Followup Study for Infant Feeding Practices Study II

0910-0696

SUPPORTING STATEMENT

A. Justification

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) has the responsibility to protect public health by assuring the safety and security of our nation's food supply and by assuring that foods are effectively labeled. In addition, the FDA is responsible for advancing public health by helping the public to get the accurate, science-based information they need to use foods to improve health. As part of its regulatory responsibility for safety of the food supply, the FDA develops and disseminates consumer messages about food safety and nutrition. As a member agency, the FDA supports the Department of Health and Human Services policies related to infant and child health, nutrition, and obesity prevention.

FDA conducts research and educational and public information programs relating to food safety pursuant to its broad statutory authority, set forth in section 903(b)(2) of the Federal Food, Drug, and Cosmetic Act (FFDCA) (21 U.S.C. 393 (b)(2), to protect the public health by ensuring that foods are "safe, wholesome, sanitary, and properly labeled," and in section 903(d)(2)(C) (21 U.S.C. 393 (d)(2)(C)), to conduct research relating to foods, drugs, cosmetics and devices in carrying out the act.

Early infant feeding patterns have been associated with a wide range of health outcomes for children and mothers. A systematic review of the associations between breastfeeding and health outcomes in developed countries by the Agency for Healthcare Research and Quality (AHRQ) (Ip, et al., 2007) concluded that breastfeeding is associated with lower risk of childhood overweight and obesity, asthma, and diabetes. The report stated that evidence is not sufficient to conclude that breastfeeding is associated with cognitive development in term infants or with lower risk of cardiovascular diseases and mortality in developed countries. It concluded that breastfeeding is associated with lower risk of atopic (allergic) dermatitis in infants with a family history of atopy (allergy), but it did not evaluate a possible association in children of this condition or of food allergy. The review did not evaluate the evidence related to a possible association between breastfeeding and general immune status of children, but it found an association in infants, as indicated by lower risk for breastfed infants of acute otitis media, non-specific gastroenteritis, and severe lower respiratory tract infections. It also did not evaluate a possible association between early feeding and child behavior or social development. The review concluded that in mothers, a history of lactation is associated with the long-term outcomes of reduced risk of type 2 diabetes and reduced risk of breast and

ovarian cancer but that the association of breastfeeding with postpartum weight loss is unclear.

Since the ARHQ review was published, three prospective studies have evaluated the association between breastfeeding and childhood behavior as measured by the Strengths and Difficulties Questionnaire (SDQ) or a longer version of this instrument called the Child Behavior Checklist CBCL). Heikkila et al. (2011) reported results from the Millennium Cohort Study in the UK (n=9,737) using infant feeding data collected at 9 months and outcome data collected at age 5 years. Oddy, et al. (2010) reported results from the Raine Study (Western Australian Pregnancy Cohort, n=2,900), which followed participants for 14 years. Kramer, et al. (2008) reported results from the PROBIT study in Belarus (n=13,889), which collected infant feeding data and then contacted the families again when the children were 6.5 years old. Heikkial et al. used the SDQ and found that in term infants, abnormal SDQ scores were less common among children who had been breastfed for four months or longer. Oddy, et al., using the CBCL, found that shorter duration of any or of exclusive breastfeeding was associated with adverse behavioral outcomes (e.g., clinically significant internalizing or externalizing behavior) through childhood and early adolescence. Kramer, et al., using the SDQ evaluated differences between mothers and children randomly assigned to participate or not in a Baby Friendly Hospital Initiative program that strongly supported breastfeeding. A much larger percent of mothers in the experimental group (43.3%) than in the control group (6.4%) were exclusively breastfeeding at infant age three months, and a larger percent in the experimental group were breastfeeding to any extent at infant age 6 months (36.1% vs. 24.4%). Therefore, differences between the groups were interpreted as indicating differences between varying durations of exclusive and of any breastfeeding. In contrast to Heikkial, et al. and Oddy, et al., no association between breastfeeding and childhood behavior was found by Kramer, et al. Thus, an association between breastfeeding and child behavior has been evaluated in three major studies with conflicting results. The studies were in different countries and used different sampling methods, different measures of breastfeeding, and either a long or a shortened measure of child behavior.

Several studies published since the ARHQ review have contributed information about the association between breastfeeding and child health. Kramer, et al. (2009) evaluated health outcomes of 6.5 year old children in the PROBIT cohort, comparing results for those exclusively breastfed 3 or 6 months. Health outcomes included anthropometric measurements, blood pressure, intelligence quotient, behavior, atopic symptoms, allergen skin-prick tests, and dental caries. They observed no differences between the groups except that the children who had been exclusively breastfed for 6 months had higher adiposity measures. The authors noted that most of the children in the 3-month group had continued to be partially breastfed through 6 months, and so the results should not be interpreted to apply to any versus no breastfeeding. Thus the possible effect of duration of any breastfeeding on these health outcomes is not addressed by this study.

