Supporting Statement

Survey of Food Safety and Nutrition Information Provided to Pregnant Women by Health Care Providers and WIC Educators

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Potential Participant Universe

The sample universe for this study is practicing health care providers from four separate professions and WIC educators. The four health care provider professions are OB/GYNs, nurse practitioners, nurse midwives, physician assistants. The sample will include only those who, at the time of data collection, provide their services to pregnant women.

The respondents for each health care provider profession will be randomly selected from the best available national lists. The lists for OB/GYNs, nurse practitioners, nurse midwives, and physician assistants will be purchased from Medical Marketing Services, a company that specializes in maintaining these lists.

The sample of OB/GYNs will be randomly drawn from the 31,100 practicing, office-based OB/GYNs listed in the American Medical Association's Physician Masterfile. This file includes all physicians practicing at least part time in the United States. Office-based OB/GYNs excludes those in teaching, administration, research, or a hospital setting. This technique for sampling physicians was used in the 2002 FDA national telephone survey "*Assessment of Physician Attitudes Toward Direct-to-Consumer (DTC) Promotion of Prescription Drugs*."

The sample of nurse practitioners will be drawn from a list derived from state registries, surveys, and conventions. The sample will include only the 7,790 specializing in obstetrics/gynecology.

The sample of nurse midwives will be drawn from the membership list of the American College of Nurse Midwives. This list includes 9,370 Certified Nurse Midwives (CNMs). CNMs are registered nurses who have received supplemental education and national certification in maternity and women's health care.

The sample of physicians' assistants will be drawn from the 900 members and non-members of the American Academy of Physician Assistants specializing in obstetrics/gynecology.

There is no comprehensive, national list of WIC educators. However, the USDA maintains a listing of the approximately 2,200 WIC agencies serving the United States, categorized by region and state. The sampling frame is the list of USDA WIC Clinic and Agencies. Table 1 shows the distribution of agencies and clinics across states and territories. The six agencies in Puerto Rico, U.S. Virgin Island, Guam, American Samoa

and the Marshall Island Protectorate will be excluded from the sampling frame. The sampling frame will include the District of Columbia.

Table 1: Distribution of Agencies

State	Number of Agencies	State	Number of Agencies	State	Number of Agencies	State	Number of Agencies
AK	18	IA	20	MS	126	PR	1
AL	100	ID	9	MT	80	RI	12
AR	102	IL	99	NC	87	SC	15
AS	1	IN	53	ND	29	SD	68
AZ	33	KS	42	NE	17	TN	14
CA	82	KY	58	NH	9	TX	77
CO	41	LA	111	NJ	18	UT	14
CT	17	MA	36	NM	14	VA	35
DC	4	MD	19	NV	15	VI	2
DE	3	ME	11	NY	103	VT	12
FL	42	MI	49	OH	75	WA	65
GA	20	MN	86	OK	26	WI	71
GU	1	MO	119	OR	47	WV	8
HI	16	MP	1	PA	24	WY	21
56	States	2278	Agencies				

B2. Procedures for the Collection of Information

B2.1 Statistical methodology for sampling and information collection

B.2.1.1 *Sampling methodology*

The target sample sizes are 400 OB/GYNs, 200 nurse practitioners, 200 nurse midwives, 200 physician assistants, and 200 WIC educators. The sample will include only those who, at the time of data collection, provide their services to pregnant women.

Simple random sampling will be used to draw the samples of OB/GYNs, nurse practitioners, nurse midwives, and physician assistants. The sampling plan for WIC educators will consist of a stratified two-stage sampling plan. The sampling plan consists of the following steps.

1. Create seven (7) strata consisting of :
   - New York City
   - Los Angeles County
   - Large metropolitan areas
   - East region
   - South region
   - Midwest region
   - West region
2. Select agencies within strata at random (Stage 1 selection) according to a set plan.

3. Contact up to 50 agencies and obtain a list of WIC educators associated with the agency.
4. Randomly select a simple random sample and interview up to 4 educators per agency (Stage 2 selection).

The sampling plan calls for seven strata. Stratum 1 is the New York City stratum, it will consist of the 5 counties/ boroughs of New York City. They are listed in Table 3.

