the requirements of Section 4(b) of the Oceans Act of 2000, CEQ is accepting comments on U.S. Ocean Commission's recommendations. Further instructions for submitting comments to the IOPG may be found at *http://ocean.ceg.gov.*

Dated: September 24, 2004.

Philip Cooney,

Chief of Staff, Council on Environmental Quality.

[FR Doc. 04–22031 Filed 9–30–04; 8:45 am]

BILLING CODE 3125–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

National Institute for Occupational Safety and Health Advisory Board on Radiation and Worker Health

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), the Centers for Disease Control and Prevention (CDC) announces the following committee meeting:

Name: Advisory Board on Radiation and Worker Health (ABRWH), National Institute for Occupational Safety and Health (NIOSH).

Subcommittee Meeting Time and Date: 9:30 a.m.–11:30 a.m., October 19, 2004.

Committee Meeting Times and Dates: 1 p.m.–4:15 p.m., October 19, 2004. 7 p.m.–8:30 p.m., October 19, 2004. 8 a.m.–4 p.m., October 20, 2004.

Place: The Westin St. Francis, 355 Powell Street, San Francisco, California 94102, telephone 415/397–7000, fax 415/774–0124.

Status: Open to the public, limited only by the space available. The meeting room accommodates approximately 65 people.

Background: The ABRWH (''the Board'') was established under the Energy Employees Occupational Illness Compensation Program Act (EEOICPA) of 2000 to advise the President, delegated to the Secretary of Health and Human Services (HHS), on a variety of policy and technical functions required to implement and effectively manage the new compensation program. Key functions of the Board include providing advice on the development of probability of causation guidelines which have been promulgated by HHS as a final rule, advice on methods of dose reconstruction which have also been promulgated by HHS as a final rule, evaluation of the scientific validity and quality of dose reconstructions conducted by the National Institute for Occupational Safety and Health (NIOSH) for qualified cancer claimants, and advice on petitions to add classes of workers to the Special Exposure Cohort.

In December 2000 the President delegated responsibility for funding, staffing, and operating the Board to HHS, which subsequently delegated this authority to the CDC. NIOSH implements this responsibility for CDC. The charter was issued on August 3, 2001, and renewed on August 3, 2003.

Purpose: This board is charged with (a) providing advice to the Secretary, HHS on the development of guidelines under Executive Order 13179; (b) providing advice to the Secretary, HHS on the scientific validity and quality of dose reconstruction efforts performed for this Program; and (c) upon request by the Secretary, HHS, advise the Secretary on whether there is a class of employees at any Department of Energy facility who were exposed to radiation but for whom it is not feasible to estimate their radiation dose, and on whether there is reasonable likelihood that such radiation doses may have endangered the health of members of this class.

Matters to be Discussed: Agenda for this meeting will focus on Program Status Reports from NIOSH and Department of Labor; Special Exposure Cohort Petition Process Procedures; Scientific Research Issues Update; Site Profile Reviews; Subcommittee Report and Recommendations; and Board working sessions. There will be an evening public comment period scheduled for October 19, 2004, and a public comment period at midday on October 20, 2004. The Subcommittee will convene on October 19, 2004, from 9:30 a.m.–11:30 a.m.

The agenda is subject to change as priorities dictate.

Contact Person for More Information: Larry Elliott, Executive Secretary, ABRWH, NIOSH, CDC, 4676 Columbia Parkway, Cincinnati, Ohio 45226, telephone 513/533–6825, fax 513/533–6826.

The Director, Management Analysis and Services Office, has been delegated the authority to sign **Federal Register** notices pertaining to announcements of meetings and other committee management activities for both CDC and the Agency for Toxic Substances and Disease Registry.

Dated: September 20, 2004.

Alvin Hall,

Director, Management Analysis and Services Office, Centers for Disease Control and Prevention.

[FR Doc. 04–22044 Filed 9–30–04; 8:45 am]

BILLING CODE 4163–19–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. 2004N–0166]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Infant Feeding Practices Study II

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 November 1, 2004.

ADDRESSES: The Office of Management and Budget (OMB) is still experiencing significant delays in the regular mail, including first class and express mail, and messenger deliveries are not being accepted. To ensure that comments on the information collection are received, OMB recommends that comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: Fumie Yokota, Desk Officer for FDA, FAX: 202–395–6974.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

I. Background on the 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 (IFPS) conducted by 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 10 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.

In the **Federal Register** of April 21, 2004 (69 FR 21548), FDA published a 60-day notice requesting public comment on the information collection provisions.

FDA received five paperwork reduction comments on the proposed Infant Feeding Practices Study II; one comment was from a member of the public, two from industry groups, one from another government agency, and one from a medical center. In the request for comments (69 FR 21548–21549), the agency invited comments on four topics. Two of the comments we received addressed the first topic: whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility. Two comments addressed the second topic: the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used. Two comments addressed the third topic: ways to enhance the quality, utility, and clarity of the information to be collected. These latter two comments were from the infant formula industry and provided detailed comments about many aspects of the study, including the sampling design, the questionnaire design and specific questions, and possible interpretations of results. No comments specifically addressed the fourth topic: ways to minimize the burden on the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

II. Comments on Topic One

Is the proposed collection of information necessary for the proper performance of FDA's functions, including whether the information will have practical utility?

(Comment 1) One comment from a member of the public states that the agency does not need additional information about infant feeding practices because there is already a substantial amount of information on this topic.

(Response) The agency is not persuaded that existing information will fulfill the agency's needs. We note that detailed, longitudinal information about infant feeding has not been collected by anyone in over a decade. In the approximate decade since the first IFPS, a number of dietary practices related to infants have changed. These changes include the availability of new formulations of infant formula (specifically the addition of docosahexaenoic acid (DHA) and arachidonic acid (ARA)—types of omega-3 and omega-6 fatty acids—to some formula), the increased use of breast pumps, and probable increased intake by infants and mothers of dietary supplements (i.e., vitamins, minerals, herbal, and botanical supplements). Knowledge related to infant feeding has also increased, including the possibility of preventing or delaying food allergy through early infant diet and evidence that certain other diseases, such as diabetes, may be related to solid food timing. Furthermore, overall breastfeeding rates have risen dramatically over the past decade, creating the need to better understand how infant feeding patterns and their determinants have changed. Breastfeeding initiation in 2002 was 70 percent, compared with 54 percent in 1992, and duration to 6 months was 33 percent, compared with 19 percent in 1992. Additionally, increased physician education related to breastfeeding, improved maternity care practices, and some State and Federal laws have altered the barriers that women face in making infant feeding decisions. There is a need to understand infant feeding in the context of these new environments. Consequently, a need exists to update the database with a current description of the practices of mothers of infants.

(Comment 2) One comment from another government unit states that staff use the data from the first IFPS and that they are in favor of the IFPS II.

(Response) The agency agrees that information from the IFPS II will be useful to many government agencies and their staff.

III. Comments on Topic Two

What is the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used?

(Comment 3) One comment from a medical center recommends that the data collection be done by an independent contractor and not by a formula manufacturer. It states that the contractor should not have any affiliation with the formula industry.

(Response) The agency agrees that the data should not be collected by a formula manufacturer. The data will be collected by an independent contractor under the direction of FDA employees.

(Comment 4) One comment from the formula industry states that the sample of the IFPS II should be representative of the general population of new mothers in the United States. The comment asks what steps will be taken to ensure that the proposed data collection is truly representative of the general population. The comment also notes, however, that the sample of the first IFPS was not representative and

acknowledges that if the sample of IFPS II is representative of the general population, FDA will not be able to validly compare results from the two data collections.

(Response) Although the agency agrees with the principle that a nationally representative sample is ideal, it disagrees that this characteristic is essential for the IFPS II. The IFPS II sample will not be representative of the general population of new mothers in the United States. The IFPS II sample will be drawn from the same consumer opinion panel (a collection of households throughout the United States in which members have agreed to answer questionnaires by mail) from which the original study sample was drawn. Before the first infant feeding study was conducted, project staff considered many possible designs and consulted with several experts. The conclusion was that screening costs would be enormous to find a large sample at the required stage of pregnancy to assemble a panel, and that subsequent nonresponse from a panel composed of the general population would be so high that the nonresponse bias would invalidate the study. The people most likely to drop out would be those not included in the consumer opinion panel, such as those with a low level of education, those from unstable households, and those with low English proficiency. Use of the consumer opinion panel will provide data primarily on a middle segment of the U.S. population, but the segment included is fairly broad. For example, 20 percent of the previous study sample participated in the Supplemental Feeding Program for Women, Infants, and Children (WIC), the same proportion as the general population of mothers of infants at the time. In this study, the nature of the bias will be known and the data will be truly longitudinal because most of those who begin the study will complete it. Panel members who have a low level of education and who are of minority race and ethnicity will be oversampled to increase the total numbers from these groups. Use of the same sample frame as the original study will enable comparison across time on some key variables.