Kramer et al. (2007) evaluated risk of allergy and asthma in the experimental and control groups of the PROBIT cohort. They found no differences between the groups. After excluding six sites with suspiciously high rates of positive skin prick tests, risk of allergy was significantly higher in the experimental (greater breastfeeding) group. However, a policy statement from the American Academy of Pediatrics, Committee on Nutrition and Section on Allergy and Immunology (Greer, et al., 2008) concluded that exclusive breastfeeding for at least 4 months prevents or delays the occurrence of atopic dermatitis, milk allergy, and wheezing in early childhood.

Literature suggests that children who were breastfed may be healthier than children not breastfed. For example, infants who are breastfed are less likely to develop ear, lower respiratory tract, and gastrointestinal infections (Ip et al., 2007), and it is likely that this protection continues for some time into childhood. Several studies have found that breastfed infants have better lung development (Guilbert et al., 2007; Ogbuanu et al., 2009). Also, Ip et al. concluded that children who had been breastfed for at least six months had a lower risk of childhood leukemia, which involves a mechanism that is thought to be related to viral infections (Stuebe and Schwarz, 2010).

Regarding maternal health, a recent analysis from a large, prospective study supported the conclusion that breastfeeding reduces maternal pregnancy weight retention when the infant is in early childhood (Baker et al., 2008).

Possible influences of early feeding patterns extend beyond an examination of breastfeeding. Some studies have suggested that diet quality in late infancy is associated with diet quality in early childhood (Skinner et al. 1997,), which in turn is related to diet quality in the teen and adult years (Singer et al., 1995; Skinner et al., 2002; Stein et al., 1991; Wang et al., 2002). Also, an important influence on childhood overweight and obesity may be the child's regulation of food intake versus externally imposed regulation by the mother (Farrow et al., 2008; Faith et al., 2004). Learning to regulate food intake may begin in infancy with behaviors such as an infant finishing all of the milk in a bottle (Li et al., 2010).

In 2005-2007, the Food and Drug Administration, in conjunction with other agencies in the Department of Health and Human Services, collected data on infant feeding attitudes, knowledge, practices; infant health status; and related information. This study was called the Infant Feeding Practices Study II (IFPS II (OMB Number 0910-0558). The sample consisted of women from a commercial opinion panel in their third trimester of pregnancy. At the time of recruitment for the IFPS II, this panel consisted of about 500,000 nationally distributed households. Panel staff review the demographic composition of the panel compared with U.S. census data and attempt to recruit specific demographic subgroups that are under-represented on any of these characteristics: census division, population density, total annual household income, panel member's age, and household size. Basic demographic information is updated annually for each panel member on a rolling basis, with about

one-fourth of the households contacted in each quarter of the year. Other household information is also collected during the demographic data updates, including age of other household members and pregnancy status. The women contacted for the IFPS II were asked to provide information about their infant approximately monthly through the first year of life. The IFPS II also collected information about dietary supplement use in infancy, mother's weight before pregnancy and at several times postpartum, and maternal dietary intake during pregnancy and at four months postpartum. FDA is proposing to collect data measuring childhood outcomes likely to be associated with infant diet from these same mothers when the children are in early childhood and also to collect select information about the mothers, particularly related to overweight and obesity.

FDA, CDC, and OWH all plan to use the information to explore topics of concern to better understand where we might want to focus research in the future and also to help define the dimensions of future research on select topics. In addition, the results will be used to provide a background for understanding issues of importance to the agencies. The reasons each of these agencies need the data are described below.

Two particular topics of concern to FDA are food allergy and nutrition. Food allergy is a growing public health problem. Despite recent advances in diagnosis and management of food allergy, many unanswered questions remain regarding the increase in food allergies. Moreover, there is a need to understand the role that food allergen and other feeding exposures in early life play in the later development of allergic diseases including food allergy and asthma or other health conditions such as diabetes, obesity, and behavioral disorders. This study will contribute to our understanding of these various factors, which may aid in preventing the morbidity and mortality of food allergy. The Follow Up Study will also provide background that FDA needs to develop specific research to inform educational guidelines and strategies for consumers and also research related to safety and risk assessments of food allergenic ingredients.

The Follow Up Study will provide FDA an opportunity to compare and expand upon the results from the food allergy cohort observations identified in first IFPS II study in several ways. In particular, information from the Follow Up Study will help in understanding these factors in this cohort:

- If and how the prevalence of food allergy has changed in the original food allergy infant cohort and what factors may be associated with changed status.

