

testing techniques (Ref. E2). The problem with this option is that finished product testing alone cannot ensure product quality for some types of products. Not every finished product currently has a test that confirms identity, purity, quality, strength, or composition, especially for multiingredient products. Tests may not have been developed, or they may not be completely reliable, or they may not be capable of evaluating every type of product defect. Also, potentially lower cost alternatives to finished product testing—such as incoming component lot testing, inprocess testing, or both—might be available and desirable to firms as a means to protect the public. Moreover, finished product testing alone is not sufficient to prevent products with microbiological or chemical contamination from being discovered because it is possible that false negatives might occur, as when there is “hotspot” contamination within a batch. Preventative controls must be imposed to achieve that goal. Finally, finished product testing alone also will not facilitate trace backs when defective products are discovered in the marketplace, nor will it facilitate responsible investigations of consumer complaints. The estimated cost of this option is lower than that of the other

options, but it does not generate the full range of benefits provided by the proposed rule.

f. *Regulate only high-risk products.* FDA could propose CGMP regulations that would cover only high-risk products. The advantage of this option is that it would impose lower costs than the proposed rule, but (if all risky products could be identified and regulated) generate the same level of benefits. Only those establishments that manufacture high-risk products or have high-risk hazards would incur the costs of adopting CGMP regulations. High-risk might be defined as those products most likely to be contaminated, or suffer other product defects. There are two problems with this option. Adverse event reporting is not mandatory, so significant underreporting is expected. Also, it is possible that the confirmed illnesses and other problems linked to particular dietary supplements may be those most easily traced, rather than those with the highest risk. High levels of identified problems may not be closely correlated with high levels of risk. In other words, problems associated with the known defective products may or may not be correlated with the highest risk. Without more data and risk assessments, it would be difficult to distinguish what risks may be associated with particular dietary

supplements. We therefore have no basis upon which to begin a full evaluation of what the high-risk products are or may be.

### 3. Coverage of the Proposed Rule

The proposed rule would cover establishments that manufacture, package, hold dietary ingredients or dietary supplements. Tables 2, 3, and 4 of this document list the estimated number of covered manufacturers, packagers, dietary ingredient suppliers, holders, and other establishments. Table 2 of this document shows the number of covered establishments by product type and size. A small business, based on the Small Business Administration definition, is any firm with 500 or fewer employees. For purposes of analysis, we defined very small establishments as having fewer than 20 employees. Table 3 of this document shows the number of establishments categorized as manufacturers, ingredient suppliers, repackers or relabelers, holders whose primary business is dietary ingredients or dietary supplements, and other (although not including other holders and distributors). Table 4 of this document shows our estimate of the number of general warehouses and wholesalers that hold dietary supplements.

TABLE 2.—COVERED ESTABLISHMENTS BY PRODUCT TYPE AND SIZE FROM DIETARY SUPPLEMENT ENHANCED ESTABLISHMENT DATABASE (DS-EED)

Product type	Very small	%	Small	%	Large	%	Unknown	%	Total
Vitamins and Minerals .....	252	29.8	223	26.5	78	9.2	290	34.5	843
Amino Acids, Proteins .....	21	31.0	16	23.0	6	6.9	27	39.1	69
Herbals and botanicals .....	148	42.6	46	13.2	5	1.1	150	43.1	348
Supplements not already classified .....	93	30.4	66	21.6	20	6.5	127	41.6	306
Total .....	514	32.8	351	22.4	106	6.8	594	38.0	1,566

TABLE 3.—COVERED ESTABLISHMENTS BY TYPE OF OPERATION FROM DS-EED

Establishment type	Number of establishments	Percent of establishments
Manufacturer .....	1,228	78.4
Dietary ingredient supplier .....	106	6.7
Repacker; relabeler .....	26	1.7
Holder .....	114	7.3
Establishments not already classified .....	92	5.9
Total .....	1,566	100.0

TABLE 4.—COVERED ESTABLISHMENTS THAT HOLD DIETARY SUPPLEMENTS

Type of holders	Source and SIC code	Number of establishments
Grocery Wholesalers or Drug Wholesalers .....	Dunn and Bradstreet: 5122, 5141 .....	25,527
Food or Drug Warehouse .....	Dunn and Bradstreet: N/A .....	738
Miscellaneous Food or Drug Warehouse .....	Dunn and Bradstreet: 4225, 4226, 5912, 5499, 5411, 5122, 5141, 5149, 5399, 5311, and 5331.	238