REQUEST FOR OMB REVIEW

Supporting Statement B

SURVEY OF CURRENT MANUFACTURING PRACTICES IN THE FOOD INDUSTRY

Submitted by

Economics Staff

Office of Regulations and Policy

Center for Food Safety and Applied Nutrition

Food and Drug Administration

Department of Health and Human Services

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B COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

B.1 Potential Respondent Universe and Sampling Frame

Universe:

The universe for this survey is all FDA-registered domestic facilities, which are those facilities registered in the 50 U.S. states, the District of Columbia, the Commonwealth of Puerto Rico and all other U.S. possessions that are engaged in manufacturing/processing of food for human consumption.[1] The primary goal of this survey is to generate general purpose descriptive statistics on registered food manufacturers/processors in five (5) key areas relevant for the food CGMPs modernization effort: employee training, sanitation and personal hygiene, allergen controls, process controls, and recordkeeping. FDA plans to use the data collected in the cost-benefit and cost-effectiveness studies of its future policies related to the food CGMPs modernization effort. Additionally, FDA might also utilize the data collected to better target its outreach and promotion materials, such as "best-practices" manuals, and food safety training courses.

The FDA Food Facility Registration database collects information about the number of manufacturers that are engaged in the manufacturing or processing of food for human consumption in the U.S. (FDA, 2008). It does not, however, contain information on the 6-digit North American Industry Classification System (NAICS) code or the employment size for the registrants in the survey universe. As described below, FDA proposes obtaining this information by matching the name and location of the facilities in the universe with facility information collected and published by Dun and Bradstreet (D&B). D&B records list both the primary and secondary NAICS industry classifications as well as the employment size of each facility. The D&B data comprehensively cover virtually all active facilities in the United States. The list of 6-digit NAICS industries in-scope for this survey is shown in Table B-1.

1.2 INDUSTRY GROUPS

FDA has divided the universe of food manufacturers into three size classes because the nature and effectiveness of manufacturing practices may likely vary by facility size. The size classes are defined in terms of the total number of employees at each facility. The boundaries for these strata are as follows:

- *Size Class 1* – Less than 20 employees,
- *Size Class 2* – 20 to 99 employees, and
- *Size Class 3* – 100 or more employees.

FDA will generate estimates of the prevalence of certain types of manufacturing practices, such as employee training, allergen control procedures, etc. and other statistics for each size class that meet the precision targets as described below. Within each size class, FDA will conduct stratified random sampling using proportional sampling among ten aggregated industry groups.

[1] All domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States are required to register with the FDA by December 12, 2003, under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) or prior to beginning operations if they were established after this date.

Table B-1: NAICS Classifications for Facilities Manufacturing/Processing Food for Human Consumption in the U.S.

NAICS	NAICS Title
311211	Flour Milling
311212	Rice Milling
311213	Malt Manufacturing
311221	Wet Corn Milling
311222	Soybean Processing
311223	Other Oilseed Processing
311225	Fats and Oils Refining and Blending
311230	Breakfast Cereal Manufacturing
311311	Sugarcane Mills
311312	Cane Sugar Refining
311313	Beet Sugar Manufacturing
311320	Chocolate and Confectionery Manufacturing from Cacao Beans
311330	Confectionery Manufacturing from Purchased Chocolate
311340	Nonchocolate Confectionery Manufacturing
311411	Frozen Fruit, Juice, and Vegetable Manufacturing
311412	Frozen Specialty Food Manufacturing
311421	Fruit and Vegetable Canning
311422	Specialty Canning
311423	Dried and Dehydrated Food Manufacturing
311511	Fluid Milk Manufacturing
311512	Creamery Butter Manufacturing
311513	Cheese Manufacturing
311514	Dry, Condensed, and Evaporated Dairy Product Manufacturing
311520	Ice Cream and Frozen Dessert Manufacturing
311711	Seafood Canning
311712	Fresh and Frozen Seafood Processing
311811	Retail Bakeries
311812	Commercial Bakeries
311813	Frozen Cakes, Pies, and Other Pastries Manufacturing
311821	Cookie and Cracker Manufacturing
311822	Flour Mixes and Dough Manufacturing from Purchased Flour
311823	Dry Pasta Manufacturing
311830	Tortilla Manufacturing
311911	Roasted Nuts and Peanut Butter Manufacturing
311919	Other Snack Food Manufacturing
311920	Coffee and Tea Manufacturing
311930	Flavoring Syrup and Concentrate Manufacturing
311941	Mayonnaise, Dressing, and Other Prepared Sauce Manufacturing
311942	Spice and Extract Manufacturing
311991	Perishable Prepared Food Manufacturing
311999	All Other Miscellaneous Food Manufacturing
312111	Soft Drink Manufacturing
312112	Bottled Water Manufacturing
312113	Ice Manufacturing

The number of facilities within each industry group and size class are currently unknown, but will be determined after the facility-specific information from the FDA Facility Registration database is enhanced with facility size and industry classification information obtained from the D&B data. Table B-2 combines related categories of food manufacturers and shows abstractly the resultant distribution of the universe by size class and industry group stratum. The table entries, $P_{ij,}$ represent the number of facilities in size class i (e.g., with fewer than 20 employees) and

industry group j (e.g., Frozen Food Manufacturing). The industry groups noted in Table B-2 are believed to have distinct processing characteristics. Thus, stratified random sampling with proportional allocation will increase the accuracy of our survey estimates.[2]

Table B-2: Number of Facilities Manufacturing/Processing Food for Human Consumption in the U.S. as Reported by the U.S. Census Bureau by Sampling Stratum