- If it appears that the major food allergens identified by the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) - milk, eggs, soy, wheat, peanuts, tree nuts, crustacea and fish - continue to be the most prevalent food allergens in children or if new and important food allergens are emerging in this population. The Follow Up Study may indicate the need for population based research in this area and will help to define the important

dimensions of such a study if the agency decides that additional research is needed.

- Whether certain dietary and/or allergen avoidance practices in the first year of life increase or decrease the risk of food allergies at age six. An example of an important dietary exposure other than allergenic foods that has been linked to enhancing food allergies includes consumption of vitamins. Also, the positive or negative impact of food allergen avoidance in the first year of life on development of food allergies remains an unsettled national public health debate.

- Whether the development of food allergies early in life is associated with increased risk for development of asthma, childhood obesity, autoimmune diseases such as diabetes, or behavioral problems.

Current FDA consumer education initiatives on nutrition that relate to children include a school-based nutrition and food safety education program and an obesity prevention program that targets children just before the teenage years and focuses on use of the food label. Future possible initiatives have not been defined. The results of associations between diet quality of the children and other factors such as source of school lunch (e.g., participation in the school lunch program vs. bringing it from home) and the home food environment may help to identify information gaps and thereby contribute to an assessment of the need for additional research regarding the messages in the school-based program.

This study is needed because, although currently available literature varies in the level of detail about breastfeeding and other infant feeding patterns, none of the available studies includes detailed information about breastfeeding patterns (such as duration of exclusive breastfeeding, duration of any breastfeeding, intensity of breastfeeding [the amount of breast milk relative to all milk], or amount of feeding of expressed breast milk versus direct breastfeeding) or other infant feeding patterns such as age of introduction of various food groups and diet quality. FDA needs to better understand how the development of food allergy, asthma, childhood overweight and obesity, and other childhood health outcomes is related to early feeding patterns that are measured in meaningful detail.

The Office on Women's Health needs the information to explore the effects of early feeding patterns (including bottle feeding behaviors and duration) on oral health of children and to assess associations between certain women's health issues, particularly overweight and obesity, and infant feeding patterns. Results from this study will be used to evaluate the need for additional research on topics of concern related to OWH work on breastfeeding, oral health, and girls' health.

In addition, CDC needs the information to evaluate possible effects of early feeding patterns on childhood overweight and obesity and on various types of childhood development. Because the development of childhood obesity is influenced

not only by infant feeding patterns, but also by many other factors, such as physical activity, TV/Screen time, maternal feeding styles, child's self-regulation of food intake, family meals or eating away from home, meal preparations, home healthy food environment, child care arrangements, school lunch, sleeping patterns, consumption of high energy dense food, fruits and vegetables, and sugar sweet beverages, etc., CDC needs these data to contribute to understand the potentially modifiable risk factors for developing childhood obesity which will contribute to developing strategic public health efforts to prevent and control childhood obesity and chronic diseases.

The study will include one mailed questionnaire asking about child and maternal outcomes that may be related to breastfeeding or other early feeding patterns and also asking about potentially confounding factors. Demographic information will come from the information kept about the panel members by the panel administrator. A separate demographic questionnaire will be mailed with the outcomes questionnaire to mothers who are no longer members of the consumer opinion panel from which the original sample was drawn.

The study will collect information about the following childhood outcomes: health (medical visits, frequency of specific infections, other health conditions); physical development (hearing, sight, digestive system); dental caries; eczema, allergy or asthma; diabetes; overweight or obesity (height and weight); psychosocial development (presence of an individualized education program, strengths and difficulties questionnaire, attention deficit disorder, developmental delay, anxiety problems, depression); and consumption of various food groups to measure diet quality. In addition, we will ask questions to determine maternal overweight or obesity.

We will measure potentially confounding factors. For dental caries: oral hygiene and sugar consumption. For allergy: exposure to cigarettes and other inhaled contaminants, presence of pets, family history. For child overweight or obesity: eating environment (such as how often the child eats dinner with an adult in the household, how often he or she eats from fast food restaurants), mother's control over the child's eating, physical activity, time spent watching a screen (TV or computer), sleep patterns, family history, maternal depression. For psychosocial development: extent of cognitive stimulation and emotional support at home, child care arrangements, maternal depression, family history. For diet quality: food allergy; family meals; maternal depression; WIC (Special Supplemental Nutrition Program for Women, Infants, and Children), food stamps, or SNAP (Supplemental Nutrition Assistance Program) participation; maternal employment. For mother's overweight and obesity: mother's physical activity, depression, pregnancies subsequent to the sample child and whether subsequent children were breastfed, employment conditions, and the mother's or child's participation in certain government programs.

