

## Supporting Statement for OMB Review

### **Infant Feeding Practices Study II**

Submitted by:

Division of Market Studies  
Office of Scientific Analysis and Support  
Food and Drug Administration  
Department of Health and Human Services

## **Infant Feeding Practices Study II Supporting Statement for Information Collection Request**

Approval is requested for a follow up of the 1993-94 Infant Feeding Practices Study with collection of additional information and an evaluation of a public information campaign developed by the Department of Health and Human Services.

### **A. . JUSTIFICATION**

#### **A.1 Necessity for the Information Collection**

The Food and Drug Administration (FDA) has the responsibility to safeguard infant health by assuring safe, nutritionally complete, and effectively labeled infant formulas and safe infant foods. In addition, the FDA is responsible for the regulation of dietary supplements and breast pumps, a medical device that is prominent in infant feeding practices in the U.S. FDA is also responsible for regulation of food additives and GRAS substances, including certain nutrients used in food fortification, such as folic acid and vitamin D. As part of its regulatory responsibility for safety of the food supply, FDA develops and disseminates consumer messages about food safety, including messages for vulnerable groups such as infants and pregnant and lactating women. As a member agency, the FDA supports the Department of Health and Human Services policies related to infant health and nutrition.

In 1993-1994, FDA conducted the Infant Feeding Practices Study (IFPS), a longitudinal study of detailed infant feeding behaviors, including patterns of breastfeeding, formula feeding, and solid food feeding. The study also measured numerous factors that might influence infant feeding choices. FDA is proposing to use for a new study the same research design that was previously approved by OMB for the IFPS. Using the same design will ensure integrity of comparisons over time, because any bias that may have occurred in the first study should be stable, and therefore measures of change should be valid.

In the approximate decade since that study, 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%, compared with 54% in 1992, and duration to six months was 33%, compared with 19% in 1992 (Ross Products Division 2003). Additionally, increased physician education of 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. In addition, DHHS has promulgated new strategies to meet Healthy People 2010 goals regarding feeding of infants, including the sponsorship of a National Breastfeeding Awareness Campaign (see Attachment A). Consequently, a need exists to update the database with a current description of the practices of mothers of infants and to evaluate the campaign.

FDA needs the information to better understand how consumers use various regulated products, including infant formula, infant foods, breast pumps, fortified foods, and dietary supplements. FDA also needs the information to better understand consumer food choices and food behaviors that relate to the Agency's development and dissemination of food safety messages for pregnant and lactating women and infants. An understanding of consumer experiences with products will provide a policy context within which to evaluate issues as they arise with regard to these products and will be used to inform consumer education programs and materials.

Other agencies that expect to analyze or use the data include the DHHS Office on Woman's Health; CDC/National Center for Chronic Disease Prevention and Health Promotion; NIH/National Institute for Child Health and Human Development; and NIH/Office of Dietary Supplements. The reasons each of these agencies need the data are described below.

In 2000, the Department of Health and Human Services (DHHS) published two national policy statements calling for increased breastfeeding of U.S. infants, including increased initiation, exclusivity, and duration: *Healthy People 2010*, Chapter 16: Breastfeeding, Newborn Screening, and Service –Systems (DHHS 2000a) and *HHS Blueprint for Action on Breastfeeding*, (DHHS 2000b). As a follow up activity to the *HHS Blueprint for Action on Breastfeeding*, the DHHS Office on Women's Health has initiated a public campaign to promote breastfeeding, the Breastfeeding Awareness Campaign, and has a need to evaluate its effectiveness. The measures of breastfeeding initiation, exclusivity, and duration, in addition to sources of information about infant feeding, attitudes towards breastfeeding and knowledge of benefits of breastfeeding, will be used for the campaign evaluation, along with the specific measures of awareness of the campaign. Variables important in the Health Beliefs Model (Streicher and Rosenstock 1997) will also be included, such as self esteem and confidence in the ability to breastfeed. FDA will analyze the data for the evaluation. See Attachment B for a detailed evaluation design.

One of the DHHS measures under the Government Performance and Reform Act of 1993 is the percentage of mothers who breastfeed their infants to six months of age. Information about detailed factors that contribute to breastfeeding duration to this age is needed. Because a large percentage of mothers of infants are in the labor force (53% in 2003) (Bureau of Labor Statistics 2004), information about breastfeeding-related factors in the workplace is particularly needed.

Breastfeeding promotion is one of four main strategies the CDC utilizes to address the national obesity epidemic. The CDC needs detailed information about breastfeeding and other infant feeding behaviors over time to inform breastfeeding promotion efforts and technical assistance to states undertaking the task of obesity prevention and control. Information about barriers to continued and exclusive breastfeeding will affect breastfeeding promotion and

support. The CDC is largely responsible for carrying out the national Healthier Worksite Initiative, of which lactation support is an integral aspect. Items in this survey address breastfeeding after mothers return to work, as well as other proximal issues to this event, such as child care providers' support for breastfeeding and milk storage, issues on which existing data are sparse and outdated.

NIH/NICHD needs the information for several reasons, including these: to assess the antecedents of breastfeeding cessation, to describe current infant sleeping arrangements and the effect of sleeping arrangements on breastfeeding, and to assess the effect of treatment for jaundice on breastfeeding cessation.

NIH/ODS has a need for these data because pregnant and lactating women, although nutritionally vulnerable groups, are not well represented in national surveys of dietary intake. For women in these life stages, there is a need to know what nutrients are likely to be inadequate from food choices and whether dietary supplements are being used to correct nutrient inadequacies or are used more often by those who least need them.

The study will include four complete questionnaires (Prenatal, Maternal Dietary Intake, Birth Screener, and Neonatal) and nine modules that will be put together in various combinations for the postnatal questionnaires. Many of the questions were asked in the previous study, which will enable comparisons of responses between the two time periods. (See Attachment C for an outline of the questionnaires with an indication of whether each question is the same as in the previous study, a different question that asks for the same information, or a new question.) Because the timing of administration of some of the questionnaires and modules is different in the new study, modification of some questions was required to reflect the new timing. Demographic data will come from the information kept about the panel by the panel administrator. Demographic variables include age of mother and age and sex of all other household members, household size, race, Hispanic ethnicity, marital status, education of mother and of partner, employment status and occupation of mother and of partner, total household income, home ownership, city of residence, geographical region, and population density.