Sampling Stratum [a]	NAICS Codes	Facility Size (in Number of Employees)			Total
		< 20	20 – 99	100 or More	
Grain & Oilseed Milling & Sugar Manufacturing	3112 31131	P_{11}	P_{21}	P_{31}	$\sum_i P_{i1}$
Chocolate & Nonchocolate Confectionery Manufacturing	31132 31133 31134	P_{12}	P_{22}	P_{32}	$\sum_i P_{i2}$
Frozen Food Manufacturing	31141	P_{13}	P_{23}	P_{33}	$\sum_i P_{i3}$
Fruit & Vegetable Canning	31142	P_{14}	P_{24}	P_{34}	$\sum_i P_{i4}$
Dairy Product Manufacturing	3115	P_{15}	P_{25}	P_{35}	$\sum_i P_{i5}$
Seafood Product Preparation	3117	P_{16}	P_{26}	P_{36}	$\sum_i P_{i6}$
Bakeries and Tortilla Manufacturing	3118	P_{17}	P_{27}	P_{37}	$\sum_i P_{i7}$
Other Food Manufacturing	3119	P_{18}	P_{28}	P_{36}	$\sum_i P_{i8}$
Perishable Prepared Food Manufacturing	311991	P_{19}	P_{29}	P_{39}	$\sum_i P_{i9}$
Soft Drink and Ice Manufacturing	31211	P_{110}	P_{210}	P_{310}	$\sum_i P_{i10}$
Total		$\sum_j P_{1j}$	$\sum_j P_{2j}$	$\sum_j P_{3j}$	$\sum_i \sum_j P_{ij}$

[a] The majority of sectors depicted correspond to 4-digit NAICS codes with the exception of "Grain &Oilseed Milling & Sugar Manufacturing," "Chocolate & Nonchocolate Confectionery Manufacturing," and "Perishable Prepared Food Manufacturing."

Sample Frame:

The sampling frame for the study will be based on the FDA Food Facility Registration database supplemented with information on facility size and 6-digit NAICS industry obtained from the Dun & Bradstreet (D&B) business facility database. The FDA Food Facility Registration database provides a listing of domestic food facilities, including manufacturers/processors, as well as foreign facilities that export food that will be consumed in the U.S. and is continuously

[2] It is well known in statistical theory that if a population can be subdivided into subpopulations for which the variances of the design variable are smaller than that for the overall population, then stratified random sampling can be used to obtain a more precise (smaller variance) estimate of the population mean for that variable. See, for example, William Cochran, *Sampling Techniques* (New York, 1977) [Third Edition], Chapter 2 and Sharon L. Lohr, *Sampling: Design and Analysis* (Pacific Grove, 1999), Chapter 4.

updated by facilities as registration information changes. Because all domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States are required to register with the FDA under the Bioterrorism Act, the FDA Food Facility Registration database represents a comprehensive listing of food manufacturing facilities.

The FDA Food Facility Registration database includes contact information and general information about the type of activity conducted at the facility (e.g., "manufacturer/processor"), but it does not contain the facility size (i.e., number of employees) or NAICS code information on registered facilities. To establish a complete sampling frame, FDA will add the size and NAICS code information for those facilities registered as manufacturer/processor by purchasing the D&B database for all food manufacturers (i.e., all records for which the listed primary or secondary 6-digit NAICS code begins with either 311 or 312) and matching it to the FDA Food Facility Registration database. D&B provides information for millions of U.S. and international public and private businesses. Virtually all active businesses in the U.S. register with D&B to obtain a DUNS number, as it is required for credit reporting and other business transactions. Company records in the D&B database include company address, type of ownership, primary and secondary NAICS codes, number of employees, amount of sales and others. There is, however, no email contact information on companies in the D&B database.

At the completion of matching D&B to the FDA Food Facility Registration database (see Figure 1), our sampling frame will be the list of facilities registered with FDA as manufacturer/processor of food for human consumption, and it will contain two categories of record types: facilities with complete information that we will call Partition A, and facilities with incomplete information that we will call Partition B. We refer to the two category types as Partitions A and B because the data will be partitioned (separated) by these two categories and sampled differently as described in section 2.2.

- *Facilities with Complete Information (Partition A)* – The record for the facility includes name, address, 6-digit NAICS, employment size, and email address for facility contact person.

- *Facilities with Incomplete Information (Partition B)* – The record for the facility includes name, address, and email address for facility contact person but does not contain information on the facility's 6-digit NAICS code or employment size.

We expect that the majority of facility records in our sampling frame will fall within Partition A, as almost all active U.S. food manufacturers will have DUNS numbers. Partition B, on the other hand, will contain a likely small number of facility records that may be:

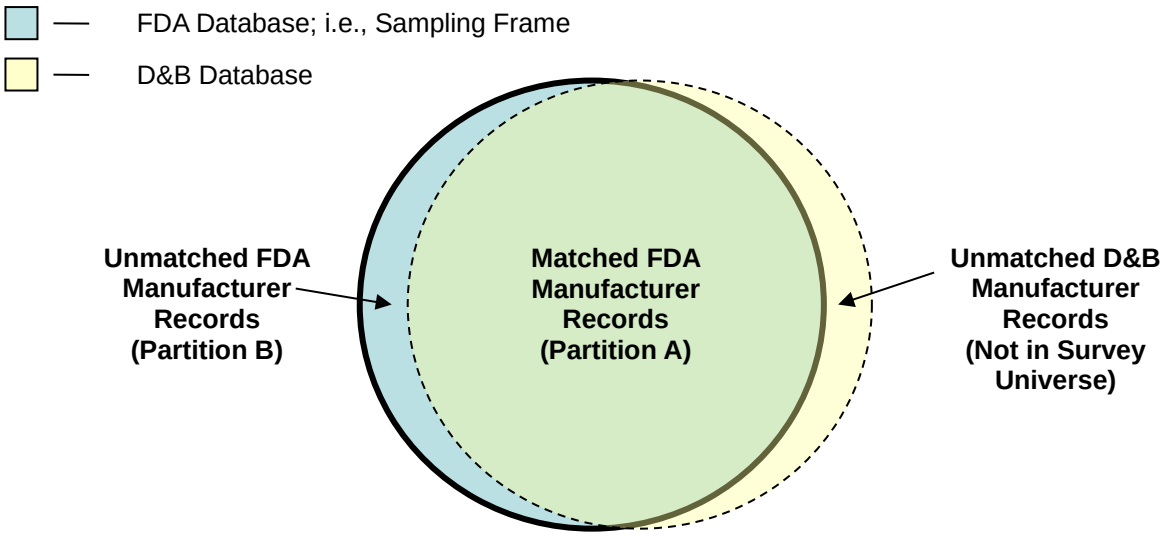
- Out of business,

- Out of scope – Those that have incorrectly classified themselves as a food manufacturer when registering with FDA,

- In-scope, but not captured in D&B data because they have registered with D&B using a non-manufacturing NAICS code, or

- In-scope, but not matchable because they registered with D&B (FDA) using a different address or name than they provided in their FDA registration (D&B).

Figure 1: Matching of D&B Database to the FDA Food Facility Registration Database



B.2 Sample Design

FDA's primary objective in designing the survey is to develop estimates of the prevalence of certain types of food manufacturing practices with 95-percent confidence intervals defined to equal the point estimator plus or minus a confidence-interval half-width of five (5) percentage points or less for each facility size class.

2.1 STRATIFICATION

To accomplish these objectives, FDA proposes a survey in which:

- Facilities with complete information (Partition A) will be sampled using a simple stratified random sample design with proportional sampling within each size class; and
- Facilities with incomplete information (Partition B) will be sampled using a simple random sample design.

For Partition A, the design ensures that each facility in a given size class has an equal probability of selection. For Partition B, the design ensures that each facility has an equal probability of selection regardless of size.

2.2 SAMPLE ALLOCATION

Let U be the population of the survey universe (all FDA-registered facilities that manufacture food for human consumption), where

(1) $$U = U^A + U^B$$

and U^A is the population of the partition of the universe of FDA-registered food manufacturers with complete information and U^B is the population of the partition of the universe consisting of FDA-registered food manufacturers with incomplete information.

Similarly, let S be the size of sampled population where

(2) $$S = S^A + S^B$$

and S^A is the sample size for FDA-registered food manufacturers with complete information and S^B is the sample size for FDA-registered food manufacturers with incomplete information.

Given that FDA will have employment size and 6-digit NAICS industry information for those facilities in Partition A, the sample S^A will be drawn based on a simple stratified random sample design with proportional allocation, with the strata defined by employment size and industry group. Thus,

(3) $$S^A = \sum_i \sum_j S_{ij}^A$$

where S_{ij}^A is the sample for i[th] size class and the j[th] industry group drawn from Partition A of the universe. Since FDA will not have employment size and 6-digit NAICS industry information for those facilities in Partition B, the sample S^B will be drawn using a simple random sample design.

If r is FDA's estimate of the overall completion rate (e.g. rate of sampling frame deficiencies and respondent nonresponse), then the overall solicited sample, SS, necessary to achieve FDA's accuracy goals is

(4) $$SS = \sum_i \sum_j \frac{1}{r}\left(S_{ij}^A + S^B\right)$$

2.2.1 Facilities with Complete Records (Partition A)

We propose to use simple stratified random sampling with three estimation cells for those facilities with complete records where each employment size class represents an estimation cell. A five percent (5%) margin of error in population parameter estimates at the 95-percent confidence level requires an overall sample size of 384 per estimation cell (or 1,152 total given that there are 3 estimation cells). Table B-3 illustrates the disposition of the target sample for the survey of facilities with complete information that manufacture food for human consumption. The design reflects simple proportionate sampling based on population size of each stratum in the study universe. Appendix C shows the underlying mathematical relationships between the accuracy objectives and the sample targets.[3]

Table B-3: Target Sample for the Survey of Facilities with Complete Records (Partition A)

	Number of Employees			
Food Sector	**< 20**	**20 – 99**	**100 or More**	**Total**

[3] The sample sizes shown in Table B-3 are based on the relationship between sample size and accuracy for simple random samples. Since FDA is proposing a stratified random sample design based on proportional sampling, the accuracy levels achieved with these samples will, in general, exceed the survey's objectives (see Appendix A).