For certain analyses the IFPS II sample will be weighted to the distributions of characteristics of new mothers in vital statistics to make the results more representative.

(Comment 5) One comment from industry states that the data collection instruments are lengthy and detailed and appear to be written for an educated, highly literate population. The comment states that this characteristic will make it difficult for the consumer sample to be representative of the general population. The comment recommends that the agency take steps to make all survey instruments appropriate for the general population, including low literacy and minority subgroups. The comment also refers to the agency's proposal to have a subset of the sample complete a modified National Institutes of Health, National Cancer Institute (NIH–NCI) Diet History Questionnaire (DHQ), and asks how the DHQ will be modified for use in the IFPS II. The comment states that the standard DHQ appears to be based primarily on a typical Western diet and collects limited information on ethnic/culture-specific foods.

(Response) The agency disagrees that the data collection instruments should be appropriate for low literacy subgroups. The agency notes that all panel members are, in fact, literate. It would be impossible to conduct a mail survey with people who have low literacy. As noted earlier, the consumer opinion panel will provide data on a fairly broad middle segment of the U.S. population, with oversampling of panel members who have a low level of education and who are of minority race and ethnicity. Thus, the sample will include a range of education and income, including some panel members with no more than a high school education and some low income respondents who qualify for the WIC program. Based on pretesting and on our experience with the first IFPS, we expect that the length and detail of the questionnaires will be appropriate for the IFPS II sample.

Major parts of the instruments were extensively tested and used successfully in the previous IFPS. In the previous study, 32 percent of the sample had no more than a high school education, and as noted above, 20 percent participated in WIC. Some of the previous questions and the new questions have been cognitively tested with a small number of WIC mothers and mothers from the panel from which the sample will be drawn. After OMB approval for the data collection, a pilot test will be conducted for additional testing. One finding from the cognitive testing is that, for some types of questions, it is easier for the mothers to give detailed answers than to answer ''in general'' responses.

In response to the question about modification of the DHQ, the original NIH–NCI Diet History Questionnaire asks participants about foods consumed during the past year. For the IFPS II, the questionnaire was modified to ask about foods consumed in the past month, a more appropriate interval for measuring diet in pregnancy and lactation. Additionally, foods and dietary supplements of special interest in pregnancy and lactation were added to the questionnaire, including certain fortified foods, foods relevant to developing messages about food safety, prenatal vitamin supplements and herbal and botanical preparations known to be used for conditions of pregnancy or breastfeeding or known to be taken by pregnant women. The wording of the question items is given in our draft modified DHQ, which was available for review at the time of our first notice of proposed data collection (69 FR 21548–21549) and is again available with the present notice.

The DHQ was designed based on food intake from a general population national dietary survey, U.S. Department of Agriculture's (USDA's) Continuing Survey of Food Intakes by Individuals 1994 to 1996. These reference data are representative of the entire U.S. adult population. It is true that the DHQ collects limited information on culture-specific foods. However, significant portions of the questionnaire inquire about consumption of whole foods, such as various fruits, vegetables, and grains which are common to many cultures. Because the DHQ was developed using nationally representative food intake data, it is appropriate for this sample of mothers from a fairly broad middle segment of the U.S. population.

Regarding the comment about length and detail of proposed survey instruments, we note that the infant related questionnaires take less time to complete than they appear because of skip patterns. All questionnaires include some questions that only mothers with certain characteristics will answer, and most mothers will skip at least some of these sections. In the postnatal questionnaires that are composed of various modules, some of the modules will be completed only by select mothers. For example, Module B, Stopping Breastfeeding, and Module C, Food Allergy, will be skipped by most mothers in most months they are sent.

The NIH–NCI DHQ may appear to be lengthy and detailed, but its design emphasizes clarity and ease of use for the respondent. The DHQ, developed using extensive cognitive testing, presents food questions individually, rather than in the older, ''grid'' format; avoids grouping food items that are not conceptually similar (although their nutrients may be similar); and uses nested questions about differing forms of a food. When compared with an older, grid format questionnaire in a

mailed survey, the DHQ had a better response rate, was rated easier to use by participants, and had fewer missing or unusable responses on portion size, even though the grid format questionnaire had fewer pages and took less time to complete. Other studies have shown that the accuracy of dietary intake using the DHQ is similar to or better than that for standard grid format questionnaires when compared with checklist or 24-hour diet recall criteria.

(Comment 6) One comment from industry states that use of the IFPS II data to evaluate the HHS National Breastfeeding Awareness Campaign will not be valid unless the sample is truly representative of the U.S. population and has an adequate sample of African-Americans, a group that the campaign especially hopes to reach.

(Response) The agency is not persuaded that this component of the campaign evaluation requires a nationally representative sample. A separate pre-post design evaluation that has a national probability sample will examine the campaign's effect on attitudes related to breastfeeding, and most of the questions used in that evaluation have been included in the IFPS II. The design of the campaign evaluation component of the IFPS II is a prospective post-test only measure using statistical controls. The analysis will statistically compare mothers who are more and less exposed to the campaign and who are more and less aware of the campaign on the dimensions of perceptions and beliefs about breastfeeding, breastfeeding confidence, feeding intentions, and the breastfeeding behaviors of initiation, duration of exclusive breastfeeding, and duration of any breastfeeding. Appropriate control variables will be included in the analysis, such as demographic characteristics and previous breastfeeding experience. Mother's race will be included in the analysis to provide information on the extent to which the campaign was effective among African-American mothers. As noted above, African-American mothers will be oversampled to ensure an adequate number for analysis.

The IFPS II includes several elements that enhance the evaluation design. One strength of the design is the prospective data collection. Information about awareness of the campaign will first be obtained during pregnancy (in addition to monthly after the infant's birth), and the outcome variables will be measured throughout the infant's first year. In addition, the data will be collected nationally, which will provide geographic variation and therefore the ability to collect data in communities with varying degrees of exposure to the campaign.

IV. Comments on Topic Three

What are the ways to enhance the quality, utility, and clarity of the information to be collected?

(Comment 7) One comment from industry urges FDA not to ask for specific formula brand name because this information is not needed for the agency purposes and could be misused by researchers outside of the agency who analyze the data. It recommends that if brands are asked, colored package photos of each brand be provided to respondents to improve accuracy.

(Response) The agency agrees that formula brand information is not needed for our purposes, and we have revised response options to obtain the information we need without identifying specific brands. Our interest is in certain characteristics of the formula, such as whether it was milk, soy, or hydrolysate based, and whether it contains DHA and ARA. We have determined that a series of questions to obtain formula characteristics directly from mothers is not the best option because some mothers do not know some of the characteristics of interest and because the series of questions required each time formula characteristics are asked would increase the length and repetitiveness of the survey. Therefore, we will ask mothers what brand of formula they are using, but the brands will be grouped so that individual brands cannot be identified. For example, all of the milk-based formulas, including store brands, without DHA and ARA will be grouped together; all of the soy-based formulas, including store brands, without DHA and ARA will be grouped together, and so forth. The exact groupings are listed in the questionnaire. Because brands are grouped, there is no need to use color photos to distinguish different formulas with similar names because the most similar ones will be in the same group.

(Comment 8) One comment from industry questions whether the two psychological testing scales should be used in a mail survey. Particularly regarding the depression scale, the concern is that the Federal Government would possess potentially life-saving information that cannot be used without violating the promise of respondent confidentiality.

(Response) The agency is confident of the appropriateness of these scales for a mail survey. The Edinburgh Postpartum Depression Scale is a publicly available instrument and is established in the field as a standard screening tool for postpartum depression. The Edinburgh Postnatal Depression Scale has been used previously in at least two large mail surveys, one of which also assessed the relation between breastfeeding and postpartum depression. It is administered as a self-completed survey when it used in clinics or other settings where face-to-face interactions are possible. The IFPS II will use a version slightly modified for consistency with the conventions of the American language, as used in the Listening to Mothers Study.