The Prenatal questionnaire will ask about many domains for which there is evidence of an association with infant feeding choices (Janke 1993; Meek 2001). These include: mother's health care and medical insurance during pregnancy, weight, tobacco use, health conditions of baby's relatives that may affect infant feeding decisions or for which breastfeeding may offer a reduction in risk to the infant (Zieger, Heller et al. 1989; Dewey 2003), employment, perceived support at work for breastfeeding, planned child care arrangements, mother's attitudes and opinions toward feeding infants, attitudes and experiences of others in the social network, awareness of Breastfeeding Awareness Campaign, embarrassment about breastfeeding, previous experience with infant feeding, and plans for feeding the new infant (Arora, McJunkin et al. 2000). It will also include questions about gestational diabetes and dietary change and the Morris Rosenberg Self Esteem scale (Rosenberg 1965; Blyth, Creedy et al. 2002). All questionnaires except the maternal dietary intake measure and the Birth Screener will ask about WIC participation, which is associated with greater rates of initiation of breastfeeding under some circumstances (Schwartz, Popkin et al. 1995). The Prenatal questionnaire will be sent in the seventh month of pregnancy.

The Maternal Dietary Intake questionnaire will provide an overview of maternal nutrition by collecting information about mothers' food consumption and their intake of nutrients from foods and dietary supplements. Nutrient intake during pregnancy can influence availability of some nutrients to the fetus during gestation. Mothers' nutrient intake during lactation can influence nutrient composition of breast milk and the nutritional status of the breastfed infant. Maternal dietary intake also provides energy and nutrients to support maternal physiological needs during pregnancy and lactation. Information on maternal dietary intake will provide context for nutritional implications of infant feeding practices.

The measure of maternal dietary intake will be a food frequency questionnaire, the Diet History Questionnaire developed by the National Cancer Institute (Subar, Thompson et al. 2001), slightly modified to be appropriate during pregnancy and lactation and to measure foods of special interest during these times. Mothers' dietary intake will be collected twice: once during the last trimester of pregnancy and again about 3 to 4 months postpartum when many mothers will be lactating. Because of the burden and expense of administering the dietary intake measurement, it will be sent to a subset of the sample. The original 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. Foods and dietary supplements of special interest were added to the questionnaire, including certain fortified foods, foods relevant to food safety message development, 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 (see for example, (Hepner, Harnett et al. 2002).

Little is known about the use of herbal products among pregnant and lactating women. Some evidence suggests that prevalence of use is great enough that survey questions on use will produce useful data. A medical center-based study in the U.S. found that 7% of 734 pregnant women reported that they had used an herbal product while pregnant (Hepner, Harnett et al. 2002) Another indicator that herbal use during pregnancy and lactation may be significant is the large percentage of midwives who recommend such alternative therapies. A study in North Carolina found that 73% of certified nurse midwives had recommended herbal therapies to their patients in the past year, and 57% had recommended some type of complementary or alternative medicine to more than 10% of their patients (Allaire, Moos et al. 2000).

The Birth Screener will consist of a very short (less than five minute) telephone interview with any adult household member to determine whether the infant has been born and to screen for qualification for the study. Calls will be made to participating households only near the due date because only full term infants will qualify for the study, and they will be made only during the periods that the mailing list is established for the next administration of the Neonatal questionnaire. The household will be called at a later time if the infant has not been born yet. It is expected that most households will not have to be contacted more than twice.

The Neonatal questionnaire includes measures of several factors that occur near the time of the birth and that affect infant feeding choices. It asks about infant feeding classes and other sources of information and support, weight gain during pregnancy, the birth (Riordan, Gross et

al. 2000) and hospital experiences just after the birth (Dungy, Christensen-Szalanski et al. 1992; Wright, Rice et al. 1996), attitudes of medical professionals about infant feeding (DiGirolamo, Grummer-Strawn et al. 2003), breastfeeding experiences, hospital discharge packs, feeding-related treatment for jaundice, and post partum depression (Henderson, Evans et al. 2003); (Morris-Rush, Freda et al. 2003). This questionnaire also includes measures of dietary intake of the infant, herb use of the infant (Spigelblatt, Laine-Ammara et al. 1994; Kemper 1996; Turow 1998; Lanski, Greenwald et al. 2003; Woolf 2003), formula feeding, confidence in breastfeeding, and campaign evaluation questions. This questionnaire will be sent when the infant is about three weeks old.

The Postnatal questionnaires will be composed of various combinations of nine modules. They will be sent monthly from infant ages 2 through 7 months, then about every 50 days: 9 months, 10.5 months, and 12 months. For some of the modules, not all questions will be asked at each administration.

*Module A: Feeding Your Baby* will be sent at each administration of the postnatal questionnaire. This module contains one of the major measures of the study, the food frequency checklist for the infant. This checklist will provide a measure of age of introduction of solid food and of allergenic foods; frequency of feeding each food group at each month of infancy; changes in eating patterns from month to month; average number of feedings of each food group at each month of age; feeding schedules; and rate of introduction of new foods. The number of feedings per day of infant formula and breast milk indicate breastfeeding exclusivity and duration. In addition, the checklist will enable an analysis of patterns of breastfeeding exclusivity, in particular whether mothers occasionally give formula to an infant who is otherwise exclusively breastfed. Patterns of feeding foods other than breast milk and formula will indicate the extent to which mothers follow current infant feeding guidelines, such as those recently published by the American Dietetic Association (Butte, Cobb et al. 2004). Information on whether foods fed to infants are baby foods or not will provide information about exposure of infants to foods marketed for older children and adults, including foods fortified at levels only appropriate for older age groups. In addition, Module A asks for details about formula feeding and breastfeeding, dietary supplement and herbal intake by infants, and health problems of the infant.

*Module B: Stopped Breastfeeding* will be included on each postnatal questionnaire, but it will be answered only once, just after the mother completely stopped breastfeeding. It establishes the infant age when breastfeeding ceased and asks reasons for breastfeeding cessation and attitudes toward breastfeeding (see (Kirkland and Fein 2003).

*Module C: Food Allergy* asks whether the mother believes that the infant has a food allergy, details of the implicated food, and details of symptoms, diagnosis, and treatment. Module C will be sent at ages 4 and 12 months.

