October 1999

Dietary Supplement Sales Information

Contract No. 223-96-2290: Task Order 4

Final Report

Prepared for

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1 Introduction

The Food and Drug Administration (FDA) needs sales information on dietary supplements to perform its regulatory mission under the Dietary Supplement Health and Education Act of 1994 (DSHEA), signed by the President on October 25, 1994. Provisions of DSHEA define dietary supplements and dietary ingredients and describe the proper use of statements of nutritional support. DSHEA also sets forth new labeling requirements and requires manufacturers of dietary supplements to notify FDA of new dietary ingredients prior to marketing. It also authorizes the Secretary of Health and Human Services to regulate dietary supplements and to prescribe good manufacturing practices (GMPs) for the industry.

FDA contracted with Research Triangle Institute (RTI) to survey dietary supplement products according to a statistical sampling plan and to provide a database containing information on dietary supplement products. This report documents the procedures we used to select a sample of approximately 3,000 dietary supplements sold in the United States through retail establishments, mail-order catalogs, and the Internet. It also describes the database—referred to as the Dietary Supplement Product Database (DSPD)—that contains the information collected on each of these products and provides a summary of the information in the database.

1.1 STUDY OBJECTIVES

The objective of this project was to collect information on dietary supplement products sold in the United States and to create a database containing the information collected from product labels,

catalogs, and Internet sites. We collected information at the "point of sale," the point at which consumers decide whether to purchase a product based on the information from the label, catalog, or Internet site. The database includes information such as the product's name, the name and address of the manufacturer or distributor, the product's ingredients, and claims about the product. Claims may be about the health benefits or nutrient content of the product or may be nutritional support statements. Thus, the database provides information on the range of products available for sale in the United States, where these products are sold, what they contain, and what claims are being made about these products. This study included both

- "purchased products," which were dietary supplements purchased from retail establishments according to a statistical sampling plan, and
- "nonpurchased products," which were dietary supplements selected from mail-order catalogs and Internet sites according to a statistical sampling plan. We collected information on these products but did not actually purchase them. These included products sold by multilevel marketers (MLMs).

For the purposes of this study, we used the DSHEA definition of dietary supplements. According to this definition, dietary supplements can be vitamins, minerals, herbals and botanicals, herbal and botanical extracts, animal extracts, amino acids, proteins, concentrates, metabolites and constituents, teas, or other miscellaneous products. Dietary supplements by definition must be taken orally. They come in many dosage forms, including pills, liquids, powders, or granules. They do not include food products or products intended to replace a meal.

1.2 OVERVIEW OF THE REPORT

This report is organized as follows. Section 2 describes the sampling plan used for purchasing products from retail outlets and for selecting products from mail-order catalogs and Internet sites. It also describes the sources from which we drew the samples. Section 3 describes in detail the procedures we followed for purchasing and selecting products. Section 4 describes the structure of the DSPD and includes descriptions of the variables, tables, and forms that make up the database. It also describes how

we constructed categories for grouping types of ingredients and claims. Finally, Section 5 provides descriptive tables of the information contained in the DSPD.

A supplement to this report contains lists of the stores, Internet sites, and catalogs from which we obtained the products or the product information. It also contains copies of the instructions, definitions, and forms that we provided to the field shoppers who purchased the products at retail outlets and copies of the worksheets used to select products from catalogs and Internet sites.

2 Sampling Plan

We developed a sampling plan for purchasing dietary supplement products from retail outlets and for selecting nonpurchased products sold by mail-order catalogs or through the Internet. The data that we collected according to this sampling plan will be useful for qualitative analyses of products and claims. However, these data are not useful for making quantitative inferences about the population of dietary supplements because the sample size is too small. In this section, we describe the sampling plan for purchased and nonpurchased products.

2.1 SAMPLING DESIGN FOR PURCHASED PRODUCTS

This section describes the statistical methods that we used for randomly selecting products to be purchased for this study. We considered all retail outlets that sell dietary supplements in counties within metropolitan statistical areas (MSAs) or consolidated metropolitan areas (CMSAs) to be part of the survey population. For cost efficiency, we limited the survey to the 48 coterminous United States and the District of Columbia. We expected dietary supplements found in retail stores in Alaska and Hawaii to be the same as those in the survey population. Furthermore, approximately 80 percent of U.S. residents live in metropolitan areas. The sampling design for purchased products was multistage and includes the following three stages: county selection, retail establishment selection, and product selection. The following sections describe each stage.

2.1.1 First-Stage Sampling Design–Counties

The first stage of sampling was to select a sample of ten counties. We refer to counties as primary sampling units (PSUs). To select counties, we purchased data from InfoUSA, formerly American Business Information (ABI). This sample frame listed the total number of stores for each target Standard Industrial Classification (SIC) code operating within each PSU.