The Listening to Mothers Survey (LtMS) was a concurrently administered mail and Web survey completed by 1,583 women who had given birth in the last 24 months. This survey was developed by the Maternity Center Association and Harris Interactive to assess a broad range of issues related to birth experiences. The survey included items on breastfeeding related to the intrapartum hospital stay and the Edinburgh Postpartum Depression Scale. The agency has consulted with the principal investigators on the LtMS, who have expertise in postpartum depression as well as this particular survey methodology, and is convinced that administration of the Edinburgh Postpartum Depression Scale survey in this medium is appropriate and does not introduce risk to the mothers involved in the IFPS II.

The comment is correct that the IFPS II will not have procedures to refer women for followup evaluation if they score relatively high on the depression scale. We note that even a high score does not indicate a life-threatening extent of depression. Previous researchers have faced this same issue of lack of followup as well, which has been reviewed in all cases by the appropriate Institutional Review Board. The Institutional Review Boards reviewing prior mail surveys have determined this risk to be minimal, and use of this measure has also been approved by FDA's Research Involving Human Subjects Committee. The Rosenberg Self-Esteem Scale measure was developed to be self-administered and has high reliability. It measures a stable characteristic of adults, and therefore a characteristic unlikely to change greatly during pregnancy and the postpartum period. The Rosenberg Self-Esteem Scale contains no items that are sensitive. It is more scientifically rigorous, as well as efficient for the government to use established reliable instruments that are available and appropriate than to develop its own.

(Comment 9) One comment from industry states that the wording and order of questions in the 1993

questionnaire have been changed so much that FDA has lost the ability to legitimately compare the two studies and draw conclusions about changes over time.

(Response) The agency is not persuaded that comparisons between all question results will be invalid because of the addition of new questions and the slight differing in order from the previous study. Nearly all repeated surveys add and drop some questions between data collections because of the imperative need to address current issues while keeping the survey length reasonable. The agency recognizes that some of the questions have changed from the 1993 study and that the context of some questions has necessarily changed because new questions have been added. However, FDA has kept the same order of questions relative to the 1993 study to the extent possible, but with some modifications to improve but questionnaire flow. In addition, for the postnatal questionnaires the modules will be placed in the same order as they appeared in the 1993 study. Most of the postnatal modules will be sent with the same frequency and at the same infant ages as in the previous study. The modules that primarily consist of new questions will be placed near the end of each postnatal questionnaire in order to minimize a change in context for the questions repeated from the previous study.

(Comment 10) One comment from industry states that the questionnaire flow, i.e., the order of topics and the transition between topics, needs to be improved. It points out that some of the problem with questionnaire flow occurs because of the difficulty of accommodating new questions within the order of the old questions.

(Response) The agency has evaluated the order of topics in some of the cognitive testing that has been conducted and will also evaluate it in the pilot tests to be conducted after OMB approval of the data collection. The comment is correct our addition of new questions and deletion of old ones has led to a less smooth questionnaire flow in some places. We have sacrificed improvements in order to maintain maximum comparability with the previous study except where the flow was especially awkward. The agency is convinced that comparability is the more important characteristic and that questionnaire flow is sufficient to achieve valid data.

(Comment 11) One comment from industry states that some of the questionnaires are extremely long and that some of the repeated questions have increased in length and complexity. The comment urges FDA to conduct pretests to identify and correct sources of respondent fatigue, confusion, or inconsistency.

(Response) The agency agrees that pretesting the questionnaires is important. We have conducted cognitive interviews on some parts of the questionnaires, and we plan to conduct larger pretests after OMB approval for information collection is granted. We disagree that any of the questionnaires are extremely long. None are longer than the questionnaires in the original study, for which response rates and data quality were very good. As part of the questionnaire development and in response to these comments, we will continue to evaluate the effect of lengthy questions before the questionnaires are fielded.

(Comment 12) One comment from industry states that some of the questionnaires do not include a WIC participation question.

(Response) The WIC participation question will appear in all questionnaires. It is in Module L, which will be sent in all postnatal questionnaires.

(Comment 13) One comment states that factual information is needed on how much influence, if any, infant formula labeling and advertising have on a woman's decision to use infant formula. It recommends that questions be added that will address formula marketing and use of infant formula. A specific question recommended is whether mothers read infant formula labels before they decide whether or not to breastfeed, and if so, how much influence the information on the labels has on their decision.

(Response) The agency is not persuaded that direct questions about the influence of various factors on infant feeding intentions will be useful. At the time of the prenatal questionnaire, mothers will have intentions for methods of feeding their babies but actual behavior will come after the infant is born. We have included questions about sources of information, which is an appropriate and related topic.

(Comment 14) One comment states that an assessment of the impact of the National Breastfeeding Awareness Campaign on a woman's decisionmaking would be useful.

(Response) The agency agrees with this comment. We note that the questionnaires have been designed to measure the association between awareness of and agreement with the campaign messages and breastfeeding behaviors promoted by the campaign.

V. Specific Comments on the Prenatal Questionnaire

(Comment 15) The questionnaire emphasizes breastfeeding, which could bias respondents postnatally. The concern is that answering questions about breastfeeding prenatally will have an artificial effect on behavior.

(Response) The agency disagrees that any effect on behavior of answering questions prenatally will be large. While the agency is concerned about the possibility of previous questions influencing behavior, it is essential to obtain a description of infant feeding intentions and attitudes from the prenatal questionnaire. Most of the sources of information about infant feeding that a pregnant woman is exposed to probably mention the value of breastfeeding, so that answering questions about breastfeeding will not introduce an idea to which the mother would not otherwise be exposed. It is unlikely that the presence of questions about breastfeeding will affect subsequent behavior differently than questions from health care professionals and important family members or information already available to pregnant women. Additionally, approximately 70 percent of new mothers in the United States initiate breastfeeding and the rates are expected to be higher in this sample because of the demographic characteristics. Therefore, most women in the sample will have thought about breastfeeding and will have planned to initiate breastfeeding before reading the IFPS II questions.

(Comment 16) One comment recommends that prenatal questions about intended feeding methods appear earlier in the questionnaire, followed by questions to elicit the primary influencers of her decision. A similar comment states that the prenatal question about exposure to breastfeeding and infant formula information from various sources is adequate to assess awareness of those sources, but that to assess impact, additional questions about how much impact the public communication or advertisements had on knowledge, decisionmaking and behavior should follow. The comment recommends that the agency ask the mother to rate the influence of certain information on her decisionmaking.

(Response) The agency agrees that moving intended feeding methods to an earlier part of the questionnaire will substantially improve the questionnaire flow and has made this change.

We are not persuaded that direct questions about the influence of labels

and advertising on infant feeding behavior are as useful as questions about exposure to various factors and the subsequent measurement of attitudes and behaviors. People are often unaware of the effect of specific information. For example, most people report that advertising has no effect on their behavior, but research indicates that this is not the case. We do ask about the reasons for certain behaviors, including stopping breastfeeding, changing formula brands, and choosing formula brands. For the first behavior, the mother is not likely to be aware of the influence of specific information such as formula advertising. For the other two behaviors, it is possible that mothers sought information from formula labels and advertising and are therefore more likely to be able to report their influence.

(Comment 17) One comment states that the question about which medical conditions the baby's relatives have will confuse the respondents, particularly the ''other relatives'' column because it is unclear how to answer if some other relatives have the condition, some do not, or their conditions are not known. It recommends that the question be reduced to ask whether anyone in the family has each condition. In addition, the comment states that the terms ''eczema,'' ''food allergy,'' and ''overweight/obesity'' are not defined, thereby allowing for a wide range of interpretations.

(Response) The agency has completed cognitive testing of this question and has found that pregnant women and mothers do not have trouble answering it. This type of checklist is commonly completed at doctor's offices and in other medical settings. The information is important to have for the mother herself because some of the conditions may affect breastfeeding. Whether the infant's first degree relatives, in contrast to other relatives, have the condition is important. The question asks about ''any'' other relatives, not ''all'' other relatives, a wording which should help the mother understand the meaning of the question.