*Module D: Breastfeeding* asks for details about breastfeeding, sources of information, dietary change because of breastfeeding, reasons for supplementing with formula, and details of expressing milk (including handling practices (Tully 2000a)) and breast pump use. Reasons for expressing milk will include work-related reasons and, like the first study, expressing to donate

to another baby. With the growth of donor milk-banking (Tully 2000b), this issue is of interest. This module will also include a measure of embarrassment about breastfeeding and how mothers manage to combine work for pay and breastfeeding. Module D will be sent 3 times, at months 2, 5, and 9.

*Module E: Infant Formula* asks for details about formula feeding (see (Fein and Falci 1999), label use and understanding, sources of information, and brand choice and brand changing. Hygiene, sterilization practices, and room temperature holding times are related to the risk of infection from infant formula (FDA 2002a; FDA 2002b), and understanding of current practices will contribute to consumer education programs. Information about mother's use of infant formula labels and their evaluation of labels will indicate how well the different parts of the label communicate to mothers. Module E will be sent four times, at months 2, 5, 7, and 9.

*Module F: Information Sources* has questions that will not be asked together, as will be the case for most modules, but rather will be inserted among questions in the other modules in appropriate. Question 1, sources of information about herbal products, will be sent at months 4 and 10.5. Questions 2-4 about general infant feeding, including feeding solid foods, will be sent in months 2, 5, and 10.5.

*Module G: Breastfeeding Awareness Campaign Evaluation* lists the direct measures of awareness of the campaign and agreement with the messages of the campaign. Like Module F questions, it will not be asked as a separate module; rather, the questions will be incorporated at appropriate places in other modules. It will be sent at infant ages 3 and 7 months.

*Module H: Sleeping Arrangements, Child Care, Work, and Health* asks about all topics other than feeding. These include sleeping arrangements and position; child care and child care support for breastfeeding; details of mother's employment and employer support for breastfeeding; how mothers manage to combine breastfeeding and work; and mother's health and weight, and her tobacco use. Module H will be sent at infant ages 3, 6, 9, and 12.

*Module L: Last Module* will not be printed as a separate module. The questions on awareness of a specific advertisement from the Breastfeeding Awareness Campaign will be incorporated into other modules at appropriate places. The questions about WIC participation and severe health problem of infant (which will disqualify the infant from the rest of the study) will be placed at the end of each postnatal questionnaire. This module will be sent on each postnatal questionnaire.

The authority for the FDA to collect these data derives from the FDA Commissioner's authority, as specified in 21USC393. A copy of that section is provided in Attachment D.

## **A.2 How, by Whom, and the Purpose for Collecting this Information**

The information will be collected from qualifying members of a commercial consumer opinion panel. An opinion panel is a collection of households that have agreed to answer questionnaires for research purposes. All data except the Birth Screener will be collected by questionnaires sent through the mail. The data collection will be conducted by Synovate, the

company that manages the panel, using questionnaires constructed by the FDA in collaboration with the participating agencies. Synovate is the same company (under a new name) that collected data for the previous study.

The data will be analyzed to provide a context for policy considerations, to support consumer information and education programs, and to evaluate various outreach efforts about child and maternal nutrition. FDA will use the data to better understand the infant formula policy context and to inform consumer messages about infant formula handling and use. The data will be analyzed to describe when, why, and how infant formula is used at various infant ages and mother's use and evaluations of formula labels. The data about breast pump practices will be used for policy context and consumer education purposes in a similar manner. Mother's consumption of specific foods will be used to evaluate acceptance of certain consumer messages related to food safety, and to provide context for future development and dissemination of consumer food safety messages. Other data will be used to provide a contextual understanding of areas of interest to the Agency, including current infant feeding practices that may affect the development of food allergy, feeding infants food marketed to the general population, use of fortified foods and dietary supplements by mothers and infants, and sources of information on various topics. The data will also be used to evaluate the Breastfeeding Awareness Campaign.

The CDC will use the data to describe current breastfeeding behavior, barriers to breastfeeding, and breastfeeding motivators. The data will also be used to understand mothers' perceptions of receipt of infant feeding advice and the extent to which such advice is followed, and to identify influences on feeding choices and behaviors, including hospital practices, workplace and child care provider factors. A clearer understanding of these factors will inform strategies to promote breastfeeding as one of the CDC's four strategies to address the obesity epidemic.

NIH/NICHD expects to use results from this study to develop and implement more effective and culturally appropriate strategies to achieve Healthy People 2010 objectives and to work with the American Academy of Pediatrics (AAP) and other professional organizations to formulate practice guidelines on several issues. For this purpose, NICHD will use the data to identify social factors that influence women's choices about infant feeding; to identify a time frame by which mothers make choices with regard to infant feeding (such as duration of exclusive breastfeeding, and timing of introduction of complementary foods); and to describe other practices that might potentially impact maternal and infant nutrition and health (such as use of dietary supplements and infant sleeping positions and arrangements). The results will also be used to inform research initiatives to further study interesting findings.

NIH/ODS will use the results to assess whether the AAP recommendations for dietary supplements for breastfeeding infants are being followed, in addition to describing dietary supplement use among pregnant and lactating women. It is necessary to know maternal dietary intake of foods in assessing supplement use. These results will be used to develop materials to educate health care professionals and clinical practitioners who work directly with pregnant and lactating women and their infants, so that they can better provide guidance on diet and on the judicious use of dietary supplements.

This data collection is not an ongoing collection, although one previous collection was conducted in 1993-1994. Those data were used in published papers by FDA to describe formula use and formula label use by consumers, and by CDC and several academic researchers to examine gastrointestinal effects of iron fortified formula, dose-response relation between extent of breastfeeding and infant morbidity, water supplementation of very young infants, effects of employment characteristics on breastfeeding, association between employment characteristics and Cesarean delivery, effect of medical advice on weight gain during pregnancy, effect of maternity care practices on breastfeeding, the role of physician and hospital staff opinions on infant feeding decisions, and reasons for stopping breastfeeding by infant age. Two papers that tested health theories were also published using these data. (See Attachment E for a list of papers published from the IFPS data). Other analyses were presented at professional meetings. These include patterns of feeding solid foods and the safety and effect on diarrhea of the infant food handling practices of mothers. In addition, the data were used for several internal purposes, including a description of exclusive breastfeeding over time and a description of vitamin supplementation of breastfeeding and formula feeding infants.