Table 3: Strata 1 Definition -- New York City

County	Borough
Bronx County	Bronx
Kings County	Brooklyn
New York County	Manhattan
Queens County	Queens
Richmond County	Staten Island

Stratum 2 is the Los Angeles(LA) County, California stratum. Using the listing of towns and cities in Table 4, we assign the WIC agencies to LA County and Stratum 2.

Table 4: Comprising Towns and Cities of Los Angeles County in Stratum 2

Acton	Diamond Bar	Lancaster	Pacific Palisades	Sherman Oaks	Valyermo
Agoura Hills	Downey	Lawndale	Pacoima	Sierra Madre	Van Nuys
Alhambra	Duarte	Littlerock	Palmdale	Santa Clarita	Venice
Altadena	El Monte	Llano	Palos Verdes Peninsu	Santa Fe Springs	Walnut
Arcadia	El Segundo	Lomita	Panorama City	Signal Hill	West Covina
Artesia	Encino	Long Beach	Paramount	South El Monte	West Hollywood
Avalon	Gardena	Los Angeles	Pasadena	South Gate	Whittier
Azusa	Glendale	Lynwood	Pearblossom	South Pasadena	Wilmington
Baldwin Park	Glendora	Malibu	Pico Rivera	Stevenson Ranch	Winnetka
Bell	Granada Hills	Manhattan Beach	Playa del Rey	Studio City	Woodland Hills
Bellflower	Hacienda Heights	Marina del Rey	Pomona	Sun Valley	
Beverly Hills	Harbor City	Maywood	Rancho Palos Verdes	Sunland	
Burbank	Hawaiian Gardens	Mission Hills	Redondo Beach	Sylmar	
Calabasas	Hawthorne	Monrovia	Reseda	Tarzana	
Canoga Park	Hermosa Beach	Montebello	Rosemead	Temple City	
Canyon Country	Huntington Park	Monterey Park	Rowland Heights	Topanga	
Carson	Inglewood	Montrose	San Dimas	Torrance	
Castaic	La Canada Flintridge	Newhall	San Fernando	Tujunga	
Cerritos	La Crescenta	North Hills	San Gabriel	Valencia	
Chatsworth	La Mirada	North Hollywood	San Marino	Valley Village	
Claremont	La Puente	Northridge	San Pedro		
Compton	La Verne	Norwalk	Santa Monica		
Covina	Lake Hughes				
Culver City	Lakewood				

Stratum 3 consists of the next larger urban centers. Table 4 shows the population counts for the top 11 urban areas and their residing counties.

Table 5: Larger Population Centers in Stratum 4
Next 11 Largest Cities

City			County containing city	
Name		**Population**	**Name**	**Population**
Chicago	IL	2,898,832	Cook	5,434,520
Houston	TX	2,878,171	Harris	3,914,022
Miami	FL	1,707,960	Miami-Dade	2,464,452
Philadelphia	PA	1,472,400	Philadelphia	1,472,400
San Antonio	TX	1,471,612	San Antonio	1,682,384
Phoenix	AZ	1,390,965	Maricopa	3,755,138
Dallas	TX	1,335,841	Dallas	2,405,581
Las Vegas	NV	1,327,959	Clark	1,843,150
San Diego	CA	1,245,511	San Diego	3,067,890
Minneapolis	MN	1,027,182	Hennepin	1,154,420
Detroit	MI	858,260	Wayne	2,028,599

The remaining 4 strata are based on the WIC regions (Table 1). The East stratum consists of the Northeast and Mid-Atlantic WIC regions, the South stratum consists of the Southeast and Southwest WIC regions, the Midwest stratum consists of the Midwest and Mountain WIC regions and the West stratum is the same as the WIC West Region.

In the first stage of sampling, 50 agencies with complete lists of WIC educators will be selected. Table 5 provides the division of the sample frame across the 7 strata. Given that Los Angeles County has only 5 agencies serving a very large community and Los Angeles only has 1 agency, the table is deceptive in representing the number of WIC participants and WIC agency work load. Table 5 also presents the distribution of the sample across the strata. The sample is the number of agencies from which FDA will obtain lists of WIC educators. The agencies will be selected at random with equal probability from within each stratum. Non-cooperating agencies will be substituted with other agencies selected at random from the same stratum.