The target SIC codes that cover grocery stores, drug stores, health food stores, and mass merchandisers include the following:

5399-01 General Merchandise—Retail[1]

5411-05 Grocers—Retail

5499-01 Health Foods—Retail

5499-04 Vitamins—Retail

5499-13 Herbs—Retail

5912 Drug Stores

After purchasing this list of stores for each target SIC, we discovered that SIC code 5912 included some types of drug stores that probably do not sell dietary supplement products. Therefore, we specified that only the following SIC codes in target SIC code 5912 should be included:

5912-01 Medicines, Patents, and Proprietary

5912-02 Health Care Products

5912-03 First Aid Supplies

5912-05 Pharmacies

We excluded the following SIC codes from target SIC code 5912:

5912-04 Elastic Stockings

5912-06 Toilet Articles

5912-07 Pharmaceutical Consultants

5912-09 Allergy Resistant Products

5912-13 Suntan Supplies

As part of the first stage of sampling, we calculated the national sampling rate for each target SIC code. The national sampling rate

[1]As described in the second-stage sampling design, general merchandise stores were eventually dropped from the sampling plan. Upon review of the list, we discovered that these stores probably do not sell dietary supplements (e.g., dollar stores, beauty supply stores).

is the fraction of establishments in the country that are in the sample. We determined the national sampling rate for each target SIC code as follows. We divided the desired sample size for retail outlets from each SIC code by the total number of establishments in that SIC code, for all PSUs, as shown below:

$$f_d = \frac{m_d}{\sum_{i=1}^{N} C_{di}} \qquad (2.1)$$

where

f_d = the national sampling rate for target SIC code d;

m_d = the desired sample size for retail outlets from SIC code d:[2]

= 16 for SIC codes 5399-01 and 5499-04, and

= 17 for SIC codes 5411-05, 5499-01, 5499-13, and 5912;

C_{di} = the number of stores in target SIC code d in PSU i; and

N = the number of PSUs, which is 844.

Next, we calculated a composite measure of size (MOS) for each PSU. As the name indicates, this is a measure of the relative size of each PSU. The calculation of MOS uses the national sampling rate, which is explained above. To calculate the MOS for each PSU, we multiplied the national sampling rate by the number of stores in that PSU for each SIC code, then summed the products, as shown below:

$$MOS_i = \sum_{d=1}^{D} f_d * C_{di} \qquad (2.2)$$

where

MOS_i = the composite measure of size for PSU i,

D = the number of target SIC codes,

[2]To calculate the desired sample size from each SIC, we started with 100, the total number of stores to be sampled, and divided by 6, the number of target SIC codes. The resulting number is 16.67. To add up to a total sample size of 100, two of the SIC codes must have a sample size of 16, and four must have a sample size of 17. Half of the stores sampled must be health food stores, and half must be nonhealth food stores. We randomly selected one health food SIC (vitamin stores) and one nonhealth food SIC (general merchandise) to have a sample size of 16 and gave the remaining four SIC codes a sample size of 17.

f_d = the national sampling rate for target SIC code d, and

C_{di} = the number of stores in target SIC code d in PSU i.

We calculated the composite MOS for all 844 PSUs. Then we sorted (stratified) these 844 PSUs into the four census regions (Northeast, Midwest, South, and West) and then sorted (stratified) them by state. Next, we calculated the relative size of each region by summing their composite MOS figures. Based on region size, we allocated the total sample size of ten PSUs to the four geographic regions. This produced a sample size of two from the Northeast and Midwest regions and a sample size of three from the South and West regions.

Using a procedure developed at RTI, known as "probability minimum replacement" (PMR) (Chromy, 1979), we selected the following ten counties:

- New York County, New York
- Middlesex County, Massachusetts
- Cook County, Illinois
- Jasper County, Missouri
- Montgomery County, Maryland
- Lexington County, South Carolina
- Dade County, Florida
- Alameda County, California
- Orange County, California
- San Francisco County, California

2.1.2 Second-Stage Sampling Design– Retail Establishments

In the next step, we selected a sample of establishments within each of the ten PSUs. We purchased detailed information from InfoUSA on all establishments in the target SIC codes for the ten sample PSUs. This information included the address and telephone number for each store. After purchasing this list, we looked at the names of the general merchandise stores and determined that most of them probably did not sell dietary supplement products. Therefore, we excluded the SIC code for general merchandise stores (5399-01) from the study.

For each of the ten sample PSUs, we stratified (sorted) the stores by SIC code and then sorted by store name within the SIC code. We determined how many stores to select from each SIC code within each PSU as follows:

$$n_{di2} = n_2 \frac{f_d * C_{di}}{MOS_i} \quad (2.3)$$

where

- n_{di2} = the number of stores to be selected from target SIC code d in PSU i,
- n_2 = the total number of stores to be selected from each sample PSU,
- f_d = the national sampling rate for target SIC code d,
- C_{di} = the number of stores in target SIC code d in PSU i, and
- MOS_i = the composite measure of size for PSU i.

We made several adjustments to the number of stores selected from each SIC code in each PSU (n_{di2}). We adjusted n_{di2} to ensure that each PSU had at least one sample store from each SIC code. We also rounded n_{di2} to the nearest integer and then made adjustments so that the sum of n_{di2} equaled n_2 for each PSU. We increased n_{di2} for grocery and drug stores to account for the exclusion of general merchandise stores.

Our goal was for the total number of stores selected from each PSU to be equal to ten (n_2 =10). While conducting the pilot test in New York, we discovered that many of the stores do not sell dietary supplement products. This was especially true for grocery stores. Therefore, we had to greatly increase the sample size (n_2) to be sure that the sample included at least ten eligible stores.

We increased the sample size (n_2) by multiplying the desired sample size for each SIC code (n_{di2}) by 7 for grocery stores and by 5 for all other store types. This produced a sample that was large enough to allow shoppers to replace ineligible stores. We used the larger multiplier for grocery stores to allow for the larger proportion of ineligible stores. In three cases, it was necessary to select all stores of a certain type in a PSU because there were so few stores of that type.