As people answer medical condition checklists, they should recognize the term if they have the condition. Cognitive tests have shown that mothers are not disturbed by encountering unknown conditions in this list. The agency has asked whether respondents or their infants or children have food allergies in the original IFPS and also in general population telephone surveys. It is likely that people who have a true food allergy, and especially a severe one, will classify themselves correctly so that the category will include nearly all of the targeted group, but will also include some that are not actually in the classification. That is, the classification will be useful even though it is not perfect. Regarding ''overweight/obesity,'' although some respondents may misclassify themselves or their relatives, prior research has demonstrated that self-report of this condition is appropriate for use in this type of research setting.

(Comment 18) One comment states that the workplace questions ask mothers to speculate on workplace receptiveness to breastfeeding but that all these questions are vague and should be qualified.

(Response) The agency is not persuaded that the workplace questions are vague nor that they ask for speculation on the part of the mother. The pregnant women we have interviewed so far have been aware of workplace issues related to breastfeeding because they are in a situation that makes the information very relevant to them. A later questionnaire asks about specific issues related to workplace and to child care support for breastfeeding, and it asks for the mother's overall impression using the same questions as in the prenatal questionnaire. Cognitive testing on the full set of questions has shown that mothers can answer the specific and the general question easily and that they see the general question as a summary of all various practices and policies of the workplace. The mother's overall impression is what the question intends to measure, and it appears to work for this purpose. The cognitive interviews suggest that mothers give the question a consistent interpretation.

(Comment 19) Both comments from industry find this question to be vague: ''Which of the following statements is closest to your opinion? The best way to feed a baby is:'' They state that the age of the baby is not specified in the question and that ''best'' is not defined in terms of the mother's or child's interest. One comment recommends a different question: ''From what you know, which is generally healthier for an infant: breastfeeding, formula feeding, both are about the same?''

(Response) The agency is not persuaded that the question is vague when asked in the context of the prenatal questionnaire. The question was asked on the original IFPS, and it was analytically useful. The context of the prenatal questionnaire leads respondents to think of very young babies rather than older ones. The question asks for a general, overall assessment by the mother, similar to the overall assessment we ask regarding the supportiveness of the workplace. We have no reason to believe that mothers have varied interpretations of this question. If we ask about the best feeding method for different interests and different dimensions, such as physical or psychological health, many additional questions would be needed, and we would not know how important the various aspects are to the mothers. The one question provides us with the information we are seeking.

In addition to these considerations, this question was asked on the population survey to assess pre-campaign attitudes toward breastfeeding. It is important to ask the same question of mothers in the IFPS II.

(Comment 20) One comment states that new mothers are notoriously poor at remembering where advertising has been seen. It suggests that responses be collapsed into a single response on the question which asks where mothers where they have seen advertisements about breastfeeding and about infant formula.

(Response) The agency disagrees that these response categories should be collapsed. This information was asked for breastfeeding on the population survey to assess precampaign attitudes toward breastfeeding. As noted previously, it is important to ask the same question of mothers in the IFPS II. It would be confusing to ask mothers one set of sources for breastfeeding and a different one for infant formula.

(Comment 21) Both comments from industry suggest that the agency differentiate between emotional commitment and understanding of scientific relationships in the following question: ''How strongly do you agree or disagree with the following statement? Infant formula is as good as breast milk'' and other statements. Both comments from industry assert that the question does not specify the meaning of ''good'' or of ''less'' likely.

(Response) This question is one asked on the population survey conducted before the National Breastfeeding Awareness Campaign launched. Each statement asks about a specific information element of the campaign. These are essential and direct measures of agreement with the campaign messages. The agency is not persuaded that the question should be changed.

(Comment 22) One comment asks that the following question be deleted because such adjective checklists of this type are typically administered immediately after exposure to an ad, not when respondents must recall their feelings about an ad they saw in the past. ''Thinking about the advertisement for breastfeeding, please mark whether

you agree or disagree with each of the following statements. It's entertaining,'' and other statements.

(Response) The agency agrees that this question should be deleted throughout the questionnaires.

(Comment 23) Both comments from industry recommend adding a question about formula feeding similar to the following question to reduce potential bias caused by a concentration on breastfeeding. ''About how many of your friends and relatives have breastfed their baby?'' It also recommends adding ''if any'' after ''about how many,'' to ensure that the response ''none'' is not underreported.

(Response) The agency agrees that it would enhance the study to include a similar question to determine whether the respondent has friends or relatives who have used formula. Because most infants receive formula some time during the first year even if they are breastfed, the more meaningful question would be how many friends and relatives used only formula from their baby's birth. We are not persuaded that the additional phrase ''if any'' is needed. The question is one from the original study, in which 3 percent of respondents chose the option ''none have breastfed.'' In addition, 1 percent said that none of their friends or relatives have children, and 8 percent responded ''don't know.'' In all, 12 percent chose an answer other than a number. While a frequency distribution cannot assure that a response was not underreported, it does at least indicate that a sizeable number of respondents noticed the response options other than numbers.

(Comment 24) One comment notes that ''never'' was added to the response options and recommends that ''never'' be replaced with ''don't know'' in the following question: ''How old do you think your baby will be when you first feed him or her formula or any other food besides breast milk?''

(Response) The agency is persuaded that ''never'' should be deleted from these response options. In order to keep the response options the same as in the original question, ''don't know'' will not be added.

(Comment 25) One comment asks that the agency delete these questions: ''How old do you think your baby will be when you completely stop breastfeeding?'' and ''Using 1 to mean 'not at all confident' and 5 to mean 'very confident,' how confident are you that you will be able to breastfeed until the baby is the age you marked in the previous question?'' The comment states that the questions are a repeated measure and that they invite mothers to speculate on when they will stop breastfeeding and their ability to do what they say (via a ''confidence'' scale). Sensitizing mothers to this issue prenatally can bias their behavior postnatally. Similarly, repeatedly asking it postnatally could also bias continued behavior.

(Response) The agency is not persuaded that the study would be improved by deleting these questions. Intended duration of breastfeeding was asked in the original study and is an important variable for explaining actual duration. The addition of how confident the mother is that she will breastfeed for that duration is a question suggested by the Health Belief Model of behavioral change. As noted previously, the agency is concerned about the possibility that asking questions about breastfeeding might affect subsequent behavior. As mentioned in the response to the first item commenting about the prenatal questionnaire, pregnant women are exposed to information about breastfeeding in multiple ways and from authoritative sources such as child birth educators, nurses, physicians, and important family members. It is unlikely that additional exposure through a questionnaire will have substantial additional effect.

VI. Birth Screener

(Comment 26) One comment recommends that the agency clarify this question: ''Did the mother/you have any medical problems that prevented (her/you) from feeding the baby for more than a week?'' The comment states that it is not clear whether the question pertains only to breastfeeding.

(Response) The agency is not persuaded that changing this question will improve the usefulness of the data because it was used in the previous study to screen out mothers with serious medical problems. However, we will add an interviewer instruction to clarify if needed to the respondent that we mean any type of feeding, not just breastfeeding. To mix the concepts of how the mother intended to feed the infant and her health in one question would change the selection criteria for the sample. Similarly, to change the question to a series of questions on mothers' health would eliminate comparability with the previous sample.

VII. Specific Comments on the Neonatal Questionnaire

(Comment 27) One comment states that unnecessary complexity to the point that it interferes with comprehension has been added to this question modified from the 1993 study: ''In your opinion, which statement best describes your doctor or health professional's attitude about feeding your baby, and the attitude of the staff in the hospital, clinic, or birth center where you delivered?'' The comment suggests that influences be simplified to obstetrician/gynecologist (OB/GYN), pediatrician, doctor on staff at hospital, and other staff at hospital. It suggests that responses be simplified to breastfeed only, formula feed only, breastfeed and formula feed, or no opinion/did not discuss. The comment also recommends a simpler alternative, asking whether any medical professionals or staff at the hospital gave advice or opinions on how to feed your baby in the hospital. Those who responded yes would be asked to check all the ways they were advised to feed their baby with the responses listed above (breastfeed only, etc.).

(Response) The agency notes that the 1993 question asked only about hospital staff and a different question asked about the recommendation of a doctor or other health professional. The new question asks about the two health professional categories in the same format while differentiating between the mother's and baby's doctors, and it asks about perception of attitude rather than recommendation.