Table 5: Distribution of WIC Agencies and the Sample Across Strata

Strata	Definition	WIC Agencies		Sample
1	New York	48	2.11	6
2	Los Angeles County	5	0.22	3
3	Top 10 Cities	41	1.80	6
4	East (NE & MA)	262	11.53	6
5	South (SE & SW)	780	34.33	16
6	Midwest (MW & MP)	869	38.26	17
7	West (WR)	267	11.75	6
	Total	2,272	100.00	60

In the second stage of sampling, a fixed sample of WIC educators will be selected from each agency list. This number should be between 3 and 4. The total sample is to be 200 WIC educators. The total number of WIC educators will be recorded for each agency. The stage 2 probability of selection is

$$p_i^{(2)} = n_a / N_a ,$$

where n_a is the number of WIC educators selected and interviewed in agency a, and N_a is the total number of WIC educators in agency a. The probability of selection for stage 1 is

$$p_h^{(1)} = m_h / M_h ,$$

where m_h is the number of agencies selected in stratum h, and M_h is the total number of agencies in stratum h. The design weight for the sample is the inverse of the overall probability of selection. The weight is

$$w_{i \in h} = 1 / p_h^{(1)} * p_i^{(2)} .$$

The design weights reflect the probability of selection, but they do not necessarily adjust for the sizes of the strata. As stated earlier, the number of agencies does not necessarily reflect the work loads within a state, county or other local geography. FDA will use the number of WIC recipients in each stratum to provide relative weighting for national estimates.

Seven strata will be created for the sampling plan: New York City; Los Angeles County; a stratum composed of the next eleven largest metropolitan areas based on the July 2005 Census estimates; and four strata for the remaining portions of the regional groups used by the USDA to list WIC agencies. The strata were selected to overcome potential problems that could occur due to considerable heterogeneity in the size of WIC agencies across the country. For example, among the 13 largest cities, Los Angeles, Philadelphia, and Jacksonville have only one WIC agency each, while New York City has 48. In some areas, one educator may be the sole provider for multiple agencies. As such, stratification will be necessary to guarantee adequate representation of WIC educators from larger cities. In any given state, there tends to be many agencies throughout the state and relatively few agencies within the largest cities. If some city strata are not created, then there would be a problem whereby WIC educators from 12 of the 13 largest cities would have small probabilities of being selected in the survey.

The proportion of WIC participants per state will be used to estimate the size of each stratum. An estimate of the percentage of WIC participants in large cities will be made using the percentage of WIC participants in the state and adjusting on the basis of the ratio of city to state population. The goal will be to give each of the seven strata a sample size that is roughly proportional to its proportion of U.S. WIC participants. The three city strata account for almost 10 percent of the U.S. population. The target sample sizes will be about 20 from the 3 city strata (5 from New York City, 4 from Los Angeles City, and 11 from the third cities stratum) and 180 from the remainder of the country.

In the first stage of sampling, 50 agencies (primary sampling units) will be selected using simple random sampling and an allocation per stratum that is roughly proportional to stratum workload. Each selected agency will then be asked to provide a list of all of its WIC educators. In the second stage, the educators (second stage sampling units) at each selected agency will be selected randomly. The first selected educator from an agency will be chosen using simple random sampling from that agency's list. Additional educators will be selected using probability proportional to remaining size

(after one educator has been selected), where size is defined as the number of WIC educators at each agency. This can be achieved by combining all of the lists from a stratum into a single list and applying simple random sampling to the remaining educators on that list. This technique will also facilitate additional sampling that may be required to adjust for non-responses.

By guaranteeing that at least one educator is contacted from each agency that provides a list, the sampling plan design will reach as many agencies as possible, given budget constraints, and obtain better national estimates as it is likely that educators within a particular agency will have similar knowledge and follow similar practices.

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.

B2.1.2. Information Collection Methodology

Each respondent will answer questions provided via a mail survey. The questionnaire will take approximately 10 minutes to complete.