We selected a systematic sample of n_2 stores from the appropriate SIC codes for each PSU. Then, we randomly selected ten stores from the total sample (n_2) for each PSU. Shoppers started with these ten stores. We sorted the remaining stores in the total sample by SIC code and then randomized them. We gave the lists of remaining stores to the project manager at SPAR/Burgoyne, a New Jersey based market research firm, to use to replace ineligible stores.

If the project manager or shopper identified any ineligible stores, then the SPAR/Burgoyne project manager selected replacement stores from those remaining on the list. The project manager classified a store as ineligible if it did not sell dietary supplements; if nobody at the store spoke English; or if it had closed, moved out of the county, or merged with another store. The shopper also classified a store as ineligible if the store manager asked the shopper to leave, if the store was located in a dangerous area, or if the store was far from the other stores in the PSU. A store that moved within the county but was otherwise unchanged remained eligible.

If the SPAR/Burgoyne project manager exhausted the list of replacement stores, we provided an additional list of randomly selected stores. For several PSUs, we did not have enough herb or vitamin stores to reach the required number of eligible sample stores of that type, so we substituted health food stores.

We purchased products from ten stores in each of ten PSUs for a total of 100 stores. The method described above to determine and adjust n_{di2} gave us a total sample of 50 health food stores (SIC codes 5499-01, 5499-04, and 5499-13) and 50 nonhealth food stores (SIC codes 5411-05 and 5912). However, we did not always have five health food stores and five nonhealth food stores in each PSU.

2.1.3 Third-Stage Sampling Design– Products

In the third stage, we prepared procedures and forms for selecting a sample of products from each store. To develop the procedures and forms, we visited a health food store and a grocery store and consulted with SPAR/Burgoyne to determine a feasible method of selecting the dietary supplement products in each type of store. We

divided the health food and nonhealth food stores into three size categories based on the quantity of dietary supplements sold:

- ➤ Small nonhealth food stores—five or fewer shelves
- ➤ Small health food stores—15 or fewer shelves
- ➤ Medium nonhealth food stores—more than five shelves but five or fewer sections
- ➤ Medium health food stores—more than 15 shelves but 15 or fewer sections
- ➤ Large nonhealth food stores—more than five sections
- ➤ Large health food stores—more than 15 sections

We created a separate form for each of the six categories above. Each form had instructions for selecting sections, shelves, and/or products, depending on the store size. We used systematic and random sampling within stores so that we could avoid bias in selecting products.[3] For health food stores (SIC codes 5499-01, 5499-04, and 5499-13), the product sample size was 15, and for nonhealth food stores (SIC codes 5411-05 and 5912), the product sample size was five. These sample sizes yielded more products from health food stores than from nonhealth food stores. Shoppers purchased 15 sample products in health food stores if the total cost was below a fixed limit of $250 and purchased five sample products in nonhealth food stores if the total cost was below a fixed limit of $50. If the total cost before tax exceeded the limit, the shopper omitted the most expensive product or products from the sample until the cost was below the limit.

For the small stores, the shoppers counted the total number of dietary supplements and then selected a systematic sample of products. For medium stores, they first counted the number of shelves and selected a systematic sample of shelves. Then they counted the number of products on each sample shelf and randomly selected one product per sample shelf. For large stores, the shoppers first counted the number of sections and selected a systematic sample of sections. Then they counted the number of shelves in each sample section and randomly selected one shelf per

[3]An example of selecting a systematic sample would be to choose every nth item from a group. An example of selecting a random sample would be to count the number of items in a group (assume 25 products), multiply that number by a random number less than one (assume 0.20), and select the corresponding item (25 X 0.20 = 5; select item 5).

sample section. Finally, they counted the number of products on each sample shelf and randomly selected one product per sample shelf.

Shoppers ignored any out-of-stock products (i.e., products usually sold but not currently on the shelf) while counting products. We considered each different type of package as a separate product so that the shoppers did not have to determine if two packages were really the same product in two different size containers or different formulations (e.g., liquid and capsule). The shoppers counted SKUs (store keeping units), so products with multiple facings on a shelf counted as one product.

Shoppers counted each free-standing store display as one shelf. Because it would be too time-consuming to determine whether items on free-standing displays were also on shelves, the shoppers were not be required to do so. Thus, some products may have had more than one chance of being selected. However, if the shopper selected a product twice, they considered the second item to be ineligible and replaced it with the next eligible product on the shelf.[4]

If a shelf or section of shelves contained at least one dietary supplement, then the shoppers considered it to be eligible. Because it was not practical for shoppers to count only eligible products, they checked a product for eligibility only after they selected it. If the shopper determined that a selected product was ineligible, they replaced it with the next eligible product on the shelf.

2.2 SAMPLING DESIGN FOR NONPURCHASED PRODUCTS

We also sampled dietary supplement products from mail-order catalogs and Internet sources (including multilevel marketers, or MLMs). We did not actually purchase these products. The

[4]Replacing an ineligible product with the next eligible product on the shelf doubles the probability of selection for any product for which the previous product was ineligible. Since we expected there to be few ineligible products selected and we are not computing weights for products selected in retail stores, we decided to follow this procedure so that we could purchase a maximum number of products.

following section describes the sampling design for these nonpurchased products.