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

This study will not use technology to reduce burden of the respondents. Self-administered paper questionnaires are a low-technology method of data collection but are convenient for respondents. Self-administered questionnaires reduce the amount of time required relative to telephone or personal interviews, and they allow the respondent both to answer at any time convenient for her and to break up the responding period as needed for her schedule.

Use of an established consumer opinion panel will reduce burden to the general public by taking advantage of an already existing system for recruiting sample members. If members of the general public were screened for pregnancy, the burden would be large because only 6.4 percent of women of childbearing age have a live birth in any given year (Ventura, Abma et al. 2003), and not all households include a woman of childbearing age. Because response rates from consumer opinion panels are high (65% to 70% for most mail surveys), fewer women will have to be recruited initially in order to have a sufficient sample in the last months of data collection. In comparison, Abbott Laboratories obtains response rates of 28 to 31 percent for their Mothers Survey, a general population survey on the same topic as the IFPS (Ryan, Wenjun et al. 2002; Ross Products Division 2003). Response rates for this study about infant feeding are expected to be higher than the general panel response rates because this was the case in the 1993-94 study.

### **A.4 Identification and Use of Duplicate Information**

Since the 1994 IFPS, no comparable data have been collected. Because the 1994 data will soon be a decade old, there is a pressing need for an updated study. The federal agency and academic experts who make up the study's questionnaire working group agree that current in-depth data on infant feeding practices are lacking and that there is a critical public health need for the information in the questionnaires. The members of the group, which includes representatives from DHHS, CDC, FDA, NIH, and USDA, are listed in A.8.

An extensive literature review confirmed the critical gaps in the existing research on infant feeding practices. The longitudinal design, national scope, and study questions for IFPS II were selected to fill these gaps. The study was also designed to evaluate the effectiveness of the national breastfeeding awareness campaign, sponsored by the DHHS Office on Women's Health and implemented by the Ad Council.

Although, there are no recent data with enough detail about infant feeding over the first year of life to meet the information needs that this study will fill, several national studies include questions on infant feeding practices. Even cumulatively, these studies only touch on the issues that will be examined by IFPS II. Data from these other studies will, however, provide a comparison for parts of the IFPS II analysis and will provide national probability estimates for some of the measures. This latter feature will be used to evaluate sample bias in the IFPS II.

National studies that address infant feeding practices include:

- ?? National Immunization Study (CDC)
- ?? National Survey of Family Growth (CDC)
- ?? Ross Mother's Survey (Abbott Laboratories)
- ?? National Health and Nutrition Examination Survey (CDC)
- ?? Feeding Infants and Toddlers Study (Gerber Products)

In 2001, the CDC's National Immunization Study (NIS) asked a random-digit-dial sample of just under 900 households with children aged 19 to 35 months three questions about breastfeeding behavior. These questions addressed whether the child was ever breastfed, to what age the child was breastfed, and how long breastfeeding was the exclusive food provided to the child (Li, Zhao et al. 2003). Unlike IFPS II, NIS was limited to a few questions about breastfeeding and did not include information about other aspects of infant feeding or the many variables associated with infant feeding decisions. In addition, the study was cross-sectional and required recall over a long period of time.

The National Survey of Family Growth (NSFG) is a cross-sectional CDC study that includes several questions relevant to IFPS II. The female component of the study sample (7,600 respondents) represents non-institutionalized women in the US between 15 and 44 years of age. The most recent data, collected in 2002 and 2003 through in-person interviews, includes information on breastfeeding initiation, exclusivity, and duration. The data set for the study will be available some time in 2004 (NCHS 2003). The limited questions on infant feeding and cross-sectional design do not allow the NSFG to answer the research questions for which IFPS II was designed. However, as noted later, this survey will provide several comparison variables with which to evaluate sample bias for the IFPS II.

For almost 50 years, the Ross Products Division of Abbott Laboratories has been collecting data on infant feeding practices. The Ross Mothers Survey is mailed each month to mothers of infants one through twelve months of age, but the data are not longitudinal because each mother is only asked about one month. The most recent update of these data is from 2002. Depending on the age of the infant, the survey asks mothers to identify what their babies were

fed in the hospital, at one week, in the last 30 days, or in the last week (Ross Products Division 2003). The emphasis of the study is describing what babies are eating, but unlike the IFPS II, it does not explore most of the prenatal and post-partum factors associated with infant feeding practices.

The National Health and Nutrition Examination Survey (NHANES) measures the dietary intake of all segments of the population. However, the samples of pregnant women, lactating women, and infants are too small for in-depth subpopulation analyses. The 1999-2000 data set includes about 360 pregnant women, 33 lactating women, and 488 infants less than 12 months of age (M. McDowell, NCHS, 2004, personal communication). Moreover, these data are cross-sectional and the study questions were not constructed to capture issues of particular interest in those groups.

Sponsored by Gerber Products, the Feeding Infants and Toddlers Study (FITS) drew a sample of 3,022 children four months to two years of age from a commercial list. In the spring of 2002, FITS collected a 24-hour dietary recall along with supplementary information on development and feeding (Devaney, Kalb et al. 2004). Unlike IFPS II, FITS is not longitudinal and does not capture prenatal data or data on the first months of life. In addition, it includes minimal information about determinants of feeding choices.

#### **A.5 FDA's Efforts to Reduce Burden on Small Businesses**

No small businesses will be involved in this collection.

#### **A.6 Impact of Not Collecting This Information or Collecting Information Less Frequently**

Without this study, FDA, CDC, and NIH will not have information critically needed for understanding the infant feeding arena as it relates to the nation's health objectives, infant formula issues, breast pump use, and other topics under their authority. This understanding is needed to inform consumer outreach programs and messages and to inform various policy issues as described in A.2 of the supporting statement. Furthermore, without the collection, the HHS Breastfeeding Awareness Campaign evaluation will not have a component that relates mothers' awareness, attitudes, and knowledge to breastfeeding behavior.

Although a similar study was conducted about a decade ago, this collection is a one time collection because a subsequent study is not planned.

