



INTERNATIONAL FORMULA COUNCIL
Formerly the Enteral Nutrition Council and Infant Formula Council

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Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852

RE: Docket No. 2004N-0166
Infant Feeding Practices
Study II

Dear Sir or Madam:

This letter is prompted by the April 21, 2004 *Federal Register* announcement of the opportunity for public comment on the Infant Feeding Practices Study II ("IFPS II"); a voluntary consumer survey about infant feeding and diet of pregnant women and new mothers (69 *FR* 21548). These comments are submitted on behalf of all the major U.S. infant formula manufacturers by the International Formula Council ("IFC")¹, an international association of manufacturers and marketers of formulated nutrition products (e.g., infant formula and adult nutritionals) whose members are predominately based in North America.

Format of IFC's Comment to the Proposed Voluntary Consumer Survey

These comments contain two major sections: General Comments and Specific Comments. The **General Comments** include comments that apply to the proposed voluntary consumer survey as a whole. **Specific Comments** address individual sections of the proposed questionnaires and modules.

IFC's General Comments to FDA's Proposed Voluntary Consumer Survey

We commend the Agency on moving forward to collect information on U.S. infant feeding practices in an effort to gain a better understanding of mothers' knowledge of infant nutrition and feeding. Nutrition plays a critical role in infant growth and development and it is important to collect accurate data on both current infant feeding practices and future trends.

We are especially pleased to have one point of emphasis be on the proper use of infant formula, and some of our specific comments focus on this aspect.

¹ International Formula Council members are: Mead Johnson Nutritionals; Nestlé USA, Inc., Nutrition Division; Ross Products Division, Abbott Laboratories; Solus Products; and Wyeth Nutrition.

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At the same time, care should be taken to ensure that the methodologies used are appropriate to minimize sample bias and allow for the broadest application of the data. Specifically, we have the following concerns with the methodology for the IFPS II outlined recently in the *Federal Register*:

- **The consumer sample should be representative of the general population of new mothers in the United States.**

The original 1993/1994 Infant Feeding Practices Survey (IFPS), was reportedly not representative. In comparison with nationally representative data from the National Maternal and Infant Health Survey, the participants in the 1993/1994 IFPS were more likely to be white (96%), older (29% > 30 years), married (93%), and of higher income and education (46% reported an income \geq \$40,000; 33% reported an educational level \geq 4 years of college.² All of these demographic factors can play significant roles in infant feeding practice decisions, particularly when considering breastfeeding rates. What steps will be taken to ensure that the new IFPS II is truly representative of the general population?

If the IFPS II is more representative of U.S. mothers than the original IFPS, than general comparisons between the two data collections—as specified in the *Federal Register* notice—may not be valid.

- **The proposed survey tools are lengthy, detailed and appear to be written for an educated, highly literate population, which will make it difficult for the consumer sample to be representative of the general population.**

To ensure a representative sample, steps should be taken to make all survey instruments appropriate for the general population, including lower literate and minority subgroups. For example, the *Federal Register* notice specifies a subset of the sample will be asked to complete a modified National Institutes of Health Diet History Questionnaire. How will the Questionnaire be modified? The current Questionnaire appears to be based primarily on a typical Western diet, and collects limited information on ethnic/culture-specific foods.

- **For several reasons, the consumer survey should not ask respondents to identify brands of products – e.g.,
Brand fed at birthing hospital (breastfeeding) – pg. 18;
Brand received in gift pack at hospital or by mail (breastfeeding) – pg. 19;
Brand fed in past 7 days – pg. 22;
Brand fed in past 7 days – pg. 30;
Brand associated with food allergy – pgs. 37, 38 and 39;
Brand stopped using – pg. 52.**

First, the Agency does not need brand names to understand how people choose formulas and why they change formulas, and that collecting such information on a branded basis could have serious and unintended ramifications. Specifically, any compilation of this data might appear to be a science-based indicator of which

² DiGirolamo AM, Grummer-Strawn LM, Fein, S. Maternity care practices: implications for breastfeeding. *Birth* 28(2): 94-100, 2001.

formulas are more or less likely to be a problem, when in fact, it is not a scientifically valid indicator at all. Moreover, the data will be publicly available, so even though the Agency may understand that it would not be fair or appropriate to draw such conclusions, the press or others may not have the same understanding

Depending on the exact intent of some of the questions, it may be appropriate to ask about the type of formula (e.g., milk-based, soy-based or specialty) or form (e.g., powder, ready to feed, concentrate) rather than the brand. However, if the purpose of these questions is to try to understand if one formula is better tolerated than another, it would be more appropriate to rely on a properly designed clinical trial.