The agency is persuaded that some of the changes recommended in the comment will improve the usefulness of the data but that other recommended changes will not. In a paper published from the previous questions on this topic, we found that many women did not report receiving positive breastfeeding messages from doctors and hospital staff and that mothers who perceived that the hospital staff expressed no preference on feeding method were significantly less likely to breastfeed beyond 6 weeks. Cognitive interviews have suggested that mothers differentiate the attitudes of their physician or obstetrician and those of the baby's doctor. Therefore, in the proposed study, it is important to ask the mother to provide an answer for each type of physician and for hospital staff and to include ''had no preference for method of feeding'' as a response option. In cognitive interviews, the question was tested with the last two response options (had no preference and had no discussion of feeding) combined, and one of the mothers expressed a need for the latter category.

The response options in the question, strongly favored breastfeeding to strongly favored bottle feeding, were tested in cognitive interviews to determine whether mothers differentiated strength of attitude. It was found that they did not. Therefore, the

agency has used the response option change recommended in the comment (breastfeed only, formula feed only, etc.), along with the no preference and no discussion response options.

(Comment 28) One comment asks that the agency reword the question on what the mother thinks is the recommended number of months to exclusively breastfeed a baby to ask whether the mother received a recommendation about how long to exclusively breastfeed. The comment expresses concern that the current question will lead mothers to assume that there are a recommended number of months and invites them to guess what it is.

(Response) The agency is not persuaded that this question should be changed as suggested. Because there is a recommendation from the American Academy of Pediatrics Work Group on Breastfeeding and from the American Dietetic Association to exclusively breastfeed for 6 months and from the American Academy of Pediatrics Committee on Nutrition to breastfeed exclusively for 4 to 6 months, and because the National Breastfeeding Awareness Campaign will include exclusive breastfeeding for 6 months as a message, the IFPS II needs to collect data on what mothers think the recommendation is, regardless of whether a health professional has made a specific recommendation to the mother. The agency added a response option, ''Don't know,'' so that mothers will not be encouraged to guess.

(Comment 29) Both industry comments state that some response options are missing from this question: ''What were the reasons you decided not to breastfeed your baby?'' Both comments are concerned that personal preference and the inconvenience of breastfeeding are not included. Both comments also suggest rewording one of the response options from ''had to go back to work/school'' to ''planned to go back to work/school.'' Both recommend that the question obtain a measure of importance for the reasons. One comment recommended including responses to identify infant formula advertising and breastfeeding promotion as reasons for the feeding choice. The comment also recommended including economic reasons because of the claimed health benefits of continued breastfeeding and associated medical care cost reductions.

(Response) The agency is persuaded that obtaining a measure of importance will improve the question because it will make it comparable to other similar questions. We note that ''breastfeeding was too inconvenient'' was a response option for a similar question on reasons for stopping breastfeeding, and we have changed this neonatal question to have the same response options, to the extent possible, as the question on stopping breastfeeding. It now includes the option, ''I thought that breastfeeding would be too inconvenient.'' The agency does not agree that ''personal preference'' will be a helpful response option because it is too vague. We also do not agree that adding a response option on economics will be useful for this question because the economic benefits are associated with breastfeeding, not with formula feeding.

As discussed earlier, we do not believe that mothers will be aware of or be able to adequately report the influence of formula labeling and advertisement. That option has not been added.

(Comment 30) One comment states that this question is vague and should be deleted ''How long was it until you became emotionally comfortable nursing your baby?''

(Response) The agency is not persuaded that this question should be deleted. One reason is that it is repeated from the original study. Another reason is that initial cognitive testing has shown that mothers for whom breastfeeding has gone well have chosen shorter times than mothers who have had more difficulty with breastfeeding.

(Comment 31) One comment recommends that this question be returned to the wording in the 1993 questionnaire: ''Did you get any help with these problems from a doctor or other health professional, a lactation consultant, or a breastfeeding support group?'' It notes that the original questions said ''did you ask for help.''

(Response) The agency notes that these two questions address very different phenomena. The original question will reveal whether mothers recognize the need for help and ask for help in the early days of breastfeeding, whereas the revised question addresses the actual provision of assistance to mothers regardless of whether they asked for help. The agency is persuaded that the 1993 question should be retained; however, the revised question will be included as well to differentiate these two experiences. Because mothers may receive help whether they ask for it or not, one question is not contingent on the other.

(Comment 32) One comment recommends changing the question on pain with breastfeeding. The comment states that the 10-point scale (from no pain at all to the worst pain you have ever felt) is not applicable to breastfeeding and risks trivializing the issue. It also states that it is debatable whether mothers can accurately recall and differentiate the pain level over four short and successive periods of time. It suggests that the question be divided into two questions. The first question would ask the mother to rate the pain the first time she breastfed on a 4-point scale from very severe to no pain. The second question would ask whether the pain became less severe over time.

(Response) The agency disagrees that changing this question will improve the data. Cognitive interviews have shown that breastfeeding pain usually begins later than the first breastfeeding and that after pain develops, it diminishes rapidly for some mothers but slowly for others. Therefore, a question will not characterize the pain if it only asks about pain at the first breastfeeding and then evolution of this pain for a time. In addition, a 10-point scale for pain with anchors similar to those used in the question is a standard pain self-assessment. We have changed the anchor to read ''worst possible pain'' to reflect the exact wording of the published anchors for this scale. Our use of this scale for different time periods will enable respondents to describe the level of pain over time, not only whether it got better. The mothers will be about 3 weeks postpartum when they answer this question, and it is unlikely that the time periods will have already blurred for them.

(Comment 33) One comment states that the questions about gift packs should be modified to reflect the possibility of multiple gift packs or multiple samples in the mail.

(Response) The agency acknowledges that mothers receive multiple gift packs and may also receive multiple samples of infant formula through the mail. A question was added that asks about receiving gift packs from places other than the hospital, and the question about receiving a gift pack from the hospital has been clarified. The issue of distinguishing formula brands from the various sources of gift packs is no longer relevant because we do not ask about formula brand.

(Comment 34) One comment states that an added response option to this question is vague and could apply to almost any brand: ''When you first began buying formula, how did you decide which brand of formula to buy for your baby?'' The option of concern is: ''Chose a brand advertised as better for my baby's development.'' The comment notes that the statement is leading because consumers are not likely to distinguish between ''advertising'' and other forms of information about brand benefits.

(Response) The agency is persuaded that the option should be changed rather than deleted, and we have reworded it as follows: ''I heard that the brand is better for my baby.'' The question is asking for the mothers' reasons for choosing a formula brand, and most of the response options could apply to any formula brand. We agree that mothers are not likely to distinguish advisements from brochures or other information about formula, and we are not interested in a narrow definition of advertisement. The new wording does not ask the mother to distinguish advertising from other information.

(Comment 35) One comment states that the reference formula in this question is unclear: ''Did you discuss your choice of formula brand with the baby's doctor.''

(Response) The agency agrees that the reference formula is unclear and has revised the question to clarify it.

(Comment 36) One comment recommends that ''brand of formula'' replace ''choice of formula'' so that it is not confused with form of formula in two questions: ''Did you discuss your choice of formula brand with the baby's doctor,'' and ''During the past two weeks, have you switched the formula you feed your baby?''

(Response) The agency notes that formula brand is already in the first question. The second one has been changed to incorporate the recommended change.

(Comment 37) One comment states that too many response options have been added to this question: ''What kind of problem(s) have you had (breastfeeding since the first week)?'' The comment states that the added response options complicate the question and contribute to driving the questionnaire to an unacceptable length.

(Response) The agency is not persuaded that adding relevant response options complicates a question. Rather, it gives respondents a way to indicate an answer that best fits them. In cognitive interviews, respondents offer additional responses to questions if they find that none of the responses fit them or if they have additional salient responses that they want to give. The agency is not persuaded that the neonatal questionnaire is an unacceptable length. The new questionnaire is about the same length as the neonatal questionnaire in the 1993 study, which had a very high response rate.

(Comment 38) One comment repeats comment 25 of this document on the prenatal questionnaire, concerning the repeated question regarding intended duration of breastfeeding and confidence in achieving the intended duration.

(Response) See response under comment 25 of this document for the prenatal questionnaire.

(Comment 39) One comment suggests that the agency change this question to ask about concerns rather than feelings: ''How often do you have the feelings described in the following statements?''