Grain & Oilseed Milling & Sugar Manufacturing	TS_{11}	TS_{21}	TS_{31}	$\sum_i TS_{i1}$
Chocolate & Nonchocolate Confectionery Manufacturing	TS_{12}	TS_{22}	TS_{32}	$\sum_i TS_{i2}$
Frozen Food Manufacturing	TS_{13}	TS_{23}	TS_{33}	$\sum_i TS_{i3}$
Fruit & Vegetable Canning	TS_{14}	TS_{24}	TS_{34}	$\sum_i TS_{i4}$
Dairy Product Manufacturing	TS_{15}	TS_{25}	TS_{35}	$\sum_i TS_{i5}$
Seafood Product Preparation	TS_{16}	TS_{26}	TS_{36}	$\sum_i TS_{i6}$
Bakeries and Tortilla Manufacturing	TS_{17}	TS_{27}	TS_{37}	$\sum_i TS_{i7}$
Other Food Manufacturing	TS_{18}	TS_{28}	TS_{36}	$\sum_i TS_{i8}$
Perishable Prepared Food Manufacturing	TS_{19}	TS_{29}	TS_{39}	$\sum_i TS_{i9}$
Soft Drink and Ice Manufacturing	TS_{110}	TS_{210}	TS_{310}	$\sum_i TS_{i10}$
Total	**384**	**384**	**384**	**1,152**

Assuming proportional stratified random sampling, the elements of Table B-3 have the following properties:

(5) $$\sum_{j=1}^{10} TS_{ij} = 384, \text{ and}$$

(6) $$T_{ij} = 384 \times \frac{P_{ij}}{\sum_{j=1}^{10} P_{ij}} \text{ for each size class i.}$$

The overall number of solicitations required to achieve the sample targets shown in Table B-3 will depend on the incidence of invalid or out-of-scope listings in the drawn sample and on the rate of nonresponse among otherwise in-scope respondents. Reasons for nonresponse include language barriers, refusal, and other circumstances, as well as the inability to contact the respondent in a timely fashion. FDA's experience with the FDA Food Facility Registration database indicates that approximately twenty percent (20%) of the listings might be expected to be outdated or duplicate registrations. Previous industry survey efforts also indicate that a nonresponse rate of no more than thirty percent (30%) is likely for a survey such as this one (see Table B-4).

Table B-4: Examples of Response Rates Achieved in Federal Agency Sponsored Surveys of Industry

Survey Title	Sponsoring Agency	Target Respondents	Response Rate
Single-Use Medical Device (SUD) Reuse and Reprocessing in Hospitals	FDA	Hospitals	79.4%
Personal Protective Equipment (PPE)	OSHA	Manufacturing Facilities	75%
Automated External Defibrillator Use	OSHA	General industry, except for	55% overall

in the Workplace		construction	73% manufacturing

Conducted by Eastern Research Group, Inc. (ERG) under contract to the sponsoring Agency.

Combined, these figures suggest that the overall completion rate (percent of completed surveys among Partition A respondents potentially solicited) of fifty-six percent (56%) or higher should be expected $\lfloor 56\% = \lfloor 100\% \times (100\% - 20\%) \times (100\% - 30\%) \rfloor \rfloor$. Thus, FDA estimates that a solicited sample of 2,058 potential respondents is necessary to achieve the sample targets for Partition A.

2.2.2 Facilities with Incomplete Records (Partition B)

We propose to use simple random sampling for those facilities with incomplete records. A five percent (5%) margin of error in population parameter estimates at the 95-percent confidence level requires an overall sample size of 384 for this partition. Assuming a completion rate similar to that for Partition A, FDA estimates that a solicited sample of 686 potential respondents is necessary to achieve the sample target for Partition B ($686 = 384 \div 0.56$).

At the completion of the survey, FDA will post-stratify the Partition B respondents into the applicable size classes based on the self-reported employment size of the respondent, mainly:[4]

- *Size Class 1* – Less than 20 employees,
- *Size Class 2* – 20 to 99 employees, and
- *Size Class 3* – 100 or more employees.

2.2.3 Supplementary Sample

Should the realized survey completion rate for either the stratified sample from Partition A or the simple random sample from Partition B be lower than estimated, FDA will draw a supplementary sample sufficiently large to ensure the stratum-specific respondent targets as derived in Table B-3 or the 384 target respondents for the Partition B sample are met. To ensure comparability, the supplementary samples, should they be necessary, will be selected from among the remaining facilities in the each size-class group using the same stratification criteria (for Partition A) or randomly selected from the remaining facilities in Partition B using the same sample selection method as used in the initial sample. FDA will use the actual completion rate obtained for the initial sample to determine the size of the supplementary sample needed to achieve the target respondent sample sizes.

B.3 Information Collection

B.3.1 Data Collection

The data collection phase of the study will be initiated with a survey invitation notice to all solicited respondents; i.e., food manufacturers with complete information and those with incomplete information (see Table B-4). According to the U.S. Census Bureau, a pre-canvas notification improves response rates in industry surveys. We believe that a survey invitation notice will have a similar effect for this effort.

[4] The survey inquires about the number of employees at the respondent's facility.

The survey invitation will also enable us to confirm whether the target respondent is in-scope (i.e., food manufacturer) and determine the target respondent's preferred mode of contact for the survey. The invitation will request the following information from the solicited respondents:

- Nature of operations at the facility and what is being manufactured to confirm that the target respondent is indeed a food manufacturer and hence within the scope of the larger survey,
- Number of employees at the facility,
- Preferred mode of contact for the survey (electronic or U.S. Postal Service mail), and
- Contact information for the person most suitable to respond to the survey.

Table B-5: Classification of Target Respondents prior to Survey Invitation

Type of Target Respondent	With Email Address	With Mail Address Only[a]
With Complete Information (Partition A)	Group A_1	Group A_2
With Incomplete Information (Partition B)	Group B_1	Group B_2

[a] Most facilities in the FDA Food Facility Registration database are believed to have provided valid email addresses. But some, apparently, have declined to provide such contact information or have failed to update the email address they provided to FDA as information changes.

