section 903(d)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 393(d)(2)), FDA is authorized to conduct research and educational and public information programs relating to foods and devices. Under this authority, FDA is planning to conduct a consumer study about infant feeding and the diet of pregnant women and new mothers. The study will provide detailed information about foods fed to infants, including breast milk and infant formula; factors that may contribute to infant feeding choices and to breastfeeding success, including intrapartum hospital experiences, mother's employment status, mother's self confidence, postpartum depression, infant sleeping arrangements; and other issues of interest to FDA, including infant food allergy, and experiences with breast pumps. The study will measure dietary intake of pregnant women and new mothers. It will also be used as one component of an evaluation of the Department of Health and Human Services (HHS) National Breastfeeding Awareness Campaign.

A sample of pregnant women will be drawn from a commercial consumer opinion panel for a longitudinal study in which almost all data will be collected by mailed questionnaires. The sample design was chosen to maximize the response rate, which is critical for the success of a longitudinal study. Almost all of the sample will be members of the consumer opinion panel from which the sample will be drawn, while a few will be household members but not the panel member. All participants will be asked to complete one questionnaire during pregnancy, a short telephone interview shortly after delivery, a neonatal questionnaire sent a few weeks after the birth, and nine postnatal questionnaires sent approximately monthly from infant age 2 to 12 months. The postnatal questionnaires consist of various combinations of nine

modules, some of which will be sent at each data collection, while others will be sent only some of the time. Seven of the questionnaires will take about 25 minutes to complete, and the other two will take about 15 minutes.

A subset of the sample will be asked to complete a modified Diet History Questionnaire (from National Institutes of Health, National Cancer Institute) during pregnancy and again when the infants are about 3 months old. Pregnant women who reside in a panel member's home but are not themselves the panel member will be sent a short additional questionnaire to collect basic demographic information.

The expected sample size is about 3,500 pregnant women, of whom about 2,250 are expected to complete questionnaires in the later infant ages. The sample will be well distributed throughout the United States. Only women who give birth to a full-term, healthy, singleton infant will be included in the study. An estimated 12 percent of the original 3,500 women will be ineligible for the study by these criteria. Many of the questions are identical to ones asked in a previous Infant Feeding Practices Study conducted by the FDA in 1993 to 1994. Use of the same questions in both time periods will enable comparison between the two data collections. Because the previous data are a decade old, and research suggests that significant changes in infant feeding issues have occurred in the past ten years, it is likely that consumer attitudes and practices have changed since the first data collection. FDA needs current information to support consumer education programs and to describe the policy context of current issues related to infant feeding. In addition, HHS and its agencies need data to evaluate various outreach efforts about child and maternal nutrition.

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

5

TABLE 1.—ESTIMATED REPORTING BURDEN¹

Questionnaire	No. of Respondents	Frequency per Response	Total Responses	Hours per Response	Total Hours
Prenatal	3,500	1	3,500	.25	875
Prenatal diet history questionnaire	900	1	900	1.00	900
Demographic questionnaire	140	1	140	.17	24
Birth screener	2,772	1	2,772	.07	194
Neonatal questionnaire	2,494	1	2,494	.25	624
Postnatal diet history questionnaire	900	1	900	1.00	900
Postnatal questionnaires A	2,250	7	15,750	.42	6,615
Postnatal questionnaires B	2,250	2	4500	.25	1,125
Total					11,257

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

The burden estimate is based on FDA's experience with the 1993 to 1994 survey mentioned in the previous paragraph and information available for the diet history questionnaire.

Dated: April 15, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

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