(Response) The agency is not persuaded that the change would improve the data. The purpose of the question is to measure the mother's confidence in breastfeeding. The concepts included are those that occur in several lengthy measures of breastfeeding confidence, none of which as a whole were determined to be appropriate for the IFPS II. It is possible for a person to be very concerned about something, and therefore more vigilant and successful, or very concerned because they are not successful. Changing the question as recommended would provide an indication of concerns without information on how the mothers coped with the concerns. In cognitive interviews, mothers have indicated that they are concerned about some statements to which they respond very positively. For example, a mother said that she is always concerned whether her infant gets enough milk at a feeding, so she observes the baby to see that he appears satisfied. She marked ''always'' for ''I feel that my baby gets enough breast milk at each feeding.'' It is the latter information that will be useful in the study.

VIII. Specific Comments on Module A

(Comment 40) One comment states that this question attempts to combine two issues that should be kept separate to minimize the risk of overstating the situation: ''During the past two weeks, how often has your baby been put to bed with a bottle of formula, juice, juice drink, or milk of any kind?'' The two issues are how often and on what occasions babies are put to sleep with a bottle.

(Response) The agency is not persuaded that the recommended change would improve the validity of the data and believes that it would be much more burdensome to respondents. This question is easy for mothers to answer and it repeats a question from the previous study. The purpose of the question is to find out how regularly the infant goes to sleep with a bottle of anything besides water. The naps and bedtimes were divided in the response options because mothers in the cognitive testing for the first study indicated that behavior sometimes differs by these sleep times.

(Comment 41) One comment states that certain medical conditions need to be defined in the check list for this question: ''Did your baby have any of the following illnesses or problems during the past two weeks?'' In particular, the comment recommends that these terms be defined as the following: food allergy, eczema, and other skin rashes.

(Response) The agency agrees that the term ''other skin rash'' is vague and has deleted it from the list of illnesses. As we stated in the response to the comment on the prenatal questionnaire item that asks the mother to report family history of medical conditions, it is likely that those mothers whose infants have a food allergy or eczema will know what the terms mean, and the others will not be concerned that they cannot define some of the terms. We do not agree that these terms need to be defined.

IX. Specific Comments on Module B

(Comment 42) One comment states that the response grid has been lengthened substantially for this question: ''How important was each of the following reasons for your decision to stop breastfeeding your baby?'' The comment states that responses located at the end of the response grid will probably be understated. It recommends that similar responses be consolidated. Another comment recommends that additional response options be added to elicit information on the influence of formula advertisements and labels as reasons the mother stopped breastfeeding.

(Response) The agency shares the comment's concern about lengthy lists of response options. The issue has been addressed in cognitive interviews, but a larger number of respondents is needed to evaluate the issue. In the previous IFPS, items at the end of the list had sizeable positive responses. For example, 20 percent of respondents to Module B at infant age 3 months marked the next-to-last item, ''I wanted my body back to myself'' as greater in importance than ''not at all important.'' (This response option was inadvertently omitted from the question and has been added.) It may be that when respondents are asked to rate each item, they are less likely to stop reading before the end of the list.

The agency will conduct tests of the effects of long lists on responses after OMB approval of the study, when the questionnaires can be administered to additional respondents. The agency has combined as many responses as it deems sufficiently similar in this and other long response option lists to

reduce the number of items, and further items will be combined if possible after additional tests. As noted earlier, the agency does not agree that information about the influence of formula advertisements and labels can be obtained from this survey, and we have not added items regarding formula labels.

(Comment 43) One comment recommends that this question should be revised and should be preceded by a question asking whether anyone said that the mother should stop breastfeeding: ''Did any of the following people want you to stop breastfeeding?'' It notes that this will enable asking a question that was on the 1993 questionnaire. It also suggests that respondent may feel uncomfortable singling out their employer or supervisor.

(Response) The agency is not persuaded that two questions should be asked. It is not persuaded that the question should be asked as in the 1993 questionnaire because ''said you should stop'' is only one form of communication; ''want you to stop'' allows for communications that are not direct statements. By asking the mother to consider whether each of the people listed wanted her to stop breastfeeding, we do not require the mothers to think through everyone they have contact with to answer a first broad question. By listing specifically those people of interest, we help the mothers remember all people of interest to us. The category, ''employer or supervisor,'' has been tested through cognitive interviewing and was not problematic. This is probably because mothers understand that their employers and supervisors do not have access to their responses on this survey. In all data files, mothers will be anonymous so that the possibility of anyone tracking down their employer or giving employers the information is even more remote.

(Comment 44) One comment is concerned that the following question is too speculative: ''How likely is it that you would breastfeed again if you had another child * * * .'' It recommends that the question be changed to ask mothers how interested they would be in breastfeeding their next baby.

(Response) The agency is not persuaded that the recommendation would improve the data. The question is repeated from the 1993 survey, so that change would destroy the possibility of comparison across time. In addition, intentionality and confidence in the decision to breastfeed have been found to be a strong predictor of actual subsequent breastfeeding behavior, whereas ''interest'' is a diffuse concept to operationalize.

X. Specific Comments on Module C

(Comment 45) One comment relates to this question: ''What brand of formula did your baby have the problem with or react to?'' The comment is concerned that the question perpetuates a misconception that formula causes intolerance symptoms and states that if formula intolerance occurs, it would be more likely to be related to the type (e.g., milk or soy-based) than brand. It recommends that if the question is kept, the 1993 version be used because it does not ask mothers to attribute causality to formula used at the time. It also notes that it has asked that all questions that ask respondents to identify brands of formula be deleted.

(Response) The agency agrees that formula brand is not needed for this question. We will ask the mother to choose a formula brand from grouped categories as described in the response to the first comment on the third topic for which we requested comments. In addition, the questions has been changed to that asked in the 1993 study.

(Comment 46) One comment concerns this question: Is there an infant formula your baby was given and did not have a reaction to? The comment notes that it has asked that all questions that ask respondents to identify brands of formula be deleted. These alternative questions are recommended: ''What other types of infant formula have you used,'' or ''What form of formula were you using when the baby did not experience any symptoms of allergy or intolerance?''

(Response) The agency agrees that brand is not needed and has changed the question.

(Comment 47) One comment concerns questions about age at first problem that mother thought was food allergy to formula and to any other food and symptoms of food allergy to formula and to food. The comment does not want specific brand to be indicated.

(Response) The agency agrees that specific formula brands are not needed for this question. The questions have been reworded.

(Comment 48) One comment concerns this question: ''Were the symptoms diagnosed as a food allergy by a doctor or other health professional?'' The comment is concerned that the question leads the respondents, and that they will interpret whatever the doctor said as indicating a food allergy. It recommends a rewording to include whether the problem was diagnosed as a food allergy or as an intolerance and offers several other options.

(Response) The agency is not persuaded that the question leads the respondents. In the previous study, about half of respondents who had consulted a doctor for the baby's symptoms said that the baby had been diagnosed as having a food allergy. Without independent assessment, it is not possible to know whether the respondents properly classified themselves, but it is certainly the case that not all respondents who had seen a doctor reported that the baby had a food allergy. We note that additional information in the questionnaire is available regarding the probable accuracy of the mother's report, including method of diagnosis and symptoms.

(Comment 49) One comment recommends that ''allergy'' be used in the following question and the instruction before it instead of ''food allergy.'' ''What method did the doctor use to diagnose the food allergy?'' The comment is concerned that the doctor may have only said ''allergy'' and not ''food allergy'' so that the question will lead to underreporting.

(Response) The agency is not persuaded that the wording of questions in this section should delete the term ''food'' to modify ''allergy.'' The section screens people in only if they state that the baby has had an allergic reaction or intolerance to food. Therefore, only people who believe that their baby has some sort of reaction to food will be answering these questions. In question 6, which asks what symptoms of food allergy or intolerance the baby had, the question may be confusing to people whose infants have had reactions to substances other than food if we only ask about ''allergy.'' The agency will test these questions for clarity before the questionnaires are finalized.

XI. Specific Comments on Module D

(Comment 50) One comment repeats comment 25 of this document on the prenatal questionnaire, concerning the repeated question regarding intended duration of breastfeeding and confidence in achieving the intended duration.

(Response) See response under comment 25 of this document for the prenatal questionnaire.

(Comment 51) One comment concerns this question: ''Where have you obtained information about breastfeeding and where have you obtained information about breast pumps for this baby or other babies?'' The comment states that recollection on sources of information for specific topics with previous children is likely to be poor. In addition, the list is too

long, risking understatement of items at the end.

(Response) The agency is persuaded that the question should be changed. As with other questions about sources of information, sources for this baby and previous babies are combined so that the mother does not have to distinguish them. More important, the question has been revised to ask about breast pumps only and has been moved to the section on breast pumps.