Finally, brands are no longer practical in the context of the questionnaires, in light of changes that have occurred in the marketplace in the past 10 years. There are now over 40 different brands of infant formula to choose from, many of which have similar names. This will make it far more difficult to ensure correct brand identification by respondents. Thus, if after considering these comments, the Agency insists on retaining brand-specific questions, we would strongly recommend colored package photos of each brand be provided to respondents to improve accuracy.

We would also recommend disaggregating store brands into those that have distinctive names (Little Ones from K-Mart, Parents' Choice from Walmart, Healthy Baby from Target, Bright Beginnings) and "other store brands". Alternatively, respondents should be provided with store brand names as examples (e.g., such as Parents' Choice from Walmart, Healthy Baby from Target, Safeway store brand). However, our experience indicates that even with photographs, some misidentification will occur.

- **It is unclear how the IFPS II will specifically be used to evaluate the Department of Health and Human Services (HHS) National Breastfeeding Awareness Campaign.**

The HHS National Breastfeeding Awareness Campaign has been positioned as targeting the general market as well as the African American community.³ Unless the IFPS II is truly representative of the general population and has an adequate sample of African Americans, both in terms of representivity (e.g., education, income) and size, it would be wrong to use the IFPS II as a measure of the National Breastfeeding Awareness Campaign's effectiveness.

- **Mail surveys have limitations and it is questionable whether the federal government should employ two known psychological testing scales in its research.**

Some of the factors identified in the *Federal Register* notice, such as postpartum depression and self-confidence may not be appropriate to measure via a mail survey, as the psychological scales that measure these factors were presumably designed for use by qualified mental health professionals who are empowered to act on the findings. (We note Question 43 of the Neonatal questionnaire is the

³ Ad Council. <http://www.adcouncil.org/campaigns/breastfeeding/>

Edinburgh Postpartum Depression scale, apparently used by clinicians, insurance companies and academics to diagnose postpartum depression, usually with the intention of recommending treatment. We also note Question 53 of the Prenatal questionnaire is the Rosenberg Self Esteem scale.) If some respondents were to show patterns of clinical disorders, such as postpartum depression, the federal government then possesses potentially life-saving information that cannot be used without violating the promise of respondent confidentiality.

- **The great extent to which wording and order of questions in the 1993 questionnaire have been changed casts great doubt on the ability to legitimately compare the two studies and draw conclusions regarding trends over time.**

Depending on the priority which is placed on comparing this proposed survey to the 1993 IFPS as a research objective, it may be necessary to either extensively modify the current survey or re-set expectations about comparisons that can realistically be made.

- **Partly due to the difficulty of accommodating old and new questions, there is substantial room for improvement in questionnaire flow (i.e., the order of topics and transition between topics).**

We believe better questionnaire flow will result in more complete and consistent responses.

- **Several of these questionnaires are extremely long.**

Although the total number of questions may not have changed substantially compared to 1993, the length and complexity of individual questions has increased. Even if the supplier is willing to subject panelists to these tasks, the quality of the information may suffer. Rotation of questions or items in a long list is not a sufficient solution. Other ways to simplify and shorten the longer questionnaires should be aggressively sought. At a minimum, it is assumed that FDA will pretest the questionnaire (via in-person debriefing) to identify and correct sources of respondent fatigue, confusion or inconsistency.

- **Some questionnaires do not include a WIC participation question.**

Unless a WIC participation question is added to those questionnaires which currently do not include such a question, WIC participation will have to be inferred from other questionnaires.