The technical obstacles to reducing burden are related to the study design. A relatively large sample size is needed to conduct the analyses planned and to make meaningful estimates of behavior (see the statistical power analysis in Attachment F). Data collection about once a month for the infant's first full year is needed to describe behaviors and attitudes prospectively and with a short enough recall period to enable accurate reporting. Although the burden will be substantial for the women in the study, it will be about the same as they would have experienced as part of the consumer opinion panel, of which they will already be members when we contact

them. Panel members routinely receive about ten to fifteen questionnaires a year. While they are participating in this study, mothers will not receive questionnaires from any other studies.

### **A.7 Special Circumstances That Occur When Collecting This Information**

The respondents will be contacted and asked to complete questionnaires approximately once a month. Although it will not be the same information each month, there will be repetition in the questions asked. This is necessary in order to measure infant feeding practices over time because feeding patterns change rapidly during infancy.

Respondents will be asked to respond as soon as possible. Because questionnaires are sent every month near the infant age for which the data are to be reported, we cannot give the mothers a month to complete each questionnaire. Such a lengthy response period would cause infant age to vary widely from the intended age. In the previous study, the average age at which each questionnaire was answered was the intended infant age. For example, the Neonatal questionnaire sent at infant age one month had a median age of 35 days.

The study design will not produce data that can be generalized to the universe of infants, pregnant women, and new mothers in the US. 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 – the low educated and unstable households. Use of the consumer opinion panel will provide data primarily on a middle segment of the US population, but the segment included is fairly broad. For example, 20% of the previous study sample participated in the Supplemental Feeding Program for Women, Infants, and Children (WIC), the same proportion as the general population 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 low education and who are of minority race and ethnicity will be oversampled to increase the total number of representatives from these groups.

No other special circumstances will occur in this data collection.

### **A.8 Identification of Outside FDA Sources**

All of the agencies that intend to use the data have participated in the Questionnaire Working Group (QWG), along with experts from other government agencies. The group has met face-to-face for two all-day meetings and one half-day meeting and has exchanged drafts and comments between and after meetings. The QWG includes the following people outside of FDA:

Larry Grummer-Strawn	CDC / National Center for Chronic Disease Prevention and Health Promotion
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Katherine Shealy	CDC / National Center for Chronic Disease Prevention and Health Promotion
Margaret McDowell	CDC/NCHS
Suzanne Haynes	DHHS/OWH
Nancy Potischman	NIH/NCI
Tonse Raju	NIH/NICHHD
Daniel Raiten	NIH/NICHHD
Rosemary Higgins	NIH/NICHHD
Susanne Strickland	NIH/NICHHD
Mary Frances Picciano	NIH/ODS
Betsy Frazao	USDA/ERS
Pat McKinney	USDA/FNS
Ann DiGirolamo	Emory University, Rollins School of Public Health
Patty Goldman	Ad Council
Kate Nammacher	Ad Council

In addition, the Project Staff have consulted with Cindy Lee Dennis (University of Toronto, Ontario) regarding measures of breastfeeding confidence; Fern Hauck (University of Virginia) and Marian Willinger (NIH/NICHHD) on infant sleeping arrangements and the possible association with SIDS; Nancy Wright (Neonatologist, Children's Hospital and Sharp Mary Birch Hospital for Women, San Diego, CA) regarding early infant feeding issues; and Kathryn Dewey (Department of Nutrition, University of California Davis) also regarding early infant feeding issues.

In the Federal Register of April 21, 2004 (69 FR 21548), FDA published a notice soliciting public comments on this information collection.

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 (69FR 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.

**Comments on 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.

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.

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%, compared with 54% in 1992, and duration to six months was 33%, compared with 19% 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.

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.

The Agency agrees that information from the IFPS II will be useful to many government agencies and their staff.

**Comments on 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.

1. 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.

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.

2. 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.

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 U.S. 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 – the low educated, 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 US population, but the segment included is fairly broad. For example, 20% 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 low 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.

**3.** 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.

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 US population, with oversampling of panel members who have low 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% of the sample had no more than a high school education, and as noted above, 20% 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 (69FR 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, USDA’s Continuing Survey of Food Intakes by Individuals 1994-96. 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 US 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.

**4.** 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.

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.

**Comments on the third topic:** ways to enhance the quality, utility, and clarity of the information to be collected.

**1.** 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 mis-used 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.

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.

2. 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.

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 is 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 twenty-four 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 follow up 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 follow up 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.

3. 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.

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.

4. 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.

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.

5. 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.

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 is 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.

6. One comment from industry states that some of the questionnaires do not include a WIC participation question.

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

7. 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.

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.

8. One comment states that an assessment of the impact of the National Breastfeeding Awareness Campaign on a woman's decision-making would be useful.

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.

9. Both comments from industry provide recommendations on specific questionnaires.

## **I. Prenatal Questionnaire**

General: 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.

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.

A. 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, decision-making and behavior should follow. The comment recommends that the Agency ask the mother to rate the influence of certain information on her decision-making.

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 is 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.

**B.** 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.

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.

**C.** 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.

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 work place. 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.

**D.** 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?"

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.

**E.** 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.

The Agency disagrees that these response categories should be collapsed. This information was asked for breastfeeding on the population survey to assess pre-campaign attitudes toward breastfeeding. As noted above, 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.

**F.** 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.

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.

**G.** 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.

The Agency agrees that this question should be deleted throughout the questionnaires.

**H.** 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.

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 three percent of respondents chose the option “none have breastfed.” In addition, one percent said that none of their friends or relatives have children, and eight percent responded “don’t know.” In all, twelve 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.

**I.** 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?”

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.

**J.** 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 [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.

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 above, 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.

## **II. Birth screener**

**A.** 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.

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.

## **III. Neonatal Questionnaire**

**A.** 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 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.).

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 six 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.

**B.** 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.

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.

**C.** 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.

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 able to adequately report the influence of formula labeling and advertisement. That option has not been added.

**D.** One comment states that this question is vague and should be deleted “How long was it until you became emotionally comfortable nursing your baby?”

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.

**E.** 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.”

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.

**F.** 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.

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.

**G.** 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.

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.

**H.** 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.

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.

**I.** 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?”

The Agency agrees that the reference formula is unclear and has revised the question to clarify it.