2.2.1 Mail-Order Catalog Sources

We ordered dietary supplement catalogs from the *1998 Directory of Mail Order Catalogs* and from Internet catalog sites. We collected a total of 57 unique catalogs that carry dietary supplement products. We selected a total of 1,020 products. If a catalog had 24 or fewer products, then we selected all products. For catalogs with more than 24 products, we selected a sample of 24 products using a sampling worksheet similar to the one developed for stores to select a sample of products. If the catalog had more than 24 products but 12 or fewer pages, then we counted the number of dietary supplement products and selected a systematic sample of products. If the catalog had more than 24 products and more than 12 pages, then we counted the number of pages, selected a systematic sample of 12 pages, counted the number of products on each sample page, and selected a simple random sample of two products from each sample page. We included all eligible sample products, although some sample products may have had little information.

2.2.2 Internet Sources

On October 1, 1998, we conducted an Internet search for sites related to dietary supplements. We listed the first 1,000 sites generated by this search. Several sites appeared on the list more than once. After removing duplicates, we had a list of 987 sites, including sites of MLMs. We randomly ordered the sites on this list as follows. We used Excel to assign a random number to each site. Then we sorted the list of sites by random number. Our goal was to select 20 products from each of 50 sites. Starting with the first site on the randomized list, we began to select products. If a site sold 20 or fewer products, we selected all of the products at that site. If the site sold more than 20 products, we randomly selected 20 products from that site. This procedure is described below.

If a site was ineligible, we moved to the next site on the list. We considered a site to be ineligible if none of the products being sold were eligible dietary supplements, or if the site was not an actual point of sale. We also skipped sites for which we had a

corresponding catalog. We continued this process until we selected approximately 1,000 products.

To select products from sites with more than 20 products, we used a sampling worksheet similar to the one used to select products from catalogs. We started by printing a list of all products sold at each site. If we were able to divide this list into more than ten sections, we did so (a section might be a page or a category of products). We considered these sites to be large. After counting the total number of sections, we selected a systematic sample of ten sections. For each of these ten sample sections, we then counted the total number of products and selected a simple random sample of two products. If the list of products from a site was too small to be divided into more than ten sections, we considered this site to be small. For these sites, we simply counted the number of dietary supplement products and selected a systematic sample of 20 products. By following these procedures, we selected a total of 1,007 products from 77 sites.

3 Selection and Purchase of Dietary Supplement Products

This section describes in detail the procedures we followed for purchasing dietary supplement products from retail outlets and for selecting products from catalogs and Internet sites according to the sampling plan described in Section 2.

3.1 PURCHASING PRODUCTS FROM RETAIL OUTLETS

For this study, RTI contracted with SPAR/Burgoyne to purchase dietary supplements from retail outlets. SPAR/Burgoyne maintains a network of more than 800 shoppers dispersed throughout the United States and has conducted hundreds of compliance checks and monitored stocking conditions for both government agencies and private firms.

Before purchasing products throughout the country, we first pilot-tested the survey procedures, which allowed us to refine field procedures and get better estimates of field costs. Because SPAR/Burgoyne's main office is in New Jersey, we conducted the pilot test in the New York PSU so that SPAR/Burgoyne's project manager could be involved. The shoppers purchased dietary supplement products from retail outlets that included grocery, drug, health food, and vitamin and herb stores. Mass merchandisers such as K-Mart and Wal-Mart were also included; they are classified as drug stores under the SIC system. We include data for the products from the pilot test in the database (see Section 4) along with the data from all of the remaining PSUs.

We provided SPAR/Burgoyne with detailed instructions for their shoppers to follow and worksheets for them to complete so that they could randomly select products in accordance with the sampling plan described in Section 2. We also provided shoppers with definitions of dietary supplement products to assist them in determining whether items were eligible. SPAR/Burgoyne conducted the pilot test in New York in February 1999. Using feedback from shoppers, we refined the instructions and worksheets before proceeding with the remaining nine PSUs.

We then gave SPAR/Burgoyne lists of names, addresses, and phone numbers for stores in each of the nine remaining PSUs. From their headquarters in New Jersey, SPAR/Burgoyne telephoned each store to determine its eligibility. They ascertained whether each store was open, had English-speaking employees, and carried dietary supplement products. Shoppers then started visiting stores. They completed shopping in the remaining PSUs during a 3-week period in March 1999.

Upon entering each store, shoppers completed the appropriate worksheets. RTI provided separate worksheets for each of the six different types of stores—small, medium, and large health food stores and small, medium, and large nonhealth food stores. The completed worksheets indicated a random selection of products to purchase. In several instances, store managers asked shoppers to leave before they were able to purchase products. When this happened, the shoppers replaced the store with another of the same type from the list.

We instructed shoppers not to purchase duplicate products. If they selected a product twice, they replaced the second one with the next eligible product on the shelf. Also, if the cost of the selected items exceeded a dollar limit ($250 for health food stores and $50 for nonhealth food stores), shoppers returned the most expensive product or products to the shelf until the cost of selected items was below the limit. Shoppers rarely exceeded the dollar limit. Only 11 products had to be returned because they exceeded the limit.

RTI provided the shoppers with pairs of numbered identification labels to be used for tracking purposes. Once shoppers made their final selections, they placed one label on the product and a matching label on the worksheet. We instructed the shoppers to

pick up any pamphlets or additional literature accompanying selected products and include these along with the products. SPAR/Burgoyne then packed and shipped all products, along with receipts and worksheets, to RTI.