Rather than asking about sources of information about breastfeeding, we ask about sources of information about infant feeding, and this question will be asked in module F only. The times of administration of module F have been revised to obtain the information earlier.

We kept the idea of including sources of information for previous babies because cognitive testing revealed that respondents with older children were concerned that they were not able to mark any sources of information, or very few, for the current baby, despite having obtained information prior to this child. They pointed out that they had already read the books, discussed issues with health professionals, etc., and didn't need to do it again. The agency is concerned about the lengthy list of sources and has shortened it.

(Comment 52) One comment notes that answer grids are inconsistent between similar questions. For example, ''How important were each of the following reasons for feeding your baby formula?'' and other questions on reasons for not breastfeeding and questions about reasons for stopping breastfeeding have similar items as reasons, but some ask the respondent to complete a four-point rating scale of importance whereas others ask the respondent to mark which reasons were important. Both industry comments suggest that the response list include advertisements for infant formula including other media such as direct mail, Internet physician brochures, as well as infant formula labels as a possible reason the mother feeds her baby formula.

(Response) The agency is persuaded that the data will be more useful if all of these types of questions have the same answer grids and have response options as similar as possible. The specific reasons have been revised to accommodate concerns about redundancy and lengthy lists to the extent possible to maintain comparability with the 1993 questions and to provide the detail needed for some classes of reasons. As noted previously, the agency does not agree that information about the influence of infant formula advertising and labels can validly be obtained from this survey.

(Comment 53) One comment offers a suggestion for changing the questions about cleaning the bottle nipples used to feed the baby expressed breast milk and about sterilizing the pump collection kit, the container used to collect the milk, and the bottle used to feed the baby the expressed milk. The suggestion is to ask two questions: ''What are all the ways you cleaned the bottle nipples in the last seven days,'' and ''Which one way did you clean the most often?''

(Response) The agency is not persuaded that the suggestion is an improvement. Asking two questions would increase the length of the questionnaire. Asking which of several possible cleaning methods was used most often would increase respondent burden without adding important information because the main interest is in the less safe methods, which will rarely be used ''most often.'' Results from cognitive interviews and reviews by experts have led to changes in the question about sterilizing the pump collection kit, etc. The question now asks how often the items are sterilized rather than whether or not they are sterilized before being used again.

(Comment 54) One comment states that the term ''hurt'' is vague in this question: ''Have you been hurt by any breast pump that you used or tried to use to express milk since this baby was born?''

(Response) The agency is not persuaded that the term ''hurt'' is vague. Cognitive interviews were conducted using the term ''injured,'' which might be seen as more specific, in the above question. Respondents were alarmed and disturbed about the possibility of being injured by a breast pump. In subsequent interviews, the term ''hurt'' was used, and respondents answered the question without expressing alarm. The term ''hurt'' will enable respondents who have been injured to provide the information without alarming other mothers who have not been injured.

XII. Specific Comments on Module E

(Comment 55) One comment states that the question asking respondents to evaluate certain characteristics of formula labels is complicated and will invite confusion and inconsistency. It recommends that respondents be asked if they have looked at certain information before they are asked to evaluate it. The comment also recommends specific questions to replace this one for the current brand of formula. The recommended questions are as follows: (1) Is there anything on the label that is hard to understand? (2) Is there any information you wanted that was missing? and (3) Is there any part of the label that you tried to look at but had difficulty finding or reading because the print size was too small? In addition, the comment asks that the agency include a question regarding the mother's perception or understanding of how important it is to follow the label directions regarding the prepared formula.

(Response) The agency agrees that respondents need to be asked whether they have looked at the various types of information on formula labels before this question asking for their evaluation. It also agrees that this question needs to be simplified and has done so. However, the changes recommended in the comment are not adequate for our information needs. One reason is that the agency wants respondents to think about the specific types of information mentioned and not other information, such as the ingredient list, which might have different reading characteristics. The agency also does not want to rely on ''top-of-the-mind'' responses from open-ended ''specify'' instructions, which may be too vague to interpret. The agency agrees that it would be useful to add a question about how important the mother believes it is to follow certain label directions.

(Comment 56) Regarding the question asking the respondent to evaluate the pictorial directions for preparing formula, one comment asks that a question be added to establish whether the mother has looked at this part of the label.

(Response) The agency agrees that a question should be added to establish whether the mother has looked at the pictorial directions before evaluating this part of the label.

(Comment 57) One comment states that respondents will not be able to recall what ingredient they were looking for when they looked at the ingredient list of the label. It suggests that we ask what ingredient they were most concerned about when they decided to look at the label, with a response option, ''no particular ingredient.''

(Response) The agency agrees that use of the phrase ''concerned about'' rather than ''looking for'' will make the question closer to the 1993 question, and the change will be made. The agency believes that respondents who were not looking for a specific ingredient are accommodated already by the preceding question that asks whether they used the list to look for any specific ingredient. Those who were not looking for a particular ingredient can mark ''no'' in this question and skip

the question about what ingredient they were looking for. In addition to these changes, the questions have been revised to allow for looking anywhere on the label for any particular ingredient or characteristics because the presence or absence of certain ingredients is often indicated somewhere else in addition to the ingredient list.

(Comment 58) One comment recommends that questions be added to determine whether mothers find the nutrition content and information on special attributes on infant formula labels useful and desirable. The comment states that it would be valuable to know if mothers understand health claims and labels claims on formula in the proper context of one formula compared to other formulas, or if the statements require rewording to avoid inappropriate comparison of formula to breastfeeding, or unintended comparisons to other foods like cow milk or juice.

(Response) The agency disagrees that the IFPS II is an appropriate mechanism to examine detailed understanding of label claims and the effect of specific label wording. These types of issues are better addressed in experimental studies where researchers know exactly what subjects are viewing when they answer specific questions. The label questions in the IFPS apply to all formula containers, whereas health and label claims differ by brand and other formula characteristics.

(Comment 59) One comment recommends that a question be added to assess mother's perception of how safe infant formula powder is from a microbiological standpoint and whether infant formula powder is sterile.

(Response) The agency agrees that this additional information will be useful and has added a question.

(Comment 60) One comment recommends a simplification of the question about cleaning bottle nipples used to feed formula. It suggests this question, ''In the past seven days, how did you usually clean the bottle nipples (select one response from list)?''

(Response) The agency is not persuaded that the suggestion is an improvement. This question needs to be parallel to the question about cleaning the nipples used to feed expressed milk (see comment 53 of this document under module D). As noted in the response to that comment, the main interest is in the less safe methods, which will probably be used only some of the time, so that asking about usual cleaning methods will not provide the information required.

(Comment 61) One comment recommends a lead-in to help mothers feel more comfortable as they answer the question about handwashing before preparing formula.

(Response) The agency agrees that a lead-in such as that recommended will improve the data and has added it.

(Comment 62) One comment points out that respondents who have switched brands of formula more than 2 weeks earlier answer a question that includes no responses related to digestibility or tolerance, in contrast to those who switched in the past 2 weeks. They recommend that either the response list for the two questions be made comparable or that the time period for formula brand switching be lengthened to any period of time.

(Response) The agency rejects the suggestion that the time period for formula brand switching be lengthened to any period of time. A longer time period for brand switching would lead to less precise answers and more misclassification because mothers would not be able to rely on their recent memory, particularly if the reasons for switching were not salient to them. Therefore, the time period has not been changed.

We examined the possibility of making the two lists comparable. However, one question asks for reasons for leaving a brand and the other asks for reasons for using a brand, and the comparable reasons do not work for the two opposite questions. We added a response on the list for reasons for choosing a brand that relates to intolerance of the previous brand: ''My previous formula brand did not agree with my baby and this brand is better for the problem.''

XIII. Specific Comments on Module F

(Comment 63) One comment recommends a different placement for the question on sources of information about herbal preparations and also states that the response list is unnecessarily detailed and too long. It also recommends that the questionnaire first establish whether the respondent has ever sought information about herbs, botanicals, or other dietary supplements.

(Response) The agency calls attention to the note at the beginning of module F, which states that these questions will not be asked as a separate module, but will be inserted in appropriate places within other modules. This question about information sources for dietary supplements will follow questions about intake of these substances, but only in months 4 and 10.5.

The agency has considered response lists for all questions about sources of information together, has make them consistent to the extent possible given the information needs, and has combined some of the detailed but similar categories. Regarding asking first whether the mother has sought information, we note that information is often unsolicited, whether or not the respondent chooses to use the substances.

