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.

PART 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 (Strecher 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 than10% 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 aged19 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

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/NICHD
Daniel Raiten	NIH/NICHD
Rosemary Higgins	NIH/NICHD
Susanne Strickland	NIH/NICHD
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/NICHD) 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.

This Information Collection Request was written prior to receiving public comments. However, the Federal Register Notice of proposed data collection was published on April 21, 2004**.** Public comments received will be considered in the final version. ***Will be revised and response to comments inserted after comments are cleared.***

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 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[1]

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

[1]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

Name	Title	Organization	Phone number	Email
Larry Grummer-Strawn	Branch Chief	CDC / National Center for Chronic Disease Prevention and Health Promotion/ Maternal and Child Nutrition Branch	770-488-5702	Lxg8@cdc.gov
Katherine Shealy	Public Health Breastfeeding	CDC / National Center for Chronic Disease Prevention	770-488-	Srk3@cdc.gov

	Specialist	and Health Promotion/ Maternal and Child Nutrition Branch	5449	
Foster McClure	Supervisory mathematical statistician, Bio-medical	FDA/CFSAN/OSAS/ Division of Mathematics	301-436-1834	Fmcclure @cfsan.fda.gov
Robert Blodgett	Mathematical Statistician, Bio-medical	FDA/CFSAN/OSAS/ Division of Mathematics	301-436-1836	Rblodget @cfsan.fda.gov
Jerome Schneidman	Mathematical Statistician, Bio-medical	FDA/CFSAN/OSAS/ Division of Mathematics	301-436-1838	Jscheid @cfsan.fda.gov
John Vidmar	Senior Vice President	Synovate	847-590-7390	John.Vidmar @synovate.com
Leigh Seaver	Senior Vice President, Public Sector Research	Synovate	703-790-9099	Leigh.Seaver @synovate.com
Alan Levy	Consumer Studies Scientist	FDA/CFSAN/OSAS/ Division of Market Studies	301-436-1762	Alevy @cfsan.fda.gov
Jordan Lin	Consumer Science Specialist	FDA/CFSAN/OSAS/ Division of Market Studies	301-436-1831	Clin @cfsan.fda.gov
Brenda Derby	Statistician	FDA/CFSAN/OSAS/ Division of Market Studies	301-436-1832	Bderby @cfsan.fda.gov

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