When the products arrived at RTI, we accounted for all products by comparing the identification labels on the products with those on the worksheets and by comparing the products with the receipts. All except three products arrived intact. These three products were lost because a box was damaged in shipping. None of the products came with pamphlets or supplemental literature. We transferred a total of 986 products to RTI's data preparation and entry center.

Upon reviewing the products, we discovered a few products were not actually dietary supplements. These were either homeopathic remedies or tea products without dietary supplement ingredients. After eliminating these ineligible products, 970 purchased products remained.

3.2 SELECTING NONPURCHASED PRODUCTS

This section describes how we selected products from catalogs and Internet sites. We did not actually purchase any products from these sources, but we used them to collect data on the types of information presented at the point of sale.

3.2.1 Selecting Products from Catalogs

Our goal was to randomly select a sample of 50 catalogs from all catalogs that sell dietary supplements and then to select 20 products from each of these catalogs for a total of 1,000 dietary supplement products. We requested catalogs from the *1998 Directory of Mail Order Catalogs* and from Internet catalog sites. We eventually obtained 57 unique catalogs. When we began selecting products from catalogs in February 1999, we used the most recent catalog received from each company. When a single company sent out multiple catalogs (not just the same catalog with different dates), we treated the catalogs as a single catalog for the purposes of selecting products.

Many of these catalogs contained fewer than 20 products. To reach our goal of approximately 1,000 products, we used all of the catalogs that we received and increased the number of products

selected from a single catalog from 20 to 24. If a catalog contained 24 or fewer products, we selected all of the products from that catalog. If a catalog contained more than 24 products, we selected a sample of 24 products using the procedure outlined in Section 2.

We attempted to eliminate ineligible products or pages before beginning the process of counting. If, however, we still selected a product that was not an eligible dietary supplement or was a duplicate, we selected the next eligible product in the catalog. We labeled all selected products, assigned identification numbers to each catalog, and delivered them to RTI's data preparation and data entry center.

3.2.2 Selecting Products from Internet Sites

To select a sufficient number of products from catalogs, we had to use all of the catalogs that we could obtain. This was not the case with Internet sites, however. There are literally thousands of sites related to dietary supplements, and many of these contain point-of-sale information.

As described in Section 2, we conducted a search for Internet sites related to dietary supplements and listed the first 1,000 sites generated by this search. Removing duplicates yielded a list of 987 sites, including sites of MLMs. We then randomized the order of these sites on the list, as explained in Section 2.2.2. Starting with the first site on the randomized list, we verified the site's eligibility. If it was a point of sale for dietary supplements and we did not have a corresponding catalog, we began to select products. We selected all of the products from sites with 20 or fewer items and a sample of 20 products from sites with more than 20 items. Section 2 describes the selection process in detail. As with catalogs, we attempted to eliminate ineligible products prior to counting but selected the next eligible product if the selected product was not an eligible dietary supplement product. We selected a total of 1,007 products from 77 Internet sites.

We printed all currently available information that was directly related to each selected product. Some sites provided very limited information. Many sites did not provide an address or telephone number, and in some cases, links within a site did not function properly, making it impossible to gather detailed product information. Some of the sites in our sample provided a complex

network of links to other sites, each containing extensive literature on subjects relating to dietary supplements. Because this study concerns information available at the point of sale, we limited the material printed to information contained within the original sample site.

After printing all relevant information, we attached labels to identify each selected product. We then reviewed all the printed material and, where possible, highlighted the first ten claims listed for each product. These records were then entered in RTI's Center for Economics Research.

4 Developing the Database Structure

We used Microsoft Access to enter and store data on purchased and nonpurchased dietary supplement products. The DSPD includes the variables needed to support the kinds of analyses FDA expects to undertake and will allow FDA to add more data in the future. The database user is able to

- sort the products by retail outlet (e.g., store, catalog, Internet site);
- sort the products by type of ingredients;
- sort the products by type of claims made;
- examine whether certain categories of products tend to make particular claims;
- observe whether products are in compliance with new labeling requirements; and
- determine whether compliance varies by manufacturer or distributor, geographic area, or product category.

The following section describes how we constructed the DSPD.

4.1 DEVELOPING THE DATA COLLECTION INSTRUMENT

We started by developing a data collection instrument that would allow us to extract the required information from both purchased and nonpurchased products. This instrument collected the following information:

- who entered the record (RTI, FDA, or other)
- source of the record (product label, Internet site, or catalog)

- date product was acquired (For purchased products, this is the date of purchase. For catalogs, this is the date on the catalog or the postmark. For Internet sites, this is the date that the site was accessed.)
- date entered
- brand name
- name of the product
- UPC
- sticker number (unique identifier for each product)
- name, address, and phone number of store, catalog company, or Internet company
- store SIC code
- web address
- name, address, and phone number of manufacturer if different from above
- dosage form (tablet, caplet, capsule, liquid, powder or granule, lozenge, loose leaves, teabags, or other)
- quantity
- units of measure (ounces, milligrams, count)
- Mg or IUs per dose
- daily dose
- price
- whether the label includes the statement: "These statements have not been evaluated by the FDA. Not intended to diagnose, treat, cure, or prevent any disease."
- whether the label says "supplement" (May say "dietary," "vitamin," "food," "nutritional," "herbal," or other together with the word "supplement.")
- whether the product includes a "Supplement Facts" box
- whether the product includes a "Nutrition Facts" box
- types of claims (see Section 4.5.1)
- whether the product includes FDA-approved claims linking calcium and osteoporosis, soluble fiber from whole oats and psyllium and coronary heart disease, folate and neural type defects
- first ten claims
- number of ingredients

- types of ingredients (see Section 4.5.2)
- first 30 ingredients

We tested the data collection instrument repeatedly on a number of product labels and on products from catalogs and Internet sites. We refined the instrument to ensure that it would collect all of the necessary information.