Responses to various survey questions will be used as measures to explore the research questions enumerated in Section A.2 of the supporting statement. The questions used to explore each research question are listed below.

R1. To assess whether health care providers make specific recommendations about food safety or nutrition to pregnant patients and clients:

"Do you ever give your pregnant clients or patients advice about specific foods they should eat or avoid during pregnancy?"

An additional measure for this assessment will be the percentage of health care providers that respond that they are "likely" or "very likely" to provide each of the following pieces of advice:

"Do not eat shark, swordfish, king mackerel, or tilefish."
"Rinse fresh fruits and vegetables thoroughly."
"Eat up to 12 ounces (two average meals) a week of a variety of fish and shellfish that are lower in mercury."
"Do not eat soft cheeses made with unpasteurized milk."

"Do not drink unpasteurized juice."
"Eat up to six ounces (one average meal) of albacore tuna per week."
"Do not eat raw meats, like steak tartar."
"Do not eat raw fish, like sushi or ceviche."
"Do not eat raw sprouts."
"Check local advisories about the safety of fish caught by family and friends in local lakes, rivers and coastal areas."
"Do not eat raw or undercooked eggs."
"Reheat luncheon meats or hot dogs until steaming hot."
"Do not eat refrigerated pate or meat spreads."
"Do not eat refrigerated smoked seafood."

R2. To assess whether health care providers and WIC educators make specific recommendations concerning fish consumption to pregnant patients that are consistent with the FDA/EPA advisory:

"Do you ever recommend that your clients or patients eat fish during pregnancy?"
"If yes, approximately how many servings of fish per week do you recommend to your pregnant clients or patients?"
"Do you advise your clients or patients about methyl mercury and fish?"

R3. To assess whether health care providers and WIC educators are aware of the risks of methyl mercury to pregnant women from consuming fish,

"Are you aware of any advice about fish consumption and the risk of methyl mercury during pregnancy?"

R4. To assess degree to which health care providers and WIC educators view food safety and nutrition advice as their role.

Level of agreement with the following statements:

"It is my role to give nutrition advice to my clients or patients."
"It is my role to give food safety advice to my clients or patients."

R5. To determine some possible reasons why health care providers may not give food safety or nutrition advice to pregnant women,

Level of agreement with the following statements

"My clients or patients need nutrition information"
"My clients or patients need information about food related illnesses."
"I have enough time and other resources to provide information about nutrition and food related illnesses to my clients or patients."
"I have been provided enough information about nutrition and food

related illnesses to give adequate advice to my clients or patients."
"I only discuss nutrition and food safety with clients or patients that have certain health problems"
"I only discuss food safety with clients or patients that eat risky foods."

R6. To assess how health care providers receive information now and would prefer to receive information in the future concerning food safety and nutrition for pregnant women

Respondents will be asked to choose from a list of formats from which they currently receive information and rate their preferences for various formats.

R8. To assess, among OB/GYNs, whether awareness and behaviors about giving advice concerning methyl mercury and fish consumption differ between coastal and non-coastal regions, the measures to the above questions will be compared between two sub-groups of OB/GYNs.

B2.2 Degree of accuracy needed for the purpose described in the justification

FDA is interested in determining whether the various groups of health care providers and WIC educators are aware of FDA advice on mercury, how likely they are to give advice on food safety concerns for pregnant women, the reasons why, and how they get information and would prefer to get information in the future. The margin of error is +/-4.9% for the sample of OB/GYNs is and +/-6.9% for each of the other provider groups. With these sample sizes, FDA should be able to determine with reasonable amount of confidence which groups have a majority of respondents that are aware of FDA advice and are likely to pass this advice on to pregnant women.

FDA is also interested in making comparisons across groups of awareness, practices and sources of information. These variations between groups may result due to the nature of the relationship the provider has with clients or patients. FDA is also interested in determining if differences exist between sub-groups of OB/GYNs, particularly those differences that may result from differences in the age or region of the provider. As examples, age may play an important role in the choice of information sources the provider uses, whereas region may play a role in the types of foods, such as fish, the provider discusses with clients or patients.

The sample sizes for the various provider groups were selected using two criteria: (1) to ensure adequate power to detect small to moderate differences between groups; and (2) to ensure adequate power to detect moderate differences within the OB/GYN group.