(Comment 64) One comment recommends that the agency not ask about sources of information for previous infants and that the response list for sources of information be consolidated and shortened. They refer to comment 53 of this document in module D.

(Response) See comment 53 of this document in module D.

XIV. Specific Comments on Module G

(Comment 65) One comment states that the questions in module G repeat questions in the prenatal and other questionnaires about the National Breastfeeding Awareness Campaign. It expresses concern that no questions determine whether the respondent has seen any of the campaign advertisements or that the campaign is responsible for any of the attitudes that are measured.

(Response) The agency does not agree that awareness of campaign advertisements is not measured. These questions appear in the prenatal questionnaire, the neonatal questionnaire, and in module L, which will be sent at each administration of the postnatal questionnaires. The questions state that ''a description of a campaign advertisement will be provided,'' although one example is given. The specific advertisements asked about will rotate among the various ads from the campaign.

It is the case that specific questions about the campaign are asked in the prenatal questionnaire and are repeated at infant ages 3 and 7 months. While the research design will not be able to prove that breastfeeding attitudes are affected by the campaign, the design will be able to provide evidence of the effect of the campaign. The analysis of breastfeeding attitudes and knowledge in geographical areas with different extents of exposure to the campaign advertisements and between individuals who have and who have not seen the advertisements will provide this evidence.

(Comment 66) One comment asks the agency to consider the comments stated in comment 20 of this document for the prenatal questionnaire regarding recall of where advertisements or other information was seen.

(Response) The agency refers to the response under that comment.

(Comment 67) One comment states that the lack of an infant age in the question asking what is the best way to feed a baby is a greater limitation in the ability to interpret the response when this question is asked of older infants.

(Response) The agency is persuaded that the same question asked in the prenatal questionnaire cannot be repeated for older infants. We have added infant age in the month 3 question and dropped the question for month 7.

(Comment 68) One comment states that comment 21 of this document for the prenatal questionnaire applies to this repeated question also. That comment concerned the question asking about agreement with campaign messages.

(Response) The agency refers to the response under that comment.

XV. Specific Comments on Module H

(Comment 69) One comment refers back to comment 18 of this document of the prenatal questionnaire for a repeated question regarding workplace supportiveness for breastfeeding.

(Response) The agency refers to the response under that comment.

(Comment 70) One comment suggests that a question on workplace policies regarding breastfeeding will require the respondent to speculate when they answer whether all mothers are covered by the policies. It recommends changing the question to a yes-no response format.

(Response) The agency agrees that respondents may not know what the workplace policy is for other mothers. The question has been changed.

(Comment 71) One comment states that the question about breastfeeding obstacles at work covers very sensitive material that may have legal implications to the extent that respondents are invited to record real or imagined improper actions by people at work.

(Response) The agency disagrees that the question is sensitive or has legal implications. The question asks the mother whether she has had certain experiences at work, but the responses will be the mothers' perceptions. Details are not asked that would be needed to determine whether illegal behavior has occurred. Furthermore, none of the experiences asked about is illegal in the general way described. None of the respondents in cognitive interviews have thought the questions sensitive.

FDA estimates the burden of this information collection as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN YEAR 1[1]

Questionnaire	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Prenatal	3,500	1	3,500	.25	875
Prenatal Diet History Questionnaire	1,400	1	1,400	1.00	1,400
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	1,400	1	1,400	1.00	1,400
Month 2 Questionnaire	2,250	1	2,250	.42	945
Month 3 Questionnaire	2,250	1	2,250	.42	945
Month 4 Questionnaire	2,250	1	2,250	.25	562.5
Month 5 Questionnaire	1,875	1	1,875	.42	787.5
Month 6 Questionnaire	1,500	1	1,500	.42	630
Month 7 Questionnaire	1,125	1	1,125	.42	472.5
Month 9 Questionnaire	375	1	375	.25	94
Total			23,331		8,953

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

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN YEAR 2[1]

Questionnaire	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Month 5 Questionnaire	375	1	375	.42	157.5
Month 6 Questionnaire	750	1	750	.42	315
Month 7 Questionnaire	1,125	1	1,125	.42	472.5

TABLE 2.—ESTIMATED ANNUAL REPORTING BURDEN YEAR 2[1]—Continued

Questionnaire	No. of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
Month 9 Questionnaire	1,875	1	1,875	.25	469
Month 10 Questionnaire	2,250	1	2,250	.42	945
Month 12 Questionnaire	2,250	1	2,250	.42	945
Total			8,625		3,304

[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: September 22, 2004.

Jeffrey Shuren,

Assistant Commissioner for Policy.

[FR Doc. 04–22052 Filed 9–30–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Preparation for the International Conference on Harmonization Meetings in Yokohama, Japan: Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of meeting.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting entitled ''Preparation for ICH meetings in Yokohama, Japan'' to provide information and receive comments on the International Conference on Harmonization (ICH) as well as the upcoming meetings in Yokohama, Japan. The topics to be discussed are the topics for discussion at the forthcoming ICH Steering Committee Meeting. The purpose of the meeting is to solicit public input prior to the next Steering Committee and Experts Working Groups meetings in Yokohama, Japan on November 15 through 18, 2004, at which discussion of the topics underway and the future of ICH will continue.

Date and Time: The meeting will be held on October 19, 2004, from 1:30 to 3 p.m.

Location: The meeting will be held at 5600 Fishers Lane, 3rd floor, Chesapeake Conference Room, Rockville, MD. For security reasons, all attendees are asked to arrive no later than 1:15 p.m., as you will be escorted from the front entrance of 5600 Fishers Lane to the Chesapeake Conference Room.

Contact Person: Sema Hashemi, Office of the Commissioner, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3050, FAX 301–480–0716, e-mail: *Sema.Hashemi@fda.hhs.gov*.

Registration and Requests for Oral Presentations: Send registration information (including name, title, firm name, address, telephone, and fax number), and written material and requests to make oral presentations, to the contact person by October 15, 2004.

If you need special accommodations due to a disability, please contact Sema Hashemi at least 7 days in advance.

Transcripts: Transcripts of the meeting may be requested in writing from the Freedom of Information Office (HFI–35), Food and Drug Administration, 5600 Fishers Lane, rm. 12A–16, Rockville, MD 20857, approximately 15 working days after the meeting at a cost of 10 cents per page.

SUPPLEMENTARY INFORMATION: The ICH of Technical Requirements for the Registration of Pharmaceuticals for Human Use was established in 1990 as a joint regulatory/industry project to improve, through harmonization, the efficiency of the process for developing and registering new medicinal products in Europe, Japan, and the United States without compromising the regulatory obligations of safety and effectiveness.

In recent years, many important initiatives have been undertaken by regulatory authorities and industry associations to promote international harmonization of regulatory requirements. FDA has participated in many meetings designed to enhance harmonization and is committed to seeking scientifically based harmonized technical procedures for pharmaceutical development. One of the goals of harmonization is to identify and then reduce differences in technical requirements for medical product development among regulatory agencies. ICH was organized to provide an opportunity for harmonization initiatives to be developed with input from both regulatory and industry representatives. ICH is concerned with harmonization among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industries Associations; the Japanese Ministry of Health, Labor, and Welfare; the Japanese Pharmaceutical Manufacturers Association; the Centers for Drug Evaluation and Research and Biologics Evaluation and Research, FDA; and the Pharmaceutical Research and Manufacturers of America. The ICH Secretariat, which coordinates the preparation of documentation, is provided by the International Federation of Pharmaceutical Manufacturers Associations (IFPMA). The ICH Steering Committee includes representatives from each of the ICH sponsors and Health Canada, the European Free Trade Area, and the World Health Organization. The ICH process has achieved significant harmonization of the technical requirements for the approval of pharmaceuticals for human use in the three ICH regions.

The current ICH process and structure can be found at the following Web site: *http://www.ich.org.*

Interested persons may present data, information, or views orally or in writing, on issues pending at the public meeting. Oral presentations from the public will be scheduled between approximately 2:30 and 3 p.m. Time allotted for oral presentations may be limited to 10 minutes. Those desiring to make oral presentations should notify the contact person by October 15, 2004, and submit a brief statement of the general nature of the evidence or arguments they which to present, the names and addresses, phone number, fax, and e-mail of proposed participants, and an indication of the approximate time requested to make their presentation.