4.2 CONSTRUCTING THE PRODUCT TABLE

Based on the data collection instrument, we constructed a list of variables. These variables make up the fields in the table that Microsoft Access uses to store data; this table is labeled "product table." Table 4-1 contains the names of all variables in the product table. It also lists the format for each variable (e.g., text, date, yes/no, currency) as well as brief descriptions of the variables.

4.3 CONSTRUCTING THE PRODUCT FORM

Access provides the ability to design a form for data entry. This form can be configured to look like a questionnaire. Data entry operators tab through the form and answer the questions as they appear. Once they have completed a record, they move to the next blank form. Access automatically enters the data into a table. Figure 4-1 presents the form, referred to as "Product Form," that we used to enter data for this study. Access stores data entered into the product form in the product table. The questions in the product form are in the same order as the original data collection instrument. We set up the tab order so that it flowed logically and included visual dividers to group together related types of questions.

4.4 CONSTRUCTING DROP-DOWN BOXES

To facilitate data entry, we included drop-down boxes on the product form wherever possible. Drop-down boxes allow the data entry operator to choose from a list of responses, rather than type in data. For each drop-down box, Access requires a separate table containing a list of possible responses.

Table 4-1. Variable Descriptions

Variable Name	Format	Description
		Product Identification
Record Number	Autonumber	Observation number automatically entered by Access
Entered By	Text	Was the record entered by RTI, FDA or Other?
Source of Record	Text	Is this record from a Product Label, Catalog, or Website?
Date Entered	Date/Time	Date the record was entered into the database—automatically entered by Access
Date	Date/Time	Date on which the product was acquired
Brand Name	Text	Brand name of the product
Product Name	Text	Name of the product
UPC Code	Text	Universal Product Code (Number under bar code)
Sticker No	Text	Number on RTI sticker —unique identifier for record
		Information on Retailer
Store Name	Text	Name of the store/catalog/website that sold the product
Retailer Address	Text	Street address
Retailer City	Text	City
Retailer State	Text	State
Retailer Zip Code	Text	Zip code
Retailer Phone	Text	Phone number
Retailer SIC Code	Text	Standard Industrial Classification Code
Web address	Text	Internet address
		Information on Manufacturer or Distributor
Company Name	Text	Name of the manufacturer/distributor if different from retailer
Division	Text	Division of the company
Company Address	Text	Street address
Company City	Text	City
Company State	Text	State
Company Zip Code	Text	Zip code
Company Country	Text	Country
Company Phone	Text	Phone number
		Information on Dosage Form, Quantity and Price
Dosage Form	Text	Dosage form of the product (e.g., capsule, tablet)
Units per Package	Text	Quantity per package

(continued)

Table 4-1. Variable Descriptions (continued)