Demographic variables include age of the mother, marital status, mother's education, race, Hispanic ethnicity, household income, household size, mother's

employment status and occupation, city of residence, geographical region, and population density.

2. Purpose and Use of the Information Collection

The information will be collected from mothers who previously participated in the IFPS II. When these women were pregnant with the sample infant, they were part of a commercial consumer opinion panel, a collection of households that agreed to answer questionnaires for research purposes. The data collection will be conducted by Synovate, the consulting firm that manages the panel, using a questionnaire constructed by the FDA in collaboration with participating agencies in HHS. Synovate collected the data for IFPS II, and only they have the contact information for the sample.

FDA will analyze the information to better understand how infant diet and feeding practices are related to child health, physical development, dental caries, atopy and food allergy, obesity, psychosocial development, and diet quality in childhood. It will also use the research to evaluate the association between infant and child consumption of botanical dietary supplements and will use the information about the mothers' weight and health status to better understand the role of weight gained and retained during pregnancy (which is related to early feeding patterns) in the development of overweight and obesity among adult women. The results will provide detailed information that is specifically relevant to FDA's mission and current concerns. For example, an issue of concern by FDA is how the progression and development of food allergy is related to infant feeding practices such as breastfeeding or formula feeding, but also to feeding expressed breast milk versus milk directly from the breast, the age of introduction of solid foods, types of foods first introduced, and the age of introduction of allergenic foods. FDA and the other involved agencies recognize that this data collection will serve the purposes of a research study and will not be appropriate to use as a basis for policy or consumer education initiatives.

Ways the information from the infant part of the study was used shows the general style and purposes for which the new data will be used. A special supplement to the journal *Pediatrics* was published by authors from FDA (Center for Food Safety and Applied Nutrition and Center for Devices and Radiological Health), the Centers for Disease Control and Prevention, National Institutes of Health, and academia. This supplement contained thirteen articles that examined feeding patterns, various aspects of breastfeeding, breast pump use, feeding patterns associated with infant overweight, sources of supplemental iron among breastfed infants, and food allergy in infants. Additional articles have been published that examine adherence to vitamin D recommendations among infants and that further examine issues related to infant overweight and breastfeeding success. In addition, information about formula feeding practices in the United States was used in a report from the World Health Organization and Food and Agriculture Organization regarding *Enterobacter sakazakii* in powdered follow up formula. Results comparing fish consumption by pregnant women, postpartum women, and women who were neither pregnant nor

postpartum (defined as not having had a baby within the past twelve months) was submitted to the World Health Organization. Specialized results were used by CFSAN to estimate infant exposure to bisphenol A by examining the percentage of infants who consumed different types of formula (powdered, liquid concentrate, and ready-to-feed in multiple serving containers or individual serving containers) and who consumed commercial baby foods and certain other foods. Other special results compared awareness of methyl mercury in food among pregnant women and women who were neither pregnant nor postpartum. These results also compared awareness among pregnant women of methyl mercury and *Listeria monocytogenes* as possible food contaminants. Another analysis examined the effect on brand selection of various types of formula marketing activities, including certain types of labeling statements.

The agencies have not developed plans for future use of the data after the issues described in this supporting statement are addressed. Future use will depend on what other agency issues arise that are relevant to the data and how much staff time is available for further analysis. We will maintain our awareness that the data cannot be used as population estimates or as the major support for policy or consumer education initiatives.

3. Use of Improved Information Technology and Burden Reduction

This study will not use new technology to reduce burden of the respondents; information will be collected using the same technology (primarily self-administered paper questionnaires) that was used in the IFPS II.

4. Efforts to Identify Duplication and Use of Similar Information

Several longitudinal studies have been conducted that included an infant feeding component and that spanned infancy through early childhood or later. Considering those from which articles have been published in English since 1995 these include the following studies, ordered from earliest to latest first birth year. The country in which the study was conducted is also listed.

New Zealand Cohort Study with birth year 1977 [New Zealand] (Fergusson and Woodward, 1999);

Rhine-Neckar Region cohort study with birth years 1986-1988 [Germany] (Buchmann et al., 2010);

Isle of Wight Cohort Study 1989-1990 [United Kingdom] (Ogbuanu et al., 2009);

Western Australian Pregnancy Cohort (Raine) Study with birth years 1989 to 1992 [Australia] (Oddy et al., 2010);

German cohort study with birth years 1989-2003 [Germany] (Ziegler et al., 2003)

The Promotion of Breastfeeding Intervention Trial (PROBIT) with birth years 1996-1997 [Belarus] (Kramer et al., 2008);

Norwegian Mother and Child Cohort Study with birth years 1999-2008 [Norway] (Vollrath et al., 2010);

The Millennium Cohort Study with birth years 2000–2001 [United Kingdom] (Sacker et al., 2006)

Tennessee longitudinal study of diet with birth year 1992 [USA] (Skinner et al., 1997).