IFC's Specific Comments to FDA's Proposed Voluntary Consumer Survey

I. Prenatal Questionnaire

Our overall concern with the Prenatal Questionnaire is whether the combination of old and new questions, which now so heavily emphasizes breastfeeding, could bias respondents postnatally (i.e., heighten their awareness to the point where it has an artificial effect on behavior). We understand this concern must be weighted against the objective of understanding mothers' beliefs and intentions regarding breastfeeding prior to birth. However, the fact that the bulk of the data collection is postnatal argues for erring on the side of less breastfeeding content prenatally. Following are our comments on specific questions:

A. Question 10: Which of the following conditions does any of the baby's relatives have?

IFC Comment: Our experience indicates this question will confuse respondents, particularly the "other relatives" column because it is unclear how to answer if some other relatives have the condition, some do not, or their conditions are not known. We suggest simplifying the response to this question by advising the respondent to check if anyone in the family has the condition. In addition, the terms "eczema," "food allergy," and "overweight/obesity" are not defined, thereby allowing for a wide range of interpretations.

B. Questions 20 – 22

IFC Comment: These questions ask mothers to speculate on workplace receptiveness to breastfeeding. However, all of the questions are very vague (e.g., what does "supportive" mean in the context of one's entire place of employment). Thus, we believe such terms should be further qualified.

C. Question 28: Which of the following statements is closest to your opinion?

IFC Comment: We find this question to be vague. First, the baby's age is not specified (e.g., at any age, currently) and mothers may give different answers in the context of different ages. (Only in Question 29 is the timeframe defined as "first few weeks.") Second, "best" is undefined in terms of the child's interest or the mother's interest. To address our second point, we suggest this question be replaced with the following: "From what you know, which is generally healthier for an infant: Breastfeeding, formula feeding, both are about the same." In this case, "best" is defined as "healthiest." As written, this question introduces bias because mothers know they are supposed to answer that breastfeeding is best.

D. Question 31: Think about all of the different places you have seen, heard or read about breastfeeding and about infant formula recently, including all of the different kinds of advertising, publicity, and other activities that talk about it. Please mark whether you have recently seen, heard, or read anything about breastfeeding and about infant formula from the places listed in the chart below.

IFC Comment: It is our experience that new mothers are notoriously poor at remembering where advertising has been seen. We suggest all advertising responses be collapsed into a single response (e.g., TV, magazine, newspaper or radio advertising).

E. Question 32: How strongly do you agree or disagree with the following statements?

IFC Comment: As written, this question only asks how strongly the mother agrees with the statement. It does not specify what “less” means, and it does not specify what “good” means. Asking, “how strongly do you agree or disagree” does not differentiate emotional commitment from understanding of scientific relationships. We believe it may be useful to differentiate between these reasons for the mother’s response in order to refine existing educational campaigns.

F. Question 34: Thinking about the advertisement for breastfeeding, please mark whether you agree or disagree with each of the following statements.

IFC Comment: We believe this question should be deleted. In our experience, adjective checklists of this type are typically administered immediately after exposure to an ad. This list of adjectives is not appropriate when respondents must recall how they felt about an ad that was seen some time in the past. If, after the Agency considers this comment, they do not agree to delete this question we strongly recommend a bipolar scale, with strong negatives and strong positives, be provided for respondents to circle instead of the largely positive to neutral adjectives that already have been provided. Suggested negative responses include: (1) It made me angry, (2) It was degrading, (3) I didn’t understand how the visuals related to the message, (4) It gave me a message I couldn’t act on, (5) I didn’t believe the message. Further, we believe these same types of negative responses should be included each time questions about the breastfeeding awareness campaign are asked throughout the survey. We would also recommend asking question 35 before question 34.

Please note these comments also apply to questions 36 – 38.

G. Question 40: About how many of your friends and relatives have breastfed their baby?

IFC Comment: We recommend adding the provision for “having friends and relatives” who had babies but did not breastfeed any of them. As an alternative, we recommend adding similar questions about formula feeding; otherwise the concentration on breastfeeding could introduce respondent bias, leading the respondent to answer according to expectation. Further, we suggest adding “if

any” after “about how many” to ensure that the response “none” is not underreported.

H. Question 49: How old do you think your baby will be when you first feed him or her formula or any other food besides breast milk?