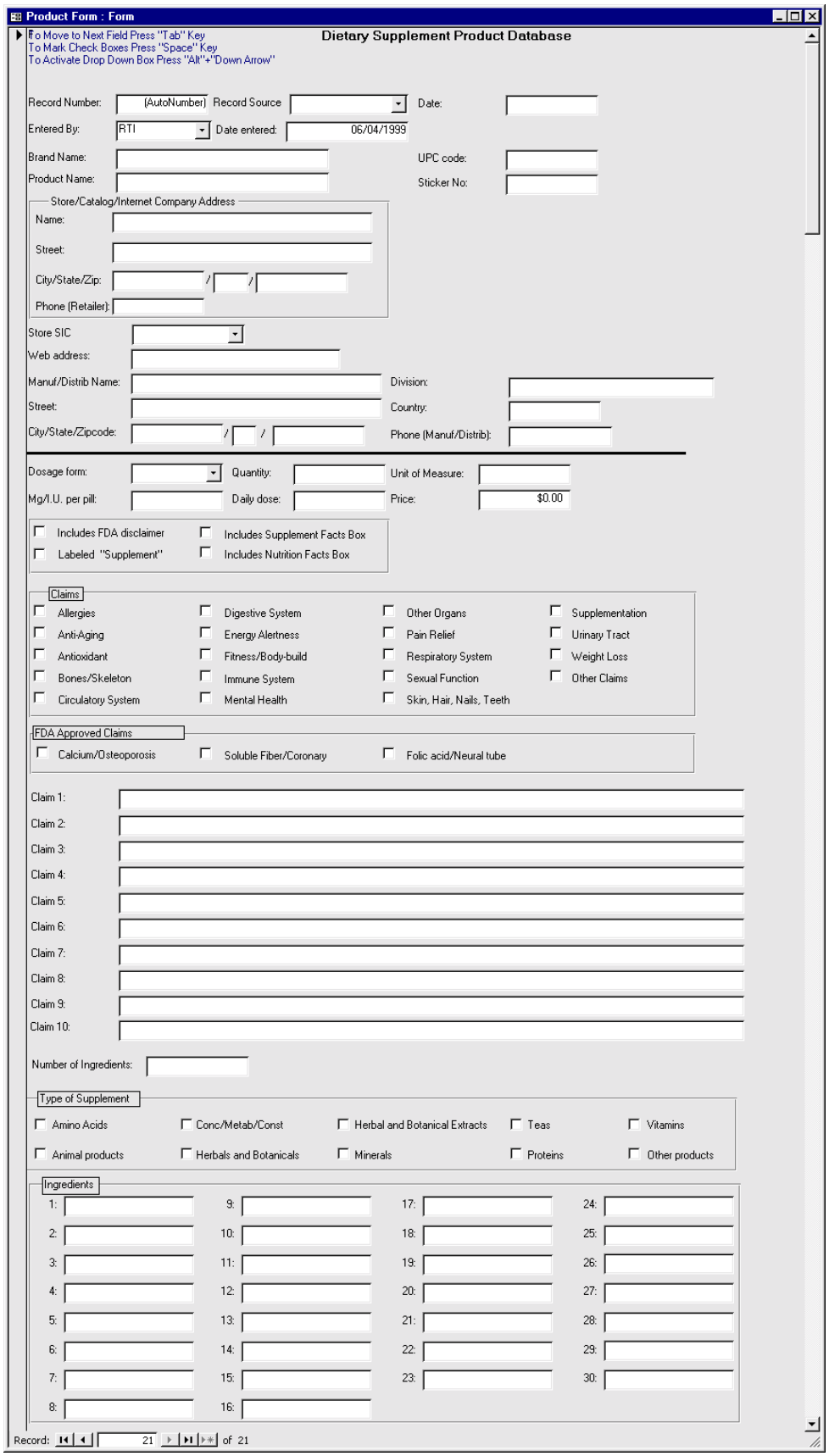
Variable Name	Format	Description
Unit of Measure	Text	How product is measured (e.g., count, ounces, milligrams)
Dose per Unit	Text	Mgs or IUs per single dose
Daily Dose	Text	Number of doses recommended per day
Price	Currency	Price of the product including discounts
		Information on Claims
Labeled with FDA Disclaimer	Yes/No	Product includes "These statements have not been evaluated by the FDA. Not intended to diagnose, treat, cure, or prevent any disease."
Labeled "Dietary Supplement"	Yes/No	Product labeled "supplement" along with "dietary," "vitamin," "food," "nutritional," "herbal," or other
Includes "Supplement Facts"	Yes/No	Product has a "Supplement Facts" box
Includes "Nutrition Facts"	Yes/No	Product has a "Nutrition Facts" box
Allergies	Yes/No	Includes claim regarding allergies
Anti-Aging	Yes/No	Includes claim regarding aging
Antioxidant	Yes/No	Includes claim regarding antioxidants
Bones/Skeleton	Yes/No	Includes claim regarding bones/skeleton
Circulatory	Yes/No	Includes claim regarding circulatory system
Digestive	Yes/No	Includes claim regarding digestive system
Energy Alertness	Yes/No	Includes claim regarding energy and alertness
Fitness	Yes/No	Includes claim regarding fitness/body building
Immune System	Yes/No	Includes claim regarding immune system
Mental Health	Yes/No	Includes claim regarding mental health
Other Organs	Yes/No	Includes claim regarding other specific organs
Pain Relief	Yes/No	Includes claim regarding pain relief
Respiratory	Yes/No	Includes claim regarding respiratory system
Sexual Function	Yes/No	Includes claim regarding sexual function
Skin, Hair, Nails, Teeth	Yes/No	Includes claim regarding, skin, hair, nails, or teeth
Supplementation	Yes/No	Includes claim regarding increasing dietary intake of nutrients
Urinary Tract	Yes/No	Includes claim regarding urinary tract

(continued)

Table 4-1. Variable Descriptions (continued)

Variable Name	Format	Description
Weight Loss	Yes/No	Includes claim regarding weight loss
Other	Yes/No	Includes other claim
Calcium/Osteoporosis	Yes/No	Includes FDA-approved claim about calcium and osteoporosis
Fiber/Heart Disease	Yes/No	Includes FDA-approved claim about soluble fiber and coronary heart disease
Folic Acid/Birth Defects	Yes/No	Includes FDA-approved claim about folic acid and neural tube defects
Claim 1—Claim 10	Text	First ten claims entered as they appear
		Information on Ingredients
Number of Ingredients	Text	Total number of ingredients, including inert ingredients
Amino Acids	Yes/No	Product contains amino acids
Animal Products	Yes/No	Product contains animal products
Conc/Metab/Const	Yes/No	Product contains concentrates, metabolites, or constituents
Herbals and Botanicals	Yes/No	Product contains herbals or botanicals
Herbal Extracts	Yes/No	Product contains herbal or botanical extracts
Minerals	Yes/No	Product contains minerals
Teas	Yes/No	Product contains teas
Proteins	Yes/No	Product contains proteins
Vitamins	Yes/No	Product contains vitamins
Other ingredients	Yes/No	Product contains other ingredients
Ingredient 1-Ingredient 30	Text	First 30 ingredients entered as they appear

Figure 4-1.
Product Form



Figures 4-2 through 4-5 contain the tables corresponding to each drop-down box used in the product form. For the purpose of entering data here at RTI, we set the default value for "Entered by" to "RTI." This allowed data entry operators to tab over this field. For "Source of Record" (see Figure 4-3), data entry operators could choose from the only three possible choices: "Product label," "Internet site," or "Catalog." Figure 4-4 presents the table containing the six sample SIC codes and their descriptions that comprised a drop-down box. Figure 4-5 lists the selections for dosage form. While drop-down boxes allow data entry operators to select from a predetermined list, they do not prevent them from entering other data into that field. For "dosage form," we instructed data entry operators to select from the list if possible, but to type in the dosage form if it did not appear on the list.

