

following four mutually exclusive categories of dietary supplements:

1. Vitamins and minerals (includes establishments that may also manufacture, package, or hold herbals and botanicals, amino acids, proteins, or animal extracts but predominately manufacture vitamins and minerals);

2. Amino acids, proteins, and animal extracts (includes establishments that also manufacture, package or hold herbals and botanicals, including extracts; excludes establishments already classified as vitamins and minerals);

3. Herbals and botanicals, including extracts (excludes establishments already classified as "vitamins and minerals" or "amino acids, proteins, or animal extracts"); and

4. Supplements not already classified (all other product types).

We further stratified each of the four product categories into four size categories, very small, small, large, and unknown—resulting in 16 sampling strata. We classified each establishment into one mutually exclusive industry category (manufacturer, dietary ingredient supplier, repacker/relabeler, holder, or establishment not already classified). Establishments that manufacture supplements and also supply, repack, or hold dietary supplements or ingredients were classified as manufacturers.

ii. Size stratification. The Small Business Administration classifies companies as "small" based on the size of the entire company, including both parent and subsidiaries. If firms that manufacture dietary supplements have 500 or fewer employees, they are classified as small. Because the DS-EED data on size are only for specific establishments and not parent firms, we had to obtain parent company information on employment or revenue to correctly classify each establishment

as part of a small or large company. To obtain parent company data for establishments in the survey universe, we sent *InfoUSA*³ the DS-EED data records (N = 2,004) and requested the name, address, primary SIC, employment size (in ranges), and revenue (in ranges) of parent company firms with establishments in the survey universe. *InfoUSA* matched 1,219 of the 2,004 records in the DS-EED to their U.S. database of 10.3 million businesses. Of the 1,219 matched records, 31 records were found to be duplicates of another record and were removed, leaving 1,188 matched records and 1,566 total records in the sampling frame. The nonmatched records did not match because: (1) They were recently established businesses, (2) they were out of business, or (3) they had recently changed their names or addresses. Because data on revenue or employment size were not available for the nonmatched records, we created an "unknown" stratum for these establishments. The survey of practices collected information on employment that allowed us to classify some of these establishments by size for the analysis.

Of the 1,188 matched records, 180 were linked to parents. The parent company data for these 180 establishments were merged with the survey universe. The remaining 1,008 records did not link to an ultimate parent company. For these records, the establishment and parent company were the same entity, so we used establishment level data to classify size. We classified each of the establishments in the survey universe as part of very small, small, or large businesses based on the employment size or annual revenues of each establishment's parent company. If an establishment or its parent company had 500 or fewer employees or sales less than \$20 million

(if data on employment were not available), then the establishment was classified as small. An establishment was classified as very small if the number of employees was less than 20.

iii. *Survey response.* Table 7 of this document presents the number of establishments surveyed, stratified by the four product types and by size. Although the sample allocation was designed to yield 400 completed surveys, we received only 238 completed mail surveys. The number of respondents was fewer than expected because the number of establishments that were ineligible was greater than we expected and because some establishments did not respond to the survey after agreeing to participate. Ineligible establishments are those that no longer produce dietary supplements because they have gone out of business or changed product lines, or they have moved and could not be located. Despite receiving fewer responses than planned, the confidence level for the final results allowed us to make meaningful inferences regarding the industry. For example, 65 percent of the establishments surveyed responded that they followed published good manufacturing practice models; the 95 percent confidence interval was 56 to 72 percent. By size category, 52 percent of very small, 73 percent of small, and 89 percent of large establishments responded that they followed published good manufacturing practice models (Ref. E2). Although we do not suggest that these percentages are precise, they do tell a plausible story of the current use of good manufacturing practice models in the supplement industry: The use of good manufacturing practice models appears to be widespread but far from universal, with use more likely the larger the establishment.

TABLE 7.—NUMBER OF COMPLETED SURVEYS BY SAMPLING STRATA

Product type	Size				
	Very small	Small	Large	Unknown	Total
Vitamins and minerals	19	39	13	1	72
Amino acids, proteins	8	7	0	5	20
Herbals and botanicals, including extracts	58	25	0	30	113
Supplements not already classified	14	13	2	4	33
Total	99	84	15	40	238

The mean survey results reflect the degree of uncertainty associated with

each practice. The use of a survey for this economic analysis often required

the use of the survey answers from more than one question to assess the impact

³ *InfoUSA* is a publicly held company that creates proprietary business databases. Their database includes such information as: Company name,

address, phone number, fax number, estimated sales, volume, number of employees, type of

business (SIC code or yellow page heading), key contact names, and titles.