**J.** 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?"

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

**K.** One comment states that too many response options have been added to this question: "What kind of problems(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.

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.

**L.** One comment repeats comment J on the prenatal questionnaire, concerning the repeated question regarding intended duration of breastfeeding and confidence in achieving the intended duration.

See response under comment J for the prenatal questionnaire.

**M.** 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?"

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.

#### **IV. Module A**

**A.** 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.

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.

**B.** 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: food allergy, eczema, other skin rash.

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.

## **V. Module B**

**A.** 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.

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% 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.

**B.** 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.

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.

**C.** 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.

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.

## **VI. Module C**

**A.** 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.

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.

**B.** 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?”

The Agency agrees that this question is not useful and has deleted it.

**C.** 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.

The Agency agrees that specific formula brands are not needed for this question. The questions have been reworded.

**D.** 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.

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.

**E.** 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 under-reporting.

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.

## **VII. Module D**

**A.** One comment repeats comment J on the prenatal questionnaire, concerning the repeated question regarding intended duration of breastfeeding and confidence in achieving the intended duration.

See response under comment J for the prenatal questionnaire.

**B.** 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.

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.

**C.** 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.

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 above, the Agency does not agree that information about the influence of infant formula advertising and labels can validly be obtained from this survey.

**D.** 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?”

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.

**E.** 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?”

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.

## **VIII. Module E**

**A.** 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 these: 1) Is there anything on the label that is hard to understand? If so, what? 2) Is there any information you wanted that was missing (if so, specify what). 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 (if so, specify what). 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.

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.

**B.** 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.

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.

**C.** 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.”

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.

**D.** 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.

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.

**E.** 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.

The Agency agrees that this additional information will be useful and has added a question.

**F.** 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).”

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 D 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.

**G.** One comment recommends a lead-in to help mothers feel more comfortable as they answer the question about hand-washing before preparing formula.

The Agency agrees that a lead-in such as that recommended will improve the data and has added it.

**H.** 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.

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.”

## **IX. Module F**

**A.** 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.

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 made 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.

**B.** 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 B of Module D.

See Comment B of Module D.

## **X. Module G**

**A.** 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.

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.

**B.** One comment asks the Agency to consider the comments stated in Comment E for the prenatal questionnaire regarding recall of where advertisements or other information was seen.

The Agency refers to the response under that comment.

**C.** 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.

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.

**D.** One comment states that Comment F for the prenatal questionnaire applies to this repeated question also. That comment concerned the question asking about agreement with campaign messages.

The Agency refers to the response under that comment.

## **XI. Module H**

**A.** One comment refers back to comment B of the prenatal questionnaire for a repeated question regarding workplace supportiveness for breastfeeding.

The Agency refers to the response under that comment.

**B.** 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.

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

**C.** 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.

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.

### **A.9 Payment or Gifts Offered to Respondents**

Members of the consumer opinion panel are routinely sent inexpensive (about a \$2.00 value) gifts to show appreciation for their efforts in answering the questionnaires. For most questionnaires, panel members used for this study will receive gifts related to infants, screened for safety and appropriateness by the Project Director or other qualified project staff. For the dietary intake questionnaires, which are much more burdensome to complete, the respondents will receive an incentive of \$10.

### **A.10 Method of Ensuring Respondent Confidentiality**

The information will be recorded in such a manner that subjects cannot be identified directly or through identifiers. No identifying information will appear on any data file. The questionnaires will be stored by the contractor in a locked, secure facility for a year, then they will be shredded. Each questionnaire will include a unique panel ID number for each respondent, but only the contractor will have the database to link ID numbers with individuals. The ID numbers that link to identifying information will not be included in the data file. No identifying information will be recorded in the data file and there will be no way to detect the identification of any respondent. This data collection has been approved by FDA's Research Involving Human Subjects Committee.

### **A.11 Use of Sensitive Questions**

The study includes an established scale to measure postpartum depression, the Edinburgh Postnatal Depression Scale as modified for consistency with the conventions of American language (Cox, Holden et al. 1987; Stuart 2000) and as used in the Listening to Mothers study (Declerq, Sakala et al. 2002). There is reasonable evidence that postpartum depression affects infant feeding choices and breastfeeding behaviors, and that postpartum depression frequently occurs shortly after delivery (Henderson, Evans et al. 2003). A longitudinal study such as the one planned is an excellent opportunity to examine further the link between postpartum depression and infant feeding behaviors. The data will be anonymous because no identifying information will appear in the data file and it will be impossible to detect the identity of any respondent. For these reasons, the risk to respondents of embarrassment from release of their specific information is nonexistent. In addition, the IFPS asks about the medical history of other family members for medical conditions that may be genetically related and may be reduced by breastfeeding, such as allergy (Zieger, Heller et al. 1989; Saarinen and Kajosaari 1995; Endres 2000), or by other early infant feeding practices, such as Type 1 diabetes (Ziegler, Schmid et al. 2003).

### **A.12. Burden Hours and Cost Associated with this Information Collection**

The initial screening for pregnancy will require no response burden for respondents because they will be identified through the consumer opinion panel during the regular periodic update which the contractor conducts. The periodic update includes questions about pregnancy.

The respondents will complete the prenatal questionnaire and a dietary intake measure during pregnancy. Someone in the household will complete the birth screener. After the birth, the mother will complete the neonatal questionnaire, a dietary intake measure of her food consumption, and nine postnatal questionnaires. If a woman in a panel household is pregnant but is not the consumer opinion panel member, a demographic questionnaire will be sent during pregnancy. This is expected to occur in four percent of respondents to the prenatal questionnaire, based on the previous study. For this sample size, about 140 women are expected to respond to the specially sent demographic questionnaire.

The charts below estimate the public reporting burden for the first and second year of the data collection. If data collection is begun in January of 2005, the charts also represent the burden for the calendar years 2005 and 2006. The charts show that the study will require about 8,953 hours the first year and 3,304 hours the second year. The cost to respondents for the hour burden for the first year of the study is \$120,060, and for the second year it is \$44,307 at \$13.41 per hour, the 2002 mean hourly wage for administrative support jobs according to the Bureau of Labor Statistics (Bureau of Labor Statistics 2003). This figure was chosen because the task asked of respondents is similar to the job description for this category.