The proposed follow up study is not duplicative of any of these studies for several reasons. One is that none of them included detailed measures of early feeding patterns, including breastfeeding duration and intensity, use of expressed milk, and patterns of introduction of food groups. A second reason is that the only one of these studies conducted in the USA was in a specific state and concerned only diet. Given different cultures, customary diets, exposures to contaminants, and other differences that occur among countries, it is possible that results in the USA will be different from those in other countries even when the same outcome is measured.

CFSAN project staff has collaborated with other agencies that are likely to collect or use the type of longitudinal data proposed here. An Expert Working Group was convened for the project that included staff from CDC, DHHS/OWH, HRSA/MCHB, AHRQ, USDA/FNS and USDA/ERS. Several academicians who worked on the infant part of the data collection were also on the EWG. None of these group members could identify research that would be duplicative of this proposed study. See item 8 below for a list of EWG members.

5. Impact on Small Businesses or Other Small Entities

No small businesses will be involved in this collection.

6. Consequences of Collecting the Information Less Frequently

This is a one-time data collection. Without this study, FDA will not have information critically needed for understanding how infant feeding patterns relate to the development and progression of childhood overweight and obesity and food allergy or how infant feeding patterns relate to diet quality in childhood. FDA will also not have information about what dietary supplements are given to young children and whether such practices are related to giving supplements to infants. CDC and the other participating agencies will not have information about whether certain details of infant feeding and care are associated with particular health and development outcomes in early childhood. This information is needed to inform consumer outreach programs and messages and to inform various policy issues as described in A.2 of the supporting statement.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

The study design will not produce data that can be generalized to the universe of young children in the USA. The Office of Management and Budget permitted the infant part of the study to use a sample that was drawn from a commercial consumer opinion panel for two major reasons. One was that the cost of screening to find eligible pregnant women for that part of the study would have been enormous. The

second was that the research design required responses from sample members approximately monthly during a period that most mothers find unusually busy and challenging. It was thought that nonresponse bias from a general population sample would be so high that the study would be invalidated. The people most likely to drop out of a general population sample are those who are underrepresented in a consumer opinion panel – mothers who are low educated or from unstable homes. The sample under represents ethnic and racial minorities, young mothers, and those with low education and low income, but it does include some members of these groups. For example, 41.9 percent of the IFPS II sample had income less than 185% of the federal poverty level, compared with 45.2% of a random sample of mothers of infants (Fein et al., 2008). The strength of the Follow Up Study will be its ability to link detailed infant feeding data with outcomes and other measures in early childhood.

No other special circumstances will occur in the data collection.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In the Federal Register of March 1, 2011 (76 FR 11251-11252), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received one comment on the proposed Followup Study for Infant Feeding Practices Study II.

(Comment) The comment asserts that America does not need this information because it has been well known for years.

(Response) FDA disagrees. The agency is not persuaded that existing information will fulfill the agency's needs. We note that, although currently available literature varies in the level of detail about breastfeeding and other infant feeding patterns, none of the available studies includes detailed information about breastfeeding patterns (such as duration of exclusive breastfeeding, duration of any breastfeeding, intensity of breastfeeding [the amount of breast milk relative to all milk], or amount of feeding of expressed breast milk versus direct breastfeeding) or other infant feeding patterns such as age of introduction of various food groups and diet quality. This detailed information is available in the data collected from the proposed sample when the children were infants. FDA needs to better understand how the development of food allergy, asthma, childhood overweight and obesity, and other childhood health outcomes is related to early feeding patterns that are measured in meaningful detail.

An Expert Working Group was formed to select the topics that should be included in the Follow Up Study and to propose appropriate questions for measuring each topic. Members outside of FDA are listed in the chart below.

Member	Affiliation

Mary Cogswell	Centers for Disease Control and Prevention (CDC)
Deborah Dee	CDC
Ann DiGirolamo	CARE USA
Elizabeth Frazao	USDA/Economic Research Service
Gerald Calnen	Private physician, pediatrics
Laurence Grummer-Strawn	CDC
Fern Hauck	University of Virginia School of Medicine
Suzanne Haynes	Office of Women's Health, DHHS
Tihesha Jenkins-Salley	USDA/Food and Nutrition Service
Judith Labiner-Wolfe	Office of Women's Health, DHHS
Michele Lawler	Health Resources and Services Administration
Rouwei Li	CDC
Bidisha Mandal	Washington State University
David Meyers	Agency for Healthcare Research and Quality
Tonse Raju	NIH/National Institute for Child Health and Human Development
Kelley Scanlon	CDC
Laura Schieve	CDC
Andrea Sharma	CDC
Katherine Shealy	CDC
Thomas Sobotka	Consultant, previously with FDA
Denise Sofka	Health Resources and Services Administration
Valery Soto	USDA/Food and Nutrition Service