IFC Comment: A fairly minor, but unnecessary, change was made to this question from the 1993 survey (original question 47). “Never” was added to the original response list, which makes no sense insofar as all children, at some point in time, will be fed something besides breastmilk. The case for late feeding is well covered by “more than 9 months.” Thus, we suggest, “Never” be replaced with “Don’t know.”

I. Questions 51 – 52

IFC Comment: We believe these questions should be deleted from all questionnaires and modules in which they appear. They are a repeated measure (i.e., asked in various other questionnaires and points in time). Further, these questions invite mothers to speculate on when they will stop breastfeeding and their ability to do what they say (via a “confidence” scale). Sensitizing mothers to this issue prenatally can bias their behavior postnatally. Similarly, repeatedly asking it postnatally could also bias continued behavior.

II. Birth Screener

A. Question 6: Did (the mother/you) have any medical problems that prevented (her/you) from feeding the baby for more than a week?

IFC Comment: It is unclear whether feeding pertains only to breastfeeding or any other feeding; thus, this question needs to be clarified.

III. Neonatal Questionnaire

A. Question 11: In your opinion, which statement best describes your doctor or health professional’s attitude about feeding your baby, and the attitude of the staff in the hospital, clinic, or birth center where you delivered?

IFC Comment: We believe unnecessary complexity has been added to the 1993 question directed at determining influences on hospital feeding to the point where it risks interfering with comprehension. We suggest the influences be simplified to OB/GYN, pediatrician, doctor on staff at hospital, other staff at hospital, and the responses be simplified to breastfeed only, formula feed only, breastfeed and formula feed, or no opinion/did not discuss. A simpler alternative to this question is to ask, “Did any medical professionals or staff at the hospital, including doctors, nurses or other hospital workers, give you advice or opinions on how to feed your baby in the hospital.” Subsequently, those that answer affirmatively would be asked, “Check all the ways you were given advice or opinions in the hospital about how to feed your baby in the hospital,” with responses limited to

breastfeed only, formula feed only, both formula feed and breastfeed. We recognize that details regarding specific information providers in the hospital will be lost, but the overall pattern of what feeding direction was obtained in the hospital will be preserved in a simple way.

B. Question 12: What do you think is the recommended number of months to exclusively breastfeed a baby, meaning the baby is only fed breast milk?

IFC Comment: We believe this question should be reworded to ask if the mother received any recommendations about how long to exclusively breastfeed the baby (e.g., wait before introducing formula and if so, what was that recommendation). The question currently leads mothers to assume that there are a recommended number of months and invites them to guess what it is. Further, the question requires a point of view be developed on the definition of “exclusive” (e.g., not feed formula or not feed anything except breastmilk, including solids).

C. Question 14: What were the reasons you decided not to breastfeed your baby?

IFC Comment: We note there is no response for the mother who made a choice not to breastfeed for personal preference or who thought breastfeeding was inconvenient in some way other than those specifically expressed in the answer grid. Thus, we suggest adding two additional responses, “Just preferred not to,” and “ Other, Specify _____.” We also suggest changing “Had to go back to work/school” to something less judgmental such as “Planned to go back to work/school.” Further, as written, this question fails to score the responses according to importance; thus, we would suggest the respondent subsequently be asked to identify the three most important reasons.

D. Question 29: How long was it until you became emotionally comfortable nursing your baby?

IFC Comment: We believe “Emotionally comfortable” is a vague term, and responses will be difficult to interpret. There is little value in perpetuating this ambiguity; thus, we recommended the question be deleted unless the Agency clarifies its intentions regarding this question so the language can be modified accordingly.

E. Question 32: Did you get any help with these problems from a doctor or other health professional, a lactation consultant, or a breastfeeding support group?

IFC Comment: A fairly minor, but unnecessary, change was made to this question from the 1993 survey (original question 20). “Ask for help” was changed to “get help.” We believe the original wording should be retained because it establishes that there was a recognized need for help.

F. Question 35: Using 0 to mean “No pain at all” and 10 to mean “The worst pain you have ever felt,” how much pain, if any, were you in when you were breastfeeding during the following time periods.