FDA will utilize a mixed-mode approach via Internet and mail to administer the survey invitation notice to the sample of 2,744 (i.e., 2,744 = 2,058 + 686) target respondents. This will involve:

- First contact – Survey Invitation
  - Solicited respondents in groups A_1 and B_1, an email invitation with individualized URL to the pre-canvas questions
  - Solicited respondents in groups A_2 and B_2, invitation letter sent via U.S Postal Mail with hard copy of pre-canvas questions attached
- Second contact – First reminder one-week after initial invitation (sent to non-respondents only)
  - Solicited respondents in Partitions A_1 and B_1, an email reminder with individualized URL to the pre-canvas questions
  - Solicited respondents in groups A_2 and B_2, postcard reminder sent via U.S Postal Mail
- Third contact – Second reminder one-week after the first reminder (sent to non-respondents only)
  - Solicited respondents in groups A_1 and B_1, a mail reminder with a hard copy of pre-canvas questions attached sent via U.S. Postal Mail
  - Solicited respondents in groups A_2 and B_2, a mail reminder with a hard copy of pre-canvas questions attached sent via U.S. Postal Mail.

We will use the information obtained from the survey invitation to divide the solicited sample according to preferred mode and point of contact as depicted in Table B-6 below. Note that those who have not responded to the survey invitation will still be solicited for the survey as described below.

Table B-6: Classification of Target Respondents after Survey Invitation

Type of Target Respondent		Category	
With Complete Information	Survey invitation respondents	Group A_{1R} (Preferred contact mode is email)	Group A_{2R} (Preferred contact mode is mail)
	Survey invitation non-respondents	Group A_{1N} (Email address available)	Group A_{2N} (Only mail address is available)
With Incomplete Information	Survey invitation respondents	Group B_{1R} (Preferred contact mode is email)	Group B_{2R} (Preferred contact mode is mail)
	Survey invitation non-respondents	Group B_{1N} (Email address available)	Group B_{2N} (Only mail address is available)

The survey will use the following protocol for contacting the solicited respondents:

- First contact – Survey invitation
  - For solicited respondents in groups A_1 and B_1, an introductory email with individualized URL to the survey (with a PDF version of the survey also attached)
  - For solicited respondents in groups A_2 and B_2, an introductory letter by U.S. Postal Service mail with a hard copy of the survey
- Second contact: First reminder one-week after initial contact (sent to non-respondents only)
  - For solicited respondents in groups A_1 and B_1, reminder email with individualized URL to the survey (with a PDF version of the survey also attached)
  - For solicited respondents in groups A_2 and B_2, reminder letter via U.S. Postal Service with a hard copy of the survey attached
- Third contact: Second reminder one-week after the first reminder (sent to non-respondents only)
  - For solicited respondents in groups A_1 and B_1, reminder postcard sent via U.S. Postal Service
  - For solicited respondents in groups A_2 and B_2, reminder postcard sent via U.S. Postal Service
- Fourth contact: Final reminder one week after the second reminder (sent to non-respondents only)
  - For solicited respondents in groups A_1 and B_1, reminder phone call
  - For solicited respondents in groups A_2 and B_2, reminder phone call

B.3.2 Sample Selection Methodology

3.2.1 Facilities with Complete Information (Partition A)

The solicited sample of facilities within each stratum will be selected using a simple random sampling procedure. To facilitate the sampling, each facility will be assigned a random index number, using a random number generator. The facilities in each stratum will then be arranged in ascending order according to their random index numbers. If SS_{ij}^{A} is the size of the solicited sample in the i[th] size class and j[th] industry group in partition A, then those SS_{ij}^{A} facilities with the smallest index numbers will be selected and included in the sample.[5]

3.2.2 Facilities with Incomplete Information (Partition B)

Similar to the sample selection process applied to Partition A, the solicited sample of facilities in Partition B will also be selected using a simple random sampling procedure. To facilitate the sampling, each facility will be assigned a random index number, using a random number generator. The facilities in the partition will then be arranged in ascending order according to their random index numbers. If SS^{B} is the size of the solicited sample in the partition, then those SS^{B} facilities with the smallest index numbers will be selected and included in the sample.

B.3.3 Weighting and Estimation Procedure

3.3.1 Weighting

Facilities with Complete Information (Partition A)

Because FDA is anticipating variable nonresponse rates by stratum, weighting procedures are necessary to produce overall estimates. The weights will be the inverse of the selection probabilities of the facilities. Each stratum will have a different weight because of the different actual nonresponse rates. The sampling weights are defined as follows:

(7) $$W_{ij}^{A} = \frac{U_{ij}^{A}}{SS_{ij}^{A}}$$

where

W_{ij}^{A} = Sampling weight for the i[th] facility size class and j[th] industry group in Partition A

U_{ij}^{A} = Number of elements in Partition A of the registrant universe defined by the i[th] size class and j[th] industry group

SS_{ij}^{1} = Size of the solicited sample in the i[th] facility class size and j[th] industry group for Partition A

Facilities with Incomplete Information (Partition B)

The sampling weight for those facilities with incomplete information will be defined as follows

[5] Alternatively, one could select the same number of facilities with the largest index numbers.

