Survey of Food Safety and Nutrition Information Provided to Pregnant Woman by Health Care Providers and WIC Educators (HCP survey)

Responses to OMB Comments of June 11, 2007

This memorandum is being sent with the following attachments: an updated version of the questionnaire, the cognitive interview guide script, and a revised supporting statement displaying changes in yellow highlight.

Supporting Statement

- With regard to hypotheses to be tested, sample size justification, and expected response rate for the survey.

  Response: *We have listed the research questions and the measures to be used to explore those questions in the supporting statement. Justification of adequate sample sizes has been placed in context of these research questions. The additional text is shown in yellow highlight in the supporting statement (see sections A.2. and B.2).*

  The following discussion of anticipated response rate for the survey appears in Section B.2.:

  The anticipated response rate for the survey is approximately 45%. This estimate is based on past FDA experience with mail surveys of physicians. The Center for Drug Evaluation and Research (CDER) at FDA recently conducted a study on the effect of incentives on physician participation in a survey of direct-to-consumer drug advertising. In this study, each physician was randomly assigned to receive an incentive of $50, $75, or $100 for their participation. An incentive of $75 resulted in a response rate ranging between 42% and 47%, depending on the inclusion of a letter of endorsement from the American Medical Association. The proposed survey will employ both an incentive and a letter of endorsement. The response rate may differ between the various groups, but FDA believes that the anticipated response rate of 45% for all groups is a conservative estimate. The response rate for the data collection will be calculated based on the American Association for Public Opinion Research (AAPOR) Response Rate 3.

- Provide cognitive interview and pretest protocol.

  Response: *Cognitive interview respondents were recruited by Synovate. Interviews were conducted by phone. Participants were asked to read each question aloud and tell us how they would answer. An FDA interviewer asked follow-up questions relevant to the response or pattern of responses. A sample of the guide script used for follow-up questioning is attached. Note that this was an iterative document, i.e., with each interview, modifications were made to the questionnaire and the guide.*

The pre-test will use the same questionnaire, sample and methods as planned for the study. The pre-test will test the sampling, mailing, and data capture procedures. The following text has been amended in the supporting statement, Section B.4.:

A pretest that includes 15 completed surveys with each of the sampled populations will be completed. This pretest study will allow us to test the mechanism for sending out surveys, receiving completed surveys and recording the data. The pretest data will be reviewed prior to conducting the full survey. The primary focus of the pretest will be to determine (1) the ease with which physicians receive survey materials, as in many cases a gatekeeper, e.g., receptionist, and not the physician, may receive the mailing materials; (2) the effectiveness of telephone calls prior to the mail-out in eliciting a completed survey; and (3) the effectiveness of the incentive in eliciting a completed response.

Questionnaire Design

- Q1: Did FDA consider using an average work week rather than a day? One day seems unnecessarily limiting.

  Response: *FDA considered other time frames for this question. Ultimately, FDA decided that the most likely purveyors of advice concerning food safety and/or nutrition to pregnant women would be those health care providers and WIC educators who have both regular and frequent contact with their pregnant patients and clients.*

- Q2: Why skip section B if the respondent answers no? If the answer is "no, I recommend that they avoid eating fish," wouldn't FDA want to know if it is because of concern about mercury?

  Response: *The respondent is not instructed to "skip section B" if the response is no to Q2. The respondent that selects either of the "no" responses is instructed to "Go to Section B", thereby skipping one question (Q3) concerning the number of servings they recommend consuming per week.*

- Q5: In asking about mercury, wouldn't it be better to ask how often practitioners provided advisories, rather than whether they did?

  Response*: In crafting this question, FDA did consider asking "how often" rather than "how likely" they provide advice. However, it became clear during conversations with health care providers that this type of advice is typically given once, if at all, to any single patient. Thus the question is worded in such a way to capture the proportion of patients to which the providers give this type of advice.*

Cognitive interviews reveal that respondents have no difficulty answering this question and that they interpret it as intended.

- Q7: What is the rationale for this question? How will the information be used?

  ***Response**: FDA included this question in order to ascertain if health care providers may be over-emphasizing the risks of methyl mercury in fish relative to other food risks during pregnancy. FDA has revised the question to clarify the intent by prefacing the question with the phrase, "Relative to other food-related risks to pregnant women…" Please refer to Section B.2. of the supporting statement for further details about how this question will be used in the analysis.*

- Q8: Did FDA consider grouping by food types for this question? For example, FDA could ask a set of questions about fish, ask another set about meat/milk and ask another set about fruits/veggies? What about throwing in something that's not a particularly risky product (e.g., peanut butter?)

  ***Response**: FDA did not consider grouping by food type due to the potential for response bias. By grouping the pieces of advice, health care providers may be prone to responding similarly to each item related to a particular food group. For example, health care providers that detect a grouping of seafood items may be more inclined to rate all seafood items the same value, such as a "3". FDA believes that by interspersing the various seafood items throughout the list of items will elicit greater thought on the part of the respondent in giving a rating for each individual item.*

  FDA does not feel it is appropriate to include foods for which the FDA does not provide advice for pregnant women. In light of the recent ConAgra recall, the inclusion of peanut butter could cause confusion in respondents. In addition, FDA does not believe that it is necessary to include some other minimally risky food as a means of testing the accuracy of responses. Experience with respondents during cognitive interviews reveals that health professionals are highly likely to select responses that are reflective of their practices

- Q8: Also, did FDA consider asking about how often practitioners advised pregnant women on the types of food listed, rather than asking about whether the likelihood of advising?

  ***Response**: As described in the response concerning Q5 above, FDA did consider asking "how often" rather than "how likely" they provide advice. However, it became clear during conversations with health care providers that this type of advice is typically given once, if at all, to any single patient. Thus the question is worded in such a way to capture the proportion of patients to which the providers give this type of advice. Cognitive interviews reveal that respondents have no difficulty answering this question and that they interpret it as intended.*

- Q13: Similar to Q8 above. Did FDA consider framing the question differently to ask about how often practitioners provided information to their patients/clients? It seems that it might better get to actual practices, as opposed to values (what they do vs what they think they should do.)

  ***Response**: Each statement represents an attitude or belief with which the provider may agree or disagree. A respondent may agree with all of the statements, however, allowing the respondent to rate the level of agreement permits the respondent to give an indication of which are the more relevant reasons for not providing this type of advice.*

- Q18: What is the relevance of the respondent's gender?

  ***Response**: Demographics may play a role in whether providers provide food safety advice. If this is true, then FDA believes that the demographic variables of interest are gender, age, and region of the provider. Gender and age may influence the types of information the providers give to their patients, the amount of time they spend with their patients, and the sources of information on which they rely to learn about food risks. Please note that a question about age has been added to the questionnaire.*