IFC Comment: It is debatable whether a scale of “No pain” to “The worst pain you ever felt” is applicable to breastfeeding and risks trivializing the issue. It is also debatable whether mothers can accurately recall and differentiate the pain level over 4 short and successive periods of time. Thus, we suggest dividing this question into two questions. We recommend initially asking the mother to rate the pain, the first time they breastfed as very severe, moderately severe, not very severe or no pain at all. Subsequently, we recommend asking the mother whether the pain, if present, became less severe over time (response options being yes/no/stopped breastfeeding after first attempt).

G. Questions 37-40

IFC Comment: We believe these questions should be modified to reflect the possibility that mothers may receive more than one gift pack or sample of formula in the mail.

H. Question 53: When you first began buying formula, how did you decide which brand of formula to buy for your baby?

IFC Comment: One statement was added (i.e., Chose a brand advertised as better for my baby’s development) to the original question from the 1993 survey (original question 48). We find the added statement to be leading because consumers are not likely to distinguish between “advertising” and other forms of information about brand benefits. This statement is also vague because being “better for my baby’s development” could apply to almost any brand.

I. Question 54: Did you discuss your choice of formula brand with the baby’s doctor?

IFC Comment: It is unclear which formula choice this refers to. The question should specify whether it is the choice of a first formula brand or any formula brand. Also, it should be noted that the previous questions refer to a brand that is purchased, but this question (“brand choice”) does not specify and could be interpreted to apply to trial of free samples.

J. Questions 54 – 55

IFC Comment: We believe these questions should specify “brand of formula,” not “choice of formula” so that it is not confused with form of formula (e.g., powder, liquid, etc).

K. Question 64: What kind of problem(s) have you had?

IFC Comment: While it is admirable to capture the range of problems that breastfeeding mothers face, in this case it has caused the number of possible

responses to double compared to the 1993 version (original question 59). This complicates the question, which, along with the addition of complex new questions, drives the questionnaire to an unacceptable length.

L. Questions 68 – 69

IFC Comment: See IFC Comment on Questions 51-51 of the Prenatal Questionnaire.

M. Question 70: How often do you have the feelings described in the following statements?

IFC Comment: We believe it would be appropriate to reword this question to read, "Mothers have told us about some concerns they have with breastfeeding. How much of a concern is each of the following to you, personally?" The list of concerns would include (1) finding information you want on breastfeeding, (2) the amount of time breastfeeding takes, (3) whether the baby is getting enough breastmilk at each feeding, (4) pain or discomfort while breastfeeding, (5) breastfeeding in front of other people, and (6) your family's attitude toward breastfeeding. The scale for each concern would be "very concerned, somewhat concerned, not concerned."

IV. Module A

A. Question 24: During the past two weeks, how often has your baby been put to bed with a bottle of formula, juice, juice drink, or milk of any kind?

IFC Comment: This question attempts to combine two issues – how often and on what occasions babies are put to sleep with a bottle; thus, we believe it would be preferable to divide this question into two parts to minimize the risk of overstating the situation. As recommended, we suggest the respondent first be asked, "How often, if ever, has your baby been put to bed with a bottle of liquids?" The respondent would be asked to fill in a number or zero, if never. Subsequently, those who fill in a number would be asked whether their baby was put to bed with a bottle of liquids at bedtime, nap time or both.

B. Question 25: Did your baby have any of the following illnesses or problems during the past two weeks?

IFC Comment: We believe it would most helpful to the respondents to define the term "food allergy." Further, it is questionable whether respondents would recognize the term "Eczema (atopic dermatitis)" and differentiate it from "Other skin rash"; thus we recommend the term "Other skin rash" be better defined.

V. Module B

A. Question 5: How important was each of the following reasons for your decision to stop breastfeeding your baby?

IFC Comment: It appears the response grid has been lengthened quite substantially and we find it to be unnecessarily redundant and excessive. Responses located at the end of this response grid will probably be understated. For example, responses w and gg are identical. We recommend responses that are very similar (e.g., m/n, s/t, y/z/aa, g/h/i/j, c/d, bb/cc/dd) be consolidated.