(8) $$W^B = \frac{U^B}{SS^B}$$

where

W^B = Sample weight for Partition B
U^B = Number of elements in Partition B of the registrant universe
SS^B = Size of the solicited sample for Partition B

3.3.2 Adjustment Factor for Nonresponse

Facilities with Complete Information (Partition A)

The adjustment factor for nonresponse will be calculated by dividing the solicited sample size in each stratum by the actual number of responses from the corresponding stratum. This is written for Partition A as:

(8) $$N_{ij}^A = \frac{SS_{ij}^A}{AR_{ij}^A}$$

where

SS_{ij}^A = Size of the solicited sample in the i^{th} class size and j^{th} industry group for Partition A
AR_{ij}^A = Actual (responded) sample in the i^{th} class size and j^{th} industry group for Partition A
N_{ij}^A = Nonresponse factor for the i^{th} class size and j^{th} industry group for Partition A

Facilities with Incomplete Information (Partition B)

Similarly for Partition B, the adjustment factor for nonresponse will be calculated as:

(9) $$N^B = \frac{SS^B}{AR^B}$$

where

SS^B = Size of the solicited sample for Partition B
AR^B = Actual (responded) sample size for Partition B
N^B = Nonresponse factor for Partition B

3.3.3 Point Estimation Procedures

The estimator, $\hat{Y}$, for the totals for a given survey variable will take the form:

(10) $$\hat{Y} = \sum_i \sum_j \sum_k W_{ij}^A N_{ij}^A Y_{ijk}^A + \sum_m W^B N^B Y_m^B$$

where

Y_{uj}^A = Response of the k^{th} respondent in the i^{th} size class and the j^{th} industry group for Partition A sample

W_{ij}^{A} = Sampling weight of the i^{th} size class and j^{th} industry group for Partition A

N_{ij}^{A} = Nonresponse adjustment of the i^{th} size class and j^{th} industry group for Partition A

Y_{m}^{B} = Response of the m^{th} respondent in Partition B sample

W^{B} = Sampling weight for Partition B

N^{B} = Nonresponse adjustment for Partition B

Estimates of the mean will be derived as follows:

$$\overline{Y} = \frac{\sum_{i}\sum_{j}\sum_{k} W_{ij}^{A} N_{ij}^{A} Y_{ijk}^{A} + \sum_{m} W^{B} N^{B} Y_{m}^{B}}{\sum_{i}\sum_{j} W_{ij}^{A} N_{ij}^{A} + W^{B} N^{B}} \quad (11)$$

Similarly, the mean for each size class, i, will be derived as follows:

$$\overline{Y} = \frac{\sum_{j}\sum_{k} W_{ij}^{A} N_{ij}^{A} Y_{ijk}^{A} + \sum_{m} W^{B} N^{B} Y_{im}^{B}}{\sum_{j} W_{ij}^{A} N_{ij}^{A} + W^{B} N^{B} n_{i}} \quad (12)$$

where

Y_{im}^{B} = Response of the m^{th} respondent in size class i in Partition B sample

n_{i} = Number of respondents in size class i in Partition B sample

B.4 Methods To Maximize Response Rates

There is considerable research that relies on the theory of social exchange to explain why someone fills out a survey. The motivation to participate in FDA's survey will naturally differ among respondents. There are, however, various time-tested methods for increasing participation rates in surveys. These include:

- Incentives, such as pre- or post-payment of small cash prizes and drawings,
- Requests for help,
- Multiple contacts,
- Pre-notification letters/emails, and
- Multiple mode administration.

Incentives use social exchange theory by causing participants to feel obligated to respond. The use of incentives is a heavily researched area in response rate literature. Although several analyses have resulted in different conclusions, published reviews paint a very clear picture with respect to two issues: first, incentives are effective in increasing the response rates, especially for self-administered surveys (mail and Web); and second, promised incentives are not as effective as enclosed incentives. Given their cost, the use of taxpayer funds, impact on survey responses, and implications for the "social contract" between FDA and industry, we judge that monetary incentives are not appropriate for this survey effort. We will provide respondents with a copy of the final report as an incentive to participate.

Requests for help – Because most people tend to follow a norm of social responsibility, they will be more likely to comply with a survey request couched in terms of asking for help. There also is some evidence in the survey literature indicating that this is indeed the case. For example, a recent study found an eighteen percent (18%) increase in response rates by including the phrase "it would really help us out" in their communications.

Multiple contacts with members of the sample is one of the most successful techniques to increase response rates. This technique is now considered standard methodology for any survey. Studies suggest that to get full benefit from multiple contacts, surveys should use a pre-notification message followed by a copy of the survey with a cover message (a reminder sent to all respondents shortly after they receive the copy of the survey), followed finally by one or more contacts with non-respondents using combination of messages and surveys. Studies using samples of the general population have found that pre-notification letters typically increase response rates by four (4) to twenty-nine (29) percentage points. A recent example of multiple contacts with a Web survey was administered at a major university regarding student housing. After the first email notification, the response rate was leveling off at around forty-four percent (44%). After an email reminder was sent to non-respondents, the response rate increased to sixty-seven percent (67%), and a final reminder to non-respondents notifying them of the deadline for the survey resulted in a final response rate of almost seventy-two percent (72%), substantially higher than the rate after the first email notification. While they often increase costs, multiple contacts with respondents are one of the best ways to ensure a good response rate. This is one reason that Web surveys are growing in popularity as three or four contacts with respondents can be virtually costless, while three or four paper mailings can be quite expensive, especially if postage is required.

Pre-notification letters/emails that provide more information on the study increase respondent confidence in the validity and the importance of the study resulting in higher response rates.

Multiple mode administration (phone and mail, mail and Web, etc) of a survey has been shown to increase response rates (Dillman, 2000). Additionally, the use of multiple modes can also reduce nonresponse error and data collection costs.

Our proposed method of data collection (see Section 3.1) incorporates all of the above techniques. Since FDA is utilizing widely-accepted data collection techniques and is devoting substantial resources to efforts designed to minimize nonresponse, we expect the response rate to this survey to be comparable or better than that achieved for surveys of similar size and scope. Furthermore, FDA's contractor for this survey effort has conducted a number of surveys of industrial facilities on a variety of topics that have achieved response rates comparable to, or exceeding, the response rate estimated for this survey.