Estimated Annual Reporting Burden Year 1<sup>1</sup>

Questionnaire	No. of Respondents	Frequency per Response	Total Responses	Hours per Response	Total Hours
Prenatal	3,500	1	3,500	.25	875
Prenatal Diet History Questionnaire	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

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

#### Estimated Annual Reporting Burden Year 2

Questionnaire	No. of Respondents	Frequency per Response	Total 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
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

#### **A.13 Annual Cost Estimate to Respondents**

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

#### **A.14 Annual Cost Estimate to FDA**

The estimated cost to the FDA for this information collection is \$426,868 for Agency staff for the years 2003-2007: .5 FTE for a GS 13 (\$39,131.5) and .5 FTE for a GS 14 (\$46,242) staff person. Other agencies are providing the funds for data collection.

#### **A.15 Changes from Previous Approval**

This is a new collection.

#### **A.16 Publishing the Results of This Information Collection**

The participating agencies will develop a set of core papers from the data that will be published as soon as possible after data collection ends. In addition, FDA and CDC will develop a final report that will be made available on the CDC website about the same time as publication of the first of the core papers. This report will include overall study methodology, descriptive tables of all study content areas with demographic breakdowns, and comparisons to 1993/94 results for a small number of key variables. The final report will not include any multivariate analyses or interpretation of tables. The core papers and final report are expected to be completed within 18 months of the receipt of the final data from the study. Data collection for the entire study is expected to be completed by September 2006 if data collection begins in January 2005.

The data set will be analyzed by the different participating agencies and by academic researchers, as was done with the previous study. Questions asked in both studies will be compared across the two time periods. Each federal agency involved in the project has a special interest in specific parts of the data set, which they will analyze. The FDA, for example, is particularly interested in the data related to the products it regulates – infant formula, commercial baby food, fortified foods, dietary supplements, and breast pumps, as well as food-related practices relevant to certain food safety messages. Additional topics for analysis will be identified by non-government researchers. Analysis and publication will continue as long as interest in these data remains. (As can be seen from the list of articles published from the first IFPS, publications have not ended yet for that data set.)

Regression analysis, logit analysis and simultaneous equation modeling will be used as appropriate. Because the study includes data from many different domains related to infant feeding and includes longitudinal data, multivariate analysis and simultaneous equation modeling are particularly appropriate.

The maternal dietary intake questionnaire responses will be processed using Diet\*Calc software developed by the National Cancer Institute. Diet\*Calc generates nutrient and food group intake estimates for either standard or modified versions of NCI's DHQ food frequency questionnaire (<http://riskfactor.cancer.gov/DHQ/>). Analysis of maternal nutrient and food group intake is of interest in itself and in relation to infant feeding practices and nutrition.

#### **A.17 Reason for Not Displaying the OMB Approval Date**

The OMB approval date will be displayed on the questionnaires.

#### **A.18 Explanations to Section 19. “Certification for Paperwork Reduction Act Submissions”**

No exceptions are requested.

## **PART B – Collection of Information Using Statistical Methods**

### **B.1 Respondent universe and sampling**

The respondent universe is all U.S. households with a healthy, single birth. The sample for the study will be drawn from the Consumer Opinion Panel, a panel consisting of 500,000 households throughout the United States. The Consumer Opinion Panel was also used for the first Infant Feeding Practices Study in 1993-94. As noted earlier, use of the same sampling design in the new study will ensure valid measures of change over time because bias should be stable. The IFPS II will over-sample low educated, African American, and Hispanic women and also women living in the Breastfeeding Awareness Campaign's Community Demonstration Project areas. The final sample size will be 2,250 mothers.

Qualifying criteria for the sample will include these: full-term birth, birth weight of at least 5.5 pounds, singleton infant, and healthy infant and mother. Feeding issues are different for premature and sick infants and for multiple births. Because the sample size will not be large enough to enable an analysis of these subgroups, they will be excluded from the sample. Health of the infant will be measured by whether the infant had to stay in the intensive care unit for more than three days and whether the infant had any special needs or medical problems that might affect his or her feeding. In questionnaires subsequent to the initial screening at birth, mothers will be asked if the infant has any long-term severe medical problems, and if so, what. An FDA pediatrician will determine whether the problem is likely to affect feeding. Health of the mother will be measured by a question asking if she had any medical problems that prevented her from feeding the baby for more than a week. These same criteria were used for the previous study.

Panel members are recruited in several ways, including from commercial list companies that offer data on specific demographic groups, through member referrals, and by distributing qualifying questionnaires at various interviewing sites.

A panel is the most efficient way to identify a reasonably representative sample of pregnant women who are likely to fill out repeated questionnaires. Although a random sample of pregnant women would be preferable for statistical inference, identifying women in the first six months of pregnancy would require enormous screening costs. The recent and highly regarded Gerber study on infant feeding, which required a sample of children aged 4 to 24 months, used a sampling frame similar to the one proposed here because the researchers determined that screening of the general population for this narrow subgroup is too inefficient (Devaney, Kalb et al. 2004). Moreover, the nature of the study requires respondents to complete a survey nearly each month from late pregnancy through their baby's first year. People who have chosen to participate in a consumer opinion panel are much more likely to complete the surveys than a random sample of the population.

The most significant disadvantage of the Consumer Opinion panel for the study is that it excludes mothers who are illiterate, non-English speaking, very low-income, very low-educated, and without a stable home. This segment of the population is difficult to survey under any circumstances. The IFPS will provide a better description of the practices of middle-America

than of the disadvantaged, although because of the over-sampling, it is expected that the sample will include a greater number of relatively disadvantaged mothers than the original study.

The estimated response rate for the study is 75% to the initial, Prenatal Questionnaire and 80% for all subsequent questionnaires. These estimates are based on the response rates for the 1993-94 IFPS, for which we had response rates above 85% for nearly all questionnaires after the Prenatal Questionnaire. These response rates may be somewhat lower because of the oversample of relatively disadvantaged groups. Analysis of demographic characteristics of the mothers who failed to provide complete data in the previous study indicated that they were more likely, compared with mothers who provided complete information, to be non-white, from the lower education categories, and enrolled in WIC (an indicator of low income) (Fein and Roe 1998). Sample attrition will be minimized by not excluding mothers from the sample for nonresponse to any of the questionnaires after the Neonatal.