9. Explanation of Any Payment or Gift to Respondents

   In appreciation for their efforts in answering the questionnaires, members of the consumer opinion panel are routinely given a choice between a sweepstakes award or Global Opinion Panel points which they can exchange for cash. The number of points given for each questionnaire is determined by the length and complexity of the survey. For this questionnaire, which is much more burdensome to complete than most the panel receives, the respondents will receive a number of points equivalent to $10.00. The pilot study offered an incentive of $15.00 to half the sample and $10.00 to the other half and found no difference in response rates between the two groups., Those respondents who are no longer panel members will receive a check for the incentive amount.

10. Assurance of Confidentiality Provided to Respondents

    The letter accompanying the questionnaire will contain a statement that responses will be kept confidential. Identifying information will not be included in the data files delivered by contractors to the agency. Details of Synovate's privacy policy can be found at https://www.globalopinionpanels.com/privacy_popup.

    All electronic data will be maintained in a manner that is consistent with the Department of Health and Human Services ADP Systems Security Policy as

described in DHHS ADP Systems Manual, Part 6, chapters 6-30 and 6-35. All data will also be maintained in consistency with the FDA Privacy Act System of Records #09-10-0009 (Special Studies and Surveys on FDA Regulated Products).

11. Justification for Sensitive Questions

The study includes questions to measure maternal depression. There is reasonable evidence that depression is related not only to early feeding patterns but also to later child care behaviors (Goodman et al., 2011; Knitzer et al., 2008; Whitaker et al., 2006; Ystrom et al., 2009). Maternal depression will be an important potentially confounding variable for several of the childhood outcomes and also maternal overweight and obesity (Riolo and Nguyen, 2009; Stunkard et al.,2003).

The IFPS II included a measure of postpartum depression. The discussion given in the OMB Supporting Statement for those questions applies here also. 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. Therefore, the risk to respondents of embarrassment or harm from release of their specific information is nonexistent.

In addition, again like the IFPS II, the Follow Up Study asks about family medical history. The information needs to be updated because some of the conditions could have occurred since the birth of the sample child. Again, there is no risk to the respondents from giving this information because the data file will contain no identifying information.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

The estimated total hour burden of the collection of information is 841 hours (Table 1).

During the questionnaire development phase, cognitive interviews were conducted with six respondents to test the new and modified questions. Although many of the questions are from previous data collection instruments, the total questionnaire will present the questions in a different context from the original, and for many questions, the form of collection will be changed from an in-person interview to a written questionnaire or a telephone interview. Therefore, a pilot study of 91 mail and 9 telephone respondents will be conducted to test the questionnaire after OMB approves the data collection. It is expected that the pilot test will refine some of the questions but not result in substantial changes in the questionnaire. The materials for the pilot study are included in the Appendices showing each specific material for the main study, except that the debriefing questionnaire is shown in Appendix I.

The cognitive interviews tested the questions about the child's diet, food environment, and mother's control of the child's eating. They also tested the

questions on exposures to pets and chemicals used in the home, mother and child's activity levels, other mother characteristics (e.g., subsequent pregnancies, employment), child care, school characteristics, child's height and weight, oral hygiene and oral health, child health, food allergy, and child's sleeping patterns. We did not test any sets of questions that we could not change, for example, the Strengths and Difficulties Questionnaire and the Home Environment scale. Because of the length of the questionnaire, we divided the questionnaire into two parts, each of which was asked of six respondents. None of the same questions was asked of both sets of respondents.

Respondents were mothers from the consumer opinion panel that the pilot sample will be selected from and that the sample for the infant part of the study was selected from. Using panel administrative data, the contractor identified mothers who worked and who had a 6 year-old child. We requested working mothers because we thought they would have more challenges reporting their child's diet than mothers who did not work. All interviews were conducted by telephone. The Project Officer conducted the interviews in the company of another FDA scientist also assigned to the project. The interviews were recorded and the responses, including responses to probe questions, were transcribed. The interview team identified questions that were confusing to the mothers, hard to answer, or misinterpreted. Respondents were probed to ascertain their understanding of the questions, to find other terms they used for concepts in the questions, and to determine if the question covered their situation. The questions were tested on two respondents, modified, tested on another two respondents, modified again, and tested on a third set of two respondents.

We asked how easy or hard it was for respondents to remember over the 12 month reference period, whether they used different terms for any of the key words in the questions, whether the response options fit their situation, and other details. Changes included re-wording questions, changing response options, and changing the order of questions. As one example of a revision, we changed the reference period for days missed from school from the past 12 months to the past school year because respondents told us that it was hard to remember for the part of the previous school year that fit into the past 12 months.