Figure 4-2. Example of Drop Down Box for Entered By

	Entered by
	FDA
	Other
	RTI

Figure 4-3. Example of Drop Down Box for Record Source

	Source of Record
	Product label
	Internet site
	Catalog

Figure 4-4. Example of Drop Down Box for SIC Code

	SIC Code of Retailer	SIC Description
	5399-01	General Merchandise
	5411-01	Grocers
	5499-01	Health Food Retail
	5499-04	Vitamins - Retail
	5499-13	Herbs - Retail
	5912-05	Drug Stores

Figure 4-5. Example of Drop Down Box for Dosage Form

	Dosage form
	Tablet
	Liquid
	Powder or granule
	Lozenge
	Loose leaves
	Teabags
	Caplet
	Capsule
	Other

4.5 CATEGORIZING DATA

To make it possible for the data to be sorted by type of claim or type of ingredient, we included categories of claims and ingredients as fields in the database. These categories are listed in Table 4-1. The following section explains these categories in more detail.

4.5.1 Categorizing Claims

The product form allows data entry operators to type in the first ten claims as they appear on the product. To allow the claims to be grouped into categories, we also listed 18 different types of claims for data entry operators to check. These types of claims represent the categories into which most claims fall. We developed this list after studying the claims from numerous product labels, catalogs, and Internet sites. Table 4-2 lists the 18 categories of claims and gives examples of the types of claims that fall into each category.

Table 4-2. Categories of Claims

This category applies if …	…the claim contains statements regarding the following:
Allergies	Allergies, hay fever
Anti-aging	Aging
Antioxidant	Free radical damage, cancer risk
Bones/Skeleton	Osteoporosis, arthritis, bones, joints
Circulatory System	Heart, cardiovascular, blood, blood pressure, circulation, cholesterol, blood sugar, varicose veins, diuretic effects
Diet Supplementation	Increases in dietary intake, nutrients not obtained in foods
Digestive System	Laxative, cleansing effect, digestion, stomach, ulcers, reflux, parasite control, hemorrhoids, removal of toxins
Energy and Alertness	Energy level, mental alertness, memory, attention, ability to concentrate
Fitness/Body-building	Building muscle; gaining weight; improving fitness, endurance, stamina, exercise
Immune System	Immune system, colds, flu, other types of infections
Mental Health	Depression, anxiety, mood, premenstrual syndrome, relaxation, sleep, overall feeling of well-being, stress
Other Specific Organs	Other organs not elsewhere included, such as liver, gall bladder, eyes, ears
Pain Relief	Pain, discomfort
Respiratory System	Asthma, breathing, snoring, bad breath, sinuses
Sexual Function	Sex drive, performance
Skin, Hair, Nails, Teeth	Skin, hair, nails, teeth
Urinary Tract	Urinary tract, bladder, prostate, kidney
Weight Loss	Weight loss, appetite control, metabolism

Data entry operators selected the categories that best represented the types of claims being made on the product. If the claims did not fit into any of these categories, they indicated "other" as the type of claim. In some cases, a single category accurately represented a product's claims. For many products, however, multiple categories applied.

Choosing the correct category for each claim was sometimes very straightforward. In many cases, however, selecting the appropriate category required judgment on the part of data preparation personnel. Some of the categories are closely related, such as Fitness/Body-building and Weight Loss, or Energy and Alertness and Mental Health. For many products, data preparation personnel had to make subjective judgments regarding the claims categories. While the data contained in these fields may be useful for estimating the frequencies of various types of claims, these data may not accurately represent all of the information contained in the claims themselves.

4.5.2 Categorizing Ingredients

The product form allows space for 30 ingredients to be entered as they appear on the product. It also lists the following categories for data entry operators to check:

- amino acids
- animal products
- concentrates/metabolites/constituents
- herbals and botanicals
- herbal and botanical extracts
- minerals
- teas
- proteins
- vitamins
- other ingredients

These categories indicate the types of ingredients contained in the product. As with categorizing claims, selecting the appropriate category for ingredients was generally straightforward but sometimes required subjective judgment. Sometimes a single ingredient fit into multiple categories. For example, gelatin could

be categorized as both an animal product and a protein. Some botanical extracts are also concentrates, metabolites, and constituents. We provided data preparation personnel with examples of the various types of supplements to assist them with selecting the appropriate category. Tables 4-3 through 4-10 contain these examples. These lists are not all-inclusive and were intended to serve as a general guide. If the data preparation personnel could not determine which category best described the product, they indicated "other" as the supplement type.

Table 4-3. Examples of Amino Acids (often start with "L-" or "D-" and end in "ine")

Alanine	L-glutamine, L-glutamic acid	