Assuming a power of 0.8 and an alpha of 0.05, a sample size of 400 OB/GYNs will be sufficient to detect a 6-7% difference in proportion between a subset of OB/GYNs differs and the population of OB/GYNs. For example, the sample size should allow for a test of whether the proportion of coastal OB/GYNs that report advising patients about mercury and fish is 7% greater (or smaller) than the proportion of all OB/GYNs that report similar behavior. Another comparison may be made with respect to age of the respondent by splitting the sample into two age groups.

Similarly, assuming a power of 0.8 and an alpha of 0.05, the sample sizes for each of the groups will be sufficient to detect differences in proportions of approximately 10% between OB/GYNs and each of the other groups and approximately 12% between the non-OB/GYN groups

B.3 Methods to Maximize Response Rate and Deal with Non-Response

FDA plans to take a number of steps to ensure a high response rate for this survey.

- All physician offices will be called prior to sending the survey to let them know that a survey will be coming in the mail shortly.
- All surveys will be sent via priority mail. This will help ensure that the survey reaches the proper respondent and that it will stand out from other mail.
- The survey package will include an introduction letter describing the purpose of the study and the importance of a response. When the final, approved survey instrument is available, we will request endorsement by the relevant health care provider professional organizations and National WIC Association and include this in the letter. We will also use the cognitive interviews to determine who at FDA should sign the introduction letter to health care providers and WIC educators to encourage participation in the survey.
- Each survey will be designed to ensure ease of completion.
- The survey will take no more than 10 minutes to complete.
- A stamped envelope with the return address already printed will be included, facilitating ease of returning the survey.
- The questions will be extensively pre-tested with cognitive interviews to ensure that each sampled group finds the questions understandable and meaningful. A well worded questionnaire on topics of interest to the selected groups will help encourage participation.
- A follow-up survey and letter will be sent to all selected participants who have not returned the survey after 3 weeks. This will help response rate, by providing a second copy to those who may have misplaced the survey.
- Each respondent will be paid an incentive for returning the questionnaire. Previous research has shown that incentives are effective at increasing response rate for these groups.

B.4 Tests, Procedures or Methods Used

Both cognitive interviews and pre tests will be conducted prior to fielding the entire survey. These tests of procedures will help ensure that the questions are understandable and meaningful to respondents and the answer categories complete and mutually exclusive.

A total of nine (9) cognitive interviews will be conducted via the phone. To date, six interviews have been conducted, two with practicing OB-GYNs, two with nurse midwives and two with WIC educators. The remaining interviews will be conducted

with a mix of WIC educators and physician assitants. Each interview lasts no more than 45 minutes. Cognitive interview participants have been recruited by phone by the contractor and have been offered an incentive for participation. The amount of incentive is approximately related to the opportunity cost of time for physicians ($250) and other health care providers and WIC educators ($150).

The interviews, thus far, have revealed no significant issues of understanding of the content and wording of the questionnaire. In general, interviewees have responded positively to the subject matter and many have asked for more information about food safety and nutrition issues. The interviews have resulted in minor improvements in question wording and survey organization.

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 mailout in eliciting a completed survey; and (3) the effectiveness of the the incentive in eliciting a completed response.

The data from the full survey will be tabulated and analyzed to address the issues covered in the questionnaire. Cross tabulation of results and comparison of mean responses between the groups of health care providers will be used to examine the advice health care providers give pregnant women, the sources from which they receive the information, and the sources from which they prefer to receive the information.

B.5 Consulting Statistician and Contractor

The contractor, Synovate, Inc. will collect the data for the Survey of Food Safety and Nutrition Information Provided to Pregnant Woman by Health Care Providers and WIC Educators on behalf of the Food and Drug Administration's Center for Food Safety and Applied Nutrition and the Environmental Protection Agency, as a task order under the Quick-Turn-Around Research Services contract. Leigh Seaver, Ph.D., is the Senior Study Director for Synovate, telephone (703) 663-7225. Conrad J. Choinière, Ph.D., HFS-727 is the Project Officer, telephone (301) 436-1844.

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