For an example of re-wording, the two sets of questions about Individualized Education Programs below show the wording in the first set of interviews and then the final wording in the Pilot Questionnaire after the third round of cognitive interviews. We changed the question and explanatory note and added one additional response option.

Round 1

1. Does your 6-year-old have a health problem, condition, or disability for which he/she has a written intervention plan at school called an Individualized Education Program or IEP?

EXPLANATORY NOTE: Some children have difficulty in school because of a health problem, condition, or disability. These children may receive services from a program called Special Education and have a written intervention plan called an Individualized Education Program or IEP. Services on an IEP might include special instruction; speech or language therapy; vision and hearing services; psychological services; health services; social work services; family counseling and support; transportation; or other services needed to support the child's educational performance.

Yes ☐ No..... ☐ →**(GO TO SECTION B)** Don't Know..... ☐

2. Why does your 6-year-old have an Individualized Education Program or IEP? **(PLEASE "X" ALL REASONS THAT APPLY).**

Speech or language therapy..... ☐
Occupational therapy or other type of therapy for help with handwriting or other motor skills..... ☐
Physical therapy..... ☐
Special instruction or help in one or more school subjects such as reading or math..... ☐
Special services because of a problem with vision or hearing..... ☐
Psychological services or counseling because of a problem with emotions, behavior, or socialization..... ☐
Special support because of a chronic health condition ..... ☐
Other reason..... ☐

Pilot Questionnaire

1. During this school year, has a special plan been developed at school to provide your 6-year-old with extra help or support such as a special needs program or an Individualized Education Program (IEP)?

EXPLANATORY NOTE: Some children have difficulty in school because of a health problem, condition, or disability. These children may receive services from a program called Special Education and have a written intervention plan called an Individualized Education Program (IEP).

Yes..... ☐ No..... ☐ Don't know..... ☐

2. During this school year, has your 6-year-old received any of the following services? **(PLEASE "X" ALL THAT APPLY)**

Speech or language therapy..... ☐
Occupational therapy or other type of therapy for help with handwriting or other motor skills..... ☐
Physical therapy..... ☐
Special instruction or help in one or more school subjects such as reading or math..... ☐
Special services because of a problem with vision or hearing..... ☐
Psychological services or counseling because of a problem with emotions, behavior, or socialization..... ☐
Behavioral support, such as a behavior management plan or individual support in the classroom by an assistant..... ☐
Special support because of a chronic health condition ..... ☐
Other (please specify)
_____..... ☐
None of these ..... ☐

The reason for the change was that we found mothers focused on the first part of the sentence in Round 1, and answered about the child's problems whether or not they resulted in an IEP. We found that mothers thought of this type of support as a program for "special needs." One mother interviewed mentioned the additional type of support we added. Also, some children received services outside of school, and for that reason we changed the second question in the set. The purpose of the question is to indicate child development problems, not school services, and the final version seems to achieve this purpose.

Below is an example of a question for which we changed the question and response options to include all situations reported by respondents:

Round 1

1. Does your 6-year-old take daily medications to manage his/her asthma?

Yes..... ☐ No..... ☐

.....

Pilot Questionnaire

1. Does your 6-year-old take daily medications either year-round or seasonally to manage his or her asthma?

Yes, year-round ☐ .....Yes, seasonally ☐.....No ..... ☐

An example of changing the order of the questions comes from the food frequency and details about the child's diet. Initially, we began the section on diet with the food frequency chart (D-13 on the Pilot Questionnaire). However, we found that mothers recalled foods that they wanted to add to the chart after they read the following questions about type of milk, bread, etc, that the child eats. We realized that asking the specific questions first helps the mother to begin thinking about the child's usual diet and makes it easier to answer the food frequency chart. Now the specific questions have been placed before the food frequency chart as questions D-3 through D-12.

To refine the questionnaire used in the study, we conducted a pilot study with 139 participants, 133 by mailed questionnaire and 6 by telephone interview. We found that it took respondents an average of 26 minutes to complete the survey, based on a question in the debriefing questionnaire which asked how long it took to complete the questionnaire.

The purpose of the pilot study was to test the total questionnaire with respondents like those who will answer the main study questionnaire and to evaluate certain elements of the study design. We examined these factors by analyzing the answers to the pilot test, analyzing responses to the debriefing questionnaire, evaluating the telephone interviews, and analyzing response rates from groups sent the two different levels of incentive.