B. Question 6: Did any of the following people want you to stop breastfeeding?

IFC Comment: We find this question to be unnecessarily complicated and will likely cause difficulty. Further, we believe respondents may feel uncomfortable singling out their employer or supervisor. We suggest dividing this question into two. First, we believe the respondent should be asked whether anyone said you should stop breastfeeding (from 1993 IFPS). For those who respond “yes,” next an abbreviated checklist of people (e.g., doctor or other healthcare professional, relative (specify), friend, someone at your workplace, other person else) should be provided.

C. Question 9: How likely is it that you would breastfeed again if you had another child, using 1 to mean “Not at all likely” and 5 to mean “Very likely.”

IFC Comment: This question asks mothers to speculate on factors that may be out of their control in the future. We believe it would be a better measure of attitude to ask mothers how interested they would be in breastfeeding their next baby.

VI. Module C

A. Question 3: What brand of formula did your baby have the problem with or react to?

IFC Comment: See IFC General Comment regarding deleting all questions that ask respondents to identify brands of formula. We believe the current wording unnecessarily perpetuates the widely held misconception that formula causes intolerance symptoms, which technically is rare. If there is formula intolerance, it would be more likely to be related to the type (e.g., milk-based, soy-based, specialty) than to the brand. If it is absolutely necessary to include the brand, the 1993 version of this question is preferable, which states, “What brand of formula were you using when allergy or intolerance developed.” This form of the question does not imply cause and effect.

B. Question 4: Is there an infant formula your baby was given and did not have a reaction to?

IFC Comment: See IFC General Comment regarding asking respondents to identify brands of formula and IFC Comment to Question 3 of Module C. We suggest this question be reworded as “What other types of infant formula have you used.” Alternatively mothers could be asked, “What form of formula were you using when the baby did not experience any symptoms of allergy or intolerance.”

C. Questions 5 – 6

IFC Comment: The identification of specific brands is not necessary to answer or interpret these questions and should be dropped. Respondents can just be told to think about the first brand they used when allergy or intolerance developed when answering the question, without specifically listing it.

D. Question 8: Were the symptoms diagnosed as a food allergy by a doctor or other health professional?

IFC Comment: We believe the wording of this question tends to lead respondents. It is unknown exactly what diagnosis the doctor made versus how it is interpreted by the parent, since symptoms are more likely to have been due to unspecific “intolerance” than specifically to “food allergy”. More specifically, we believe the risk is that the wording of the question will encourage respondents to interpret whatever the doctor told them as “food allergy”. Thus, we recommend the Agency elaborate on the definition of allergy: “Did the doctor or health care professional diagnose the symptoms as an allergy, or something else such as intolerance? A. For problem with infant formula? B. For problem with other food?” Answer grid: “allergy, intolerance/other diagnosis, don’t remember, not applicable”. Another alternative would be to delete the question entirely, on the grounds that consumers will have difficulty recalling nuances in the diagnosis and that the information is redundant with that captured by other questions in the module. Further, another option would be to delete any reference to the term “food allergy” in Question 8 in order to capture the broadest spectrum of those who sought a medical opinion.

E. Question 9: What method did the doctor use to diagnose the food allergy?

IFC Comment: We note the instruction before Question 9 and to Question 9 should be modified to change the phrase “food allergy” to “allergy.” The term “food” may or may not have been included in the doctor’s diagnosis of the allergy, so to include it here (or in Question 8) may lead to under-reporting.

VII. Module D

A. Questions 2 – 3

IFC Comment: See IFC Comment to Questions 51 – 52 of the Prenatal Questionnaire.

B. Question 4: Where have you obtained information about breastfeeding and where have you obtained information about breast pumps for this baby or other babies?

IFC Comment: We recommend columns b and d be deleted since recollection on sources of information for specific topics with previous children is likely to be poor. If desired, “obtained information with previous baby” could be added to the response list. However, we also find the list to be much too long, risking understatement of items at the end. Alternatively, we would suggest combining all references to book or video, support hotline and support group, and create another question to address the three website responses (e.g., “Which, if any, of the following websites have you visited specifically for information on breastfeeding or breast pumps?”).

