

TABLE 6.—COMPARISON OF CONSUMPTION PER PERSON WITH CONSUMPTION PER USER: EVIDENCE THAT THE DIETARY SUPPLEMENT MARKET IS BECOMING BROADER NOT DEEPER—Continued

Average Growth	1994	1995	1996	1997	1998	1999	1994–2000
% Growth	15.48	10.79	9.45	11.60	9.17	11.30
Consumption prevalence (percent)	8.20	12.10	12.10	12.10	28	49
Reference	Ref. E8	Ref. E8	Ref. E8	Ref. E9	Ref. E10	Ref. E7
% Growth	47.56	0.00	0.00	131.40	75.00	50.79
Consumption per user (units)	15.64	12.24	13.56	14.84	7.16	4.47
% Growth	–21.74	10.79	9.45	–51.77	–37.62	–18.18%
C. Supplements Other than Vitamins and Minerals and Herbals and Botanicals							
Per capita consumption (units per U.S. resident)	1.28	1.34	1.44	1.47	1.53	1.58
% Growth	4.53	7.26	2.26	3.95	3.23	4.24
Consumption prevalence (percent)	5.1	8.8	11.2	14.2	18.1	23.0
Reference	Ref. E8	Ref. E8	Ref. E8	Ref. E8	Ref. E8	Ref. E7
% Growth	72.55	27.15	27.15	27.15	27.14	36.23
Consumption per user (units)	25.15	15.24	12.85	10.34	8.45	6.86
% Growth	–39.42	–15.64	–19.58	–18.25	–18.81	–22.34

b. *Manufacturer's baseline practices.* FDA contracted with RTI to conduct a survey of the dietary supplement industry to learn about both baseline (existing) manufacturing practices and the existing standards used for manufacturing dietary ingredients and dietary supplements (Ref. E2). A sample of 966 dietary supplement establishments from the DS–EED database was selected from an estimated eligible population of 1,566 firms in the industry. The sample was stratified by manufacturer's product type and the size of firm in the industry. Stratification helps ensure that estimates of the subpopulations are more precise. Establishments that were stratified by manufacturer's product type were classified as primarily: (1) Vitamins and minerals; (2) amino acids, proteins, or animal extracts; (3) herbals and botanicals; or (4) all other product types not already classified. The product type strata were further stratified by four size categories: (1) Very small, (2) small, (3) large, and (4) unknown. This categorization generated 16 sampling strata.

The contractor, RTI, sent each of the 966 firms in the sample a lead letter on FDA letterhead and a one-page brochure to explain the purpose of the survey, the value of the establishment's participation, and the agency's confidentiality procedures. Following the mailing, RTI placed telephone calls to each establishment to screen for eligibility and to recruit eligible establishments for the mail survey. To be eligible for the survey, establishments had to currently manufacture, repack, supply dietary ingredients, hold, import or export dietary supplements for human consumption. Almost 50 percent of the

establishments sampled were not eligible for the survey because they were no longer in operation at the listed address or did not handle any dietary supplements or ingredients for human consumption.

To achieve the highest possible response rate, RTI operated a toll-free help line and attempted to contact each establishment up to eight times before assigning a disposition of nonresponse. RTI also attempted up to two refusals conversions, which are attempts to persuade firms that declined to answer the survey to respond. The survey was conducted over a 10-week period, November 29, 1999, to February 4, 2000. There were a total of 238 completed surveys, resulting in a final disposition of: (1) An overall eligibility rate of close to 50 percent, and (2) a response rate of 50 percent.

Determining baseline practices is necessary in order to determine the new activities that are likely to take place as a result of implementation of this proposed rule. Each of the new activities potentially brought about by the proposed rule has both a marginal (or incremental) cost and a marginal (or incremental) benefit. These incremental costs and benefits of likely new activities form the basis of our economic analysis of the proposed rule.

The survey asked establishments a series of questions about existing practices; we used the responses to estimate how many establishments in the industry already operated in accordance with the requirements of the proposed regulation. One key assumption in this analysis is that no firms are expected to stop CGMPs and no firms are expected to start good manufacturing practices in the absence of this rule. The universe for the survey

includes the establishments discussed in section VII.B.3 of this document. If firms start good manufacturing practices in the absence of this rule, both the costs and benefits of the rule would be less than we estimate. If firms were to stop in the absence of the rule, both the costs and benefits would be more than we estimate. We lack information about the trend in the industry, so we assumed that the survey reflects both the current and future practices in the industry. We request comment or information about the industry trend in adopting good manufacturing practices.

i. *Stratification.* The survey was stratified by product type and establishment size. Stratification ensures that samples are representative of the industry population.² The subdivisions of the population of interest here were establishment size (by the number of employees) and product type, because these characteristics are likely to influence whether an establishment already has adopted the practices that would be required by the regulation. The DS–EED includes nine product types: (1) Vitamins and minerals; (2) herbals and botanicals; (3) herbal and botanical extracts; (4) amino acids; (5) proteins; (6) animal extracts; (7) tea like products; (8) concentrates, metabolites, or constituents; and (9) supplements not already classified (all other supplements). Establishments may produce more than one product type; establishments with multiple product types were, however, only classified in one category. For stratification and reporting purposes, we defined the

² Stratification is a subdivision of the population of establishments in the dietary supplement industry by a unique characteristic such as product type or number of employees.