

TABLE 4.—COVERED ESTABLISHMENTS THAT HOLD DIETARY SUPPLEMENTS—Continued

Type of holders	Source and SIC code	Number of establishments
Dietary Supplement	DS—EED	114
Total	26,617

We consulted several sources to estimate the number of establishments reported in tables 2, 3, and 4 of this document. The number shown in tables 2 and 3 of this document, 1,566, is the estimated number of establishments in the DS—EED that manufacture, repack, supply dietary ingredients, or hold dietary supplement products in the United States. RTI developed the DS—EED using FDA's Official Establishment Inventory (OEI) and supplemented that source with information from trade organizations, trade shows, and electronic databases (Refs. E1 and E2).

The number of establishments in the DS—EED that hold dietary supplements is not the total number of holders covered by the proposed regulation. The holding establishments in the DS—EED identified holding dietary supplements as their primary business. To estimate the total number of establishments that could hold dietary ingredients or dietary supplements but do not consider dietary supplements as their primary business, we performed three searches of firms that are listed with Dun and Bradstreet's Dialog database. We first looked for a count of firms that had standard industrial classification (SIC) codes for wholesalers of groceries or drugs. Next we looked for a count of firms that met the description of warehouses of groceries or drugs (no SIC codes were used). Finally, we looked for a count of any firms that had both warehouse SIC codes and miscellaneous drug stores, food stores, sundries, and general merchandise (SIC 4225, 4226, 5912, 5499, 5411, 5122, 5141, 5149, 5399, 5311, and 5331). The results are shown in table 4 of this document. We concluded that the total number of establishments in this category that could hold dietary ingredients or dietary supplements and would be covered by the regulation was approximately the sum of the numbers counted in the three searches, or 26,617.

The number of establishments that hold dietary ingredients or dietary supplements includes retailers that sell dietary supplements to consumers, and transporters of dietary ingredients and dietary supplements. We made no effort to determine the number of such holders, because the proposed

requirements do not apply to retailers and transporters. We believe that retailers and transporters may voluntarily adopt provisions related to the holding of these products and thus there may be changes in the marketplace with accompanying costs and benefits. However, we expect that the only retailers and transporters that will voluntarily adopt the proposed requirements are those that expect the private benefits of adoption will exceed the private costs.

4. Baseline Practices

a. *Consumer baseline practices.*
Baseline consumer and manufacturer practices, governed by current market forces and existing government regulations, give rise to the current risks associated with the manufacturing of dietary supplements. When determining baseline manufacturing practices, it is necessary to estimate both the practices that are used now, as well as the likely changes in manufacturing practices that will occur even in the absence of new regulations. The risks to consumers from these products can be associated with a combination of consumption habits, the contamination of the products, or both. Contamination may be caused by current manufacturing practices. Consumption is influenced by the price and quality of dietary supplements, set by the interaction of market participants. Finally, changes in practices of either consumers or manufacturers caused by new regulatory requirements will give rise to changes in risks, as estimated by changes in costs and benefits.

The consumption of dietary supplements has grown in recent years. Consumers report that they are using a wider range of product types, and that they are using dietary supplements for more reasons than they were in the past.

Table 5 of this document illustrates the rapid sales growth of the dietary supplement industry from 1994 to 2000. Panel A of table 5 of this document shows annual sales of three general categories of dietary supplements, a measure of the market size of the supplement industry. Annual increases in sales of herbals and botanicals were the greatest, averaging 18 percent per year, while annual increases in sales of

supplements that were neither vitamins and minerals nor herbals and botanicals increased less, averaging 11 percent per year. The lowest annual sales increases were for vitamins and minerals, averaging 8 percent per year. For all dietary supplements combined, sales increased an average of 12 percent a year since 1994 (not shown on the table).

While the sales growth shown in table 5 of this document, Panel A, is impressive, only part of this apparent growth represents increased use. Population growth and rising prices also contributed to the apparent growth. The real (growth inflation-adjusted) increase in dietary supplement prices is estimated by subtracting the inflation rate from the rate of price increases of dietary supplements (Ref. E4). As shown in table 5 of this document, Panel B, between 1995 and 1997 the real price of vitamins and minerals and supplements other than vitamins and minerals all increased. Rising real price indicates that demand is growing rapidly.

Table 5 of this document, Panel C, shows estimated annual increases in per capita consumption of dietary supplements.¹ As shown in table 5 of this document, Panel C, the estimated per capita consumption of the different categories of dietary supplements has increased since 1994.

For the consumption estimates in table 5 of this document, we averaged dietary supplement use over the entire U.S. population, 275 million. In table 6 of this document, we included estimated average supplement use for the population of supplement users, 160 million (Ref. E13). The three panels in table 6 of this document show the annual consumption per supplement user and the annual change in consumption per supplement user for

¹ An index measuring per capita consumption of dietary supplements can be derived using the following equation: $PCC_t = [1,000 \times Sales_t] / [POP_t \times P_t]$, where, t = year index; PCC_t = per capita consumption (# of unit sales); $Sales_t$ = millions of dollars of sales; POP_t = thousands of U.S. residents; P_t = average price of supplement. In the formula, we measure consumption as the number of dietary supplement units (bottles, packages, etc.) sold per U.S. resident for a given year.