C. Question 16: How important were each of the following reasons for feeding your baby formula?

IFC Comment: It is unclear why this answer grid is inconsistent with similar questions related to using formula or discontinuing breastfeeding other modules (such as Module B, Question 5). We believe these types of questions should be designed consistently; including the resolution of problems identified with length and redundancy in Question 5 of Module B. We suggest the response list include advertisements for infant formula including other media like direct mail, internet, physician brochures, as well as infant formula labels as a possible reason the mother feeds her baby formula.

D. Questions 30 – 31

IFC Comment: We believe it would be more preferable to ask, “What are all the ways you cleaned the bottle nipples in the last seven days, and “Which ONE way did you clean them most often” (repeating for breastmilk pump equipment generally, not each piece of the pump separately).

E. Question 46: Have you been hurt by any breast pump that you used or tried to use to express milk *since this baby was born*?

IFC Comment: This is the first question in a series designed to identify respondents who had some negative physical experience with a breastmilk pump. The experience is defined as “hurt”, which is we find to be vague. Those who had discomfort but not injury can qualify at Question 50, but it is unclear why this distinction has been made.

VIII. Module E

A. Question 2: Formula packages have directions for preparing the formula and three kinds of storage information, how to store the package after opening it, how to store formula after you have prepared it, and what to do with formula left over in the bottle after feeding your baby. In the chart, please mark: a) How easy to understand the different kinds of information were, b) Whether all the information you needed was included, and c) Whether the print size was large enough to read easily.

IFC Comment: We find this question to be complicated and believe it will invite confusion and inconsistency. First, we believe it must be established whether respondents have ever looked at the four kinds of information mentioned in the question (preparation, store package, formula and leftover bottle). If they have not, they are not qualified to comment. Second, we believe it is doubtful that even those who have looked at the label in detail are going to make distinctions between the different pieces of information in terms of ease, completeness and print size.

We suggest replacing this question with three separate questions regarding the label on the formula package they are currently using (unspecified): (1) Is there anything on the label that is hard to understand (if so, specify what), (2) Is there any information you wanted that was missing (if so, specify what), and (3) Is there any part of the label that you tried to look at but had difficulty finding or reading because the print size was too small (if so, specify what).

We also believe it would be appropriate to add a question regarding mother's perception or understanding of how important it is to follow the label directions to feed, refrigerate or discard the formula within a very short period of time, for safety reasons.

B. Question 3: In addition to written directions, packages of infant formula also have pictures showing how to prepare the formula. How useful did you find the pictures?

IFC Comment: See IFC Comment to Question 2 of Module E. We believe it must first be established whether respondents have ever looked at the pictures showing how to prepare the formula.

C. Question 7: In the table below, please write in what ingredient you were looking for and check whether you wanted to avoid the ingredient or include it in your baby's diet.

IFC Comment: Based on our experience, consumers will not be able to recall what, specifically, they look for (since most cannot articulate why they look at the ingredient list or what they are looking for). At most, they might be asked what ingredient(s), if any, they were most concerned about when they decided to look at or check the label – the corresponding answers being “none/no particular ingredient,” specific ingredient (specify _____),” and “don't remember.”

D. Question 13: During the last seven days, how often were the bottle nipples used to feed formula clean in the following ways?

IFC Comment: We suggest this question be simplified by revising it to read, “In the past seven days, how did you usually clean the bottle nipples (select one response from list).”

E. Question 14: Before preparing formula, do you usually rinse your hands with water, wipe them, wash them with soap, or do you usually prepare formula without cleaning your hands?

IFC Comment: To help respondents feel comfortable choosing a “socially incorrect” response, it may help to modify the question with a lead-in acknowledging that mothers are always on the go and may not always have ideal conditions in which to prepare formula.

F. Question 20: For what reasons did you decide to use the brand of formula you are feeding your baby now.

IFC Comment: Those respondents who have switched brands are directed to Question 19 instead of 20 only if the switch took place in the past 2 weeks. However, respondents who switched brands more than 2 weeks earlier will answer Question 20, which contains no reasons for formula use related to digestibility or tolerance. We believe the response list for Question 20 needs to be amended to account for these reasons for use. Alternatively, the timeframe in which the mother “switched the brand of formula” in Question 16 needs to be extended to any period of time (in which case Question 19 would reflect reasons for more than one switch).