B.5 Tests of Procedures or Methods

FDA plans to administer a pretest of the survey instrument. These facilities will be selected based on a random sample by employment size of the target survey population using the following simple random sample design (see Table B-7).

Pretest results will be evaluated to ensure that the survey questions are clearly understandable, terms are well defined, and the survey format is logical.

Table B-7: Survey Pretest Sample

Type of Target Respondent	Facility Size (in Number of Employees)	Pretest Sample Size
With Complete Information (Partition A)	< 20 Employees	10
	20 to 99 Employees	7
	100 or More Employees	7
With Incomplete Information (Partition B)	Not Applicable	6
Total		**30**

B.6 Expert Review

The statistical aspects of the survey design have been reviewed by:

Aylin Sertkaya, Ph.D.
Eastern Research Group, Inc.
110 Hartwell Ave.
Lexington, MA 02421
781-674-7227

Chester Fenton, Ph.D. (ABD)
Eastern Research Group, Inc.
110 Hartwell Ave.
Lexington, MA 02421
781-674-7326

Peter Vardon, Ph.D.
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740
301-436-1830

The data will be collected and processed by:

Nyssa Ackerley
Eastern Research Group, Inc.
110 Hartwell Ave.
Lexington, MA 02421
781-674-7271

Thomas Gajnak
Eastern Research Group, Inc.
110 Hartwell Ave.
Lexington, MA 02421
781-674-7263

The summary statistics will be analyzed by:

Jordan Lin, Ph.D.
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway

College Park, MD 20740
301-436-1831

Angela Lasher, Ph.D.
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740
301-436-1763

Peter Vardon, Ph.D.
U.S. Food and Drug Administration
Center for Food Safety and Applied Nutrition
5100 Paint Branch Parkway
College Park, MD 20740
301-436-1830

Aylin Sertkaya, Ph.D.
Eastern Research Group, Inc.
110 Hartwell Ave.
Lexington, MA 02421
781-674-7227

Chester Fenton, Ph.D. (ABD)
Eastern Research Group, Inc.
110 Hartwell Ave.
Lexington, MA 02421
781-674-7326

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Appendix A 21 USC 393

Sec. 393. Food and Drug Administration

- (a) In general
  There is established in the Department of Health and Human Services the Food and Drug Administration (hereinafter in this section referred to as the "Administration").

- (b) Mission
  The Administration shall -
  - (1) promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner;
  - (2) with respect to such products, protect the public health by ensuring that -
    - (A) foods are safe, wholesome, sanitary, and properly labeled;
    - (B) human and veterinary drugs are safe and effective;
    - (C) there is reasonable assurance of the safety and effectiveness of devices intended for human use;
    - (D) cosmetics are safe and properly labeled; and
      (E) public health and safety are protected from electronic product radiation;
  - (3) participate through appropriate processes with representatives of other countries to reduce the burden of regulation, harmonize regulatory requirements, and achieve appropriate reciprocal arrangements; and
    (4) as determined to be appropriate by the Secretary, carry out paragraphs (1) through (3) in consultation with experts in science, medicine, and public health, and in cooperation with consumers, users, manufacturers, importers, packers, distributors, and retailers of regulated products.

- (c) Interagency collaboration
  The Secretary shall implement programs and policies that will foster collaboration between the Administration, the National Institutes of Health, and other science-based Federal agencies, to enhance the scientific and technical expertise available to the Secretary in the conduct of the duties of the Secretary with respect to the development, clinical investigation, evaluation, and postmarket monitoring of emerging medical therapies, including complementary therapies, and advances in nutrition and food science.

- (d) Commissioner
  - (1) Appointment
    There shall be in the Administration a Commissioner of Food and Drugs (hereinafter in this section referred to as the "Commissioner") who shall be appointed by the President by and with the advice and consent of the Senate.
  - (2) General powers
    The Secretary, through the Commissioner, shall be responsible for executing this chapter and for -
    - (A) providing overall direction to the Food and Drug Administration and establishing and implementing general

policies respecting the management and operation of programs and activities of the Food and Drug Administration;
        - (B) coordinating and overseeing the operation of all administrative entities within the Administration;
        - (C) research relating to foods, drugs, cosmetics, and devices in carrying out this chapter;
        - (D) conducting educational and public information programs relating to the responsibilities of the Food and Drug Administration; and
        (E) performing such other functions as the Secretary may prescribe.

- (e) Technical and scientific review groups
  The Secretary through the Commissioner of Food and Drugs may, without regard to the provisions of title 5 governing appointments in the competitive service and without regard to the provisions of chapter 51 and subchapter III of chapter 53 of such title relating to classification and General Schedule pay rates, establish such technical and scientific review groups as are needed to carry out the functions of the Administration, including functions under this chapter, and appoint and pay the members of such groups, except that officers and employees of the United States shall not receive additional compensation for service as members of such groups.