A secondary purpose of the pilot study was to conduct an experiment to test the effect on response rates of different levels of incentives. The panel administrators recommended this addition and the incentive levels to be tested. The sample for the pilot was randomly assigned to receive points value of either $10 or $15. These levels were selected based on usual incentives for surveys of the length of the Follow Up Study. The incentive amount for the main study will be based on the results of the analysis of the response rates between the two groups. The results found no difference between the two groups (66 of one group and 67 of the other group returned the questionnaire) and so an incentive of $10.00 will be offered.

All IFPS II participants who completed at least two surveys after their infants were born and for whom current contact information can be found will be sent the mailed questionnaire. The sample base is expected to be about 2,847 participants. We expect to find current contact information for 90 percent of those who qualify (2,562 sample members). We estimate that 1,538 respondents will return the mail questionnaire (60%) and that it will take an average of 26 minutes to complete, for a total of 666 hours. An additional 513 mothers (20%) are expected to complete the telephone interview of 38 minutes, for a total of 325 hours. These estimates are based on the time required in the pilot study. The initial design was that sample members who are no longer a panel member would be asked to complete a questionnaire to update their demographic information. An estimated 1,380 participants (67%) were expected to return the demographic questionnaire, which will require 5 minutes to complete, for a total of 115 hours. However, because the demographic information will come from different time periods for panel and non-panel respondents under this design, we decided to ask everyone in the sample to complete the demographic questionnaire at the same time they complete the study questionnaire. This feature will require that 2,051 people complete the 5-minute demographic questionnaire, which will total 171 burden hours. Thus, the total estimated burden is 1,204 hours. FDA's burden estimate is based on prior experience with consumer surveys that are similar to this proposed data collection and on results of the pilot study.

Table 1. Estimated Annual Reporting Burden

Portion of Study	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in Hours)[2]	Total Hours
Pilot study mailed questionnaire	91	1	91	25/60	38
Pilot study telephone interview	9	1	9	25/60	4
Main study mailed questionnaire	1538	1	1538	26/60	666
Main study telephone interview	513	1	513	38/60	325
Demographic questionnaire (respondents are a subset of the main study sample and are not added to the total below)	2051	1	2051	5/60	171
Total	2151				1204

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Burden estimates of less than 1 hour are expressed as a fraction of an hour in the format "[number of minutes per response]/60".

12 b. Annualized Cost Burden Estimate

The annualized cost to all respondents for the hour burden for the collection of information is $19,264 (1204 x $16) at $16 per hour (the 2009 median wage rate in the U.S.) See http://www.bls.gov/oes/current/oes_nat.htm#00-0000, dated May 14, 2010, the latest estimate available as of May 2011.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/ Capital Costs

There are no capital, start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimated total cost to the Federal Government for this information collection is $500,000. This includes the value of a task order to develop and conduct the collection of information, the value of a contract for assistance with the literature

review and for development of other documents associated with the project, and the value of two part-time employees to develop, monitor and analyze the data collection.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Conventional statistical techniques for survey data analysis will be used. These will include descriptive statistics, logistic regression models, generalized linear models, and other techniques appropriate to the specific research question. Statistical techniques appropriate for longitudinal data will also be used as appropriate. For example, analyses of data from the infant part of the study have included Cox Proportional Hazard Analysis, survival analysis, and other such techniques.

Because we expect to publish results in professional journals, a number of articles (not only one study summary) will have to be published on focused topics. The first topics that will be analyzed are those of most importance to the agency at the time the data become available, probably those relating to food allergy for FDA, obesity for CDC, and oral health for OWH. Scientists from other agencies involved will choose topics depending on their priorities. Generally, results are presented at professional meetings before they are published. The annual meeting of the American Public Health Association is often chosen for presentations because it reaches a variety of health care professionals, industry professionals, government scientists, and academic scientists. The purpose of the presentations and articles will be to share the research findings and to engage in discussions with other researchers doing related work in order to establish a stronger foundation for future research. The planned schedule for project activities is shown in Table 2.

Table 2. Project Schedule

Date	**Activity**	**Expected Duration**
Within 3 days after receipt of OMB approval of collection of information	Notify contractor to start pilot study	Not applicable
Within 6 weeks after receipt of OMB approval of collection of information	Complete data collection for pilot study	1-1/2 months
Within 3 months after receipt of OMB approval of collection of information	Analyze pilot study data and finalize questionnaires for the main study	1-1/2 months
Within 7 months after	Collect data for the main study	4 months

receipt of OMB approval of collection of information		
Within 1 month after completion of data collection	Receive data and methods report from contractor	1 month
Within 3 months after receipt of final data files	Delivery of a written top line report of findings	3 months
Within 24 months after receipt of final data files	Submission of manuscript(s) to professional journals to disseminate information and analytical findings	24 months

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The OMB approval and expiration date will be displayed on all materials associated with the study. No exemption is requested.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

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