## **B.2 Procedures for Collecting the Information**

All data, except for a very brief telephone interview near the time of the infant's birth, will be collected by questionnaires sent through the mail, as described above. The completed questionnaires will be sent by respondents directly to the contractor, who will scan them to construct the data files. The infant ages at which the various questionnaires and modules will be sent are listed in Attachment G. Letters that will be sent to respondents are in Attachment H. The infant feeding questionnaires can be found in Attachment I, and the Maternal Dietary Intake questionnaire is in Attachment J.

The statistical power analysis in Attachment F shows that with a sample size of 2,250, the study will have the power to detect real but small differences between subgroups. For example, we will have 79% or greater power to detect a real difference of 5% between two groups with sample sizes of 500 and 1,750, for percentage estimates less than or equal to 20 and using a one-tailed test. Using a two-tailed test, we will have 84% or greater power to detect a real difference of 5% when the subgroups are evenly divided with 1,125 respondents each, and percentage estimates are 20 or less. The sample size will enable us to compare demographic and other subgroups of interest, such as first-time vs. higher parity mothers.

As noted above, the major sampling challenges in this study are identifying women at the needed stage of pregnancy and maintaining a high response rate to preserve the longitudinal characteristic of the data. The sampling plan described will meet these challenges, but the trade-off is that the study will not be based on a probability sample. To evaluate potential bias from having a non-probability sample, we will compare results from the IFPS II with nationally representative data on available relevant characteristics, including breastfeeding measures and demographic characteristics. We will compare our results with results from probability samples on the following variables:

*Initiation and duration of breastfeeding* (Ross data; National Immunization Survey, National Survey of Family Growth [NSFG])

*Marital status* (NSFG)

*Cesarean vs vaginal delivery* (NSFG)

*Smoking status during pregnancy* (NSFG)

*Birth weight* (NSFG)

*Mother's employment characteristics*, such as employment during pregnancy, duration of total maternity leave, and duration of paid maternity leave (NSFG).

In addition to comparing our results with nationally representative data, we will also be able to compare some of our detailed infant feeding patterns with the FITS results. Although this study for feasibility reasons had to use an incomplete national sampling frame, the researchers made an extensive effort to produce nationally valid results (Devaney, Kalb et al. 2004). The sample is drawn in a way similar in some aspects to the way panel members are recruited, so comparison of feeding data is very appropriate.

In general, in estimating relations between variables, non-response will be handled by deleting records with missing data from the analysis, known as listwise deletion. This method has the advantages that it does not bias the estimates of standard deviations and bias from failure to meet the 'missing-completely-at-random' assumption is generally small (Allison 2000). In some circumstances and for some variables, missing values will be imputed by considering related data that are not missing. For example, one breastfeeding measure may be duration of breastfeeding to six months of infant age. If the six month questionnaire is not returned but the mother was breastfeeding at five months and at seven months, she will be presumed to have been breastfeeding at six months also. The same type of imputations will be made if the mother completed the relevant questionnaire but failed to answer the question of interest. This type of imputation will only be made when appropriate. For example, the same reasoning does not apply to exclusive breastfeeding because the infant could have been fed something other than breast milk in the month with the missing data.

### **B.3 Methods to Increase or Maximize the Response Rate**

Because the questionnaires will be sent out approximately monthly, there is no time for follow-up if a survey is not returned before the next is sent out. Based on the results of the first IFPS, non-response is not expected to be a large problem. During that data collection, of the 1,803 mothers who completed the first three questionnaires, 81 percent completed at least nine of the eleven total questionnaires.

Numerous methods will be used to encourage response. The initial contact letter will discuss the importance of the study and its scientific purpose. At about four months, a letter from the CFSAN Director encouraging continued participation will be sent (see Attachment H). In keeping with the Panel policy that an incentive is given after each questionnaire returned, an inexpensive (about a \$2.00 value), baby-related incentive will be sent after each questionnaire is returned. In addition, the sample will be designated as a special study group to help the mothers feel that they are participants in an especially important project.

The Diet History Questionnaire will have an incentive of \$10.00 because it requires more time to complete than the other questionnaires. Response rates for this questionnaire in other settings have been relatively high (Subar, Ziegler et al. 2001).

#### **B.4 Tests, Procedures, or Methods Used**

The questions and questionnaires used in the previous IFPS were extensively tested through cognitive interviews and small pretests. Reliability of some of the questions is shown by consistency in responses from month to month (data examined but not published). The validity of the data produced from that study is indicated by the similarity of certain study estimates with other data (see for example, (Scariati, Grummer-Strawn et al. 1997) and by deviation of the study estimates in expected ways (see (Roe, Whittington et al. 1999).

To ensure that measures are accurate and valid, new sections of questions will undergo cognitive testing. Fewer than 10 people will be asked the same questions for this process, and mothers participating in the WIC program or other low income or low educated mothers will be recruited for some of this testing.

Development of the DHQ food frequency questionnaire by NCI included extensive cognitive testing of this instrument (Subar, Ziegler et al. 2001; Thompson, Subar et al. 2002). DHQ questionnaire development also included validation of estimates of food and nutrient intake (Subar, Thompson et al. 2001; Thompson, Subar et al. 2002). For measurement of maternal dietary intake in the IFPS II, we will do cognitive testing of some modified DHQ question items. Because some of the original cognitive testing of the DHQ used a one-month time frame, we will not do additional cognitive testing of this modification (Thompson, Subar et al. 2002).

After OMB approval, certain questionnaires will be pretested with members of the Consumer Opinion Panel, as deemed necessary. Because it will be three months between the first administration of the Prenatal questionnaire and the first administration of the Month 2 questionnaire, which will be the first to use the Postnatal modules, it will be possible to conduct pretests concurrently with the initial data collection activities.

To minimize the number of questions that need to be tested, previous questions are used whenever they will meet the needs of the new study. This decision, more importantly, enables a comparison of results across time. For a list of questions that are repeated from the first study, see Attachment C. In addition, some of the variables will be measured using established instruments that have been tested by other researchers. These include the self-esteem scale, the postpartum depression scale, and the maternal dietary intake measure.

#### **B.5 Identification of Consultants on Statistical Aspects of the Design**

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