- (f) Agency plan for statutory compliance
    - (1) In general
      Not later than 1 year after November 21, 1997, the Secretary, after consultation with appropriate scientific and academic experts, health care professionals, representatives of patient and consumer advocacy groups, and the regulated industry, shall develop and publish in the Federal Register a plan bringing the Secretary into compliance with each of the obligations of the Secretary under this chapter. The Secretary shall review the plan biannually and shall revise the plan as necessary, in consultation with such persons.
    - (2) Objectives of agency plan
      The plan required by paragraph (1) shall establish objectives and mechanisms to achieve such objectives, including objectives related to -
        - (A) maximizing the availability and clarity of information about the process for review of applications and submissions (including petitions, notifications, and any other similar forms of request) made under this chapter;
        - (B) maximizing the availability and clarity of information for consumers and patients concerning new products;
        - (C) implementing inspection and postmarket monitoring provisions of this chapter;
        - (D) ensuring access to the scientific and technical expertise needed by the Secretary to meet obligations described in paragraph (1);
        - (E) establishing mechanisms, by July 1, 1999, for meeting the time periods specified in this chapter for the review of all

applications and submissions described in subparagraph (A) and submitted after November 21, 1997; and
(F) eliminating backlogs in the review of applications and submissions described in subparagraph (A), by January 1, 2000.

- (g) Annual report
  The Secretary shall annually prepare and publish in the Federal Register and solicit public comment on a report that -
  - (1) provides detailed statistical information on the performance of the Secretary under the plan described in subsection (f) of this section;
  - (2) compares such performance of the Secretary with the objectives of the plan and with the statutory obligations of the Secretary; and
    (3) identifies any regulatory policy that has a significant negative impact on compliance with any objective of the plan or any statutory obligation and sets forth any proposed revision to any such regulatory policy.

Appendix B Information Collection Instrument

(See a separate document)

Appendix C: Sample Size and Precision

The following discussion shows the mathematical relationships underlying the association between FDA's precision objectives detailed in Section 2 and the target sample sizes shown in Table B-3. The basic relationships relating sample size and statistical confidence intervals can be derived as follows: Let $Y = (y_1, y_2, y_3, ..., y_n)$ be a simple random sample selected with replacement from the population with mean μ and variance σ^2. Then, the sample mean, $\bar{y}$, is expressed as

(A-1) $$\bar{y} = \frac{1}{n}\sum_{i=1}^{n} y_i$$

where y_i is the value of the i[th] element of the sample and n is the size of the sample. Further, the standard deviation of the sample, s, is defined as

(A-2) $$s = \sqrt{\frac{1}{n-1}\sum_{i=1}^{n}(y_i - \bar{y})^2}$$

And, it can be shown that $\bar{y}$ and s^2 are unbiased estimators of μ and σ^2, respectively. If a series of samples is taken from the population, it can also be shown that the resulting probability distribution of the sample means will have an expected value of μ and a variance s^2, such that

(A-3) $$s^2 = \frac{\sigma^2}{n}$$

With the Central Limit Theorem, it can be shown that as n increases, the sample mean, $\bar{y}$, will have a distribution that approaches a normal distribution with mean μ and a standard deviation $\frac{\sigma}{\sqrt{n}}$. Alternatively, the relationship

(A-4) $$z = \frac{\bar{y} - \mu}{s}$$

is approximately normal, with mean zero and standard deviation of one for a sufficiently large sample. Further, equation (A-4) can be rewritten using (A-3) as

(A-5) $$z = \frac{(\bar{y} - \mu)}{\frac{\sigma}{\sqrt{n}}}$$

Values from the normal distribution will define the range or confidence interval around the mean within which the values of a normally distributed random variable may be expected to lie with a given probability, $1 - \alpha$, such that

(A-6) $$P\left(-z_{\alpha/2} \le \frac{(\bar{y} - \mu)}{\frac{\sigma}{\sqrt{n}}} \le z_{\alpha/2}\right) = 1 - \alpha$$

If the population standard deviation σ were known, the upper and the lower confidence limits (UCL and LCL) for the population mean, μ, are then defined as follows:

(A-7a) $$UCL = \bar{y} + z_{\alpha/2} \frac{\sigma}{\sqrt{n}}$$

(A-7b) $$LCL = \bar{y} - z_{\alpha/2} \frac{\sigma}{\sqrt{n}}$$

Equations (A-6) and (A-7) show the basic relationships that relate the confidence interval, the level of precision, and the sample size. To determine the necessary sample size, the sample designer must, therefore, specify two parameters: the confidence level (the value of α) and the desired precision, e (i.e., the maximum value of $\bar{y} - \mu$). Then, for a maximum error of $e = \bar{y} - \mu$ and a desired confidence level of α, the minimum desired sample size becomes

(A-8) $$n \geq \frac{z_{\alpha/2}^2 \sigma^2}{e^2}$$

The requisite sample size, however, also depends on σ^2, the population variance, which is generally not known. Thus, two approaches are typically used to estimate the value of σ^2. First, the sample designer may have *a priori* information about the population distribution that permits the approximation of σ^2. This may come from previous surveys or published studies. More commonly, a worst case assumption about the response frequencies is used as follows: Suppose a key survey question asks respondents about an important attribute of their manufacturing practice. Let p be the probability that this attribute is present for the respondents in the survey universe. A random variable with a value of 1 if the attribute is present and 0 if not, therefore, is binomially distributed with an expected value of p and a variance of $\sigma^2 = (1 - p)p$. This variance is maximized where $p = 0.5$. Thus, substituting $pq = 0.5^2 = 0.25$ for σ^2 in (A-8) will ensure that the sample size is large enough to meet the precision and confidence level objectives.

For example, tables of the normal distribution show than a normally distributed random variable with mean zero and variance 1 will have values between ± 1.96 with a 95-percent probability. Thus, a sample size of n, where

(A-9) $$n = \frac{0.25 \times 1.96^2}{e^2}$$

will result in a sample sufficient to achieve a precision of at least e at the 95-percent confidence level. That is, $|\bar{y} - \mu| \leq e$ with a probability of ninety-five percent (95%).