IX. Module F

A. Question 1: Whether or not you take herbal or botanical preparations, please mark which of the following people and places you have gotten information about herbs, botanicals, or other dietary supplements.

IFC Comment: We recommended this question be moved to the end of this module, since it is not directly related to babies or infant feeding. Moreover, we believe it suffers from an unnecessarily detailed and long response list and does not first establish whether the respondent has, in fact, ever sought information about herbs, botanicals or other dietary supplements.

B. Questions 2 – 3

IFC Comment: See IFC Comment at Question 4 of Module D. We believe it would be difficult for mothers to remember where they got information with previous children, and they will have difficulty deciding how to answer if they got information from a source with some previous children but not others. It is recommended to delete the column, “Yes, another baby.” In addition, the response lists should be consolidated and shortened, consistent with recommendations for previous questions (i.e., aggregate advertising sources

since respondents cannot usually remember where advertising was seen, aggregate different kinds of relatives, address use of specific websites in a separate question).

X. Module G

All of the questions in Module G repeat portions of the Prenatal Questionnaire and others. It is unclear how useful the questions will be since none of them determines that the specific Breastfeeding Awareness Campaign has been seen, or that the campaign is responsible for any of the attitudes that are measured.

A. Question 1: Think about all of the different places you have seen, heard or read about breastfeeding and about infant formula recently, including all of the different kinds of advertising, publicity, and other activities that talk about it. Please mark whether you have recently seen, heard, or read anything about breastfeeding and about infant formula from the places listed in the chart below.

IFC Comment: See IFC Comment to Question 31 of Prenatal Questionnaire.

B. Question 2: Which of the following statements is closest to your opinion? The best way to feed a baby is: Breastfeeding; Formula Feeding; A mix of both breastfeeding and formula feeding; Breastfeeding and formula feeding are equally good ways to feed a baby.

IFC Comment: Question 2 duplicates Question 28 in the Prenatal Questionnaire. We note there is no reference to time frame (i.e., age of baby), so a mother cannot answer differently depending on whether the baby is older or younger. The implication is that one answer (presumably breastfeeding) is correct at any age.

C. Question 3: How strongly do you agree or disagree with the following statements?

IFC Comment: See IFC Comment to Question 32 of Prenatal Questionnaire.

XI. Module H

A. Question 10: Using 1 to mean “Not at all supportive” and 5 to mean “Very supportive,” how supportive of breastfeeding is your place of employment.

IFC Comment: See IFC Comment to Question 20 of Prenatal Questionnaire.

B. Question 13: Does your place of employment: (Please answer this question whether or not you are breastfeeding)

IFC Comment: We suggest this list express the term “you” rather than “pregnant women and new mothers”. This would not require the respondent to speculate

on who is or is not covered by the service and can simplify the responses to a yes/no format.

C. Question 17: Have you had any of the following experiences while breastfeeding and working?

IFC Comment: We believe this series of questions related to breastfeeding obstacles at work covers very sensitive material that may have legal implications to the extent that respondents are invited to record real or imagined improper actions by supervisors or coworkers and threats to their job security. We believe a more appropriate alternative would be to ask the mother to rate whether or not breastfeeding at work has affected each of the following: Ability to perform your job, type of job or assignments you are given, other employees' opinions of you, courteous treatment by other employees, etc.

Conclusion

The International Formula Council appreciates the opportunity to comment on this proposed voluntary consumer survey. If FDA has any questions or requires clarification of any aspects of this document, it should feel free to contact Rachel Spector.

Respectfully submitted,

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Docket Management Comment Form

Docket: 2004N-0166 - Agency Information Collection Activities; Proposed Collection; Comment Request; Infant Feeding Practices Study II
Temporary Comment Number: 3161

Submitter:	Dr. Rachel Spector	Date:	06/21/04
Organization:	International Formula Council		
Category:	Association		
Issue Areas/Comments			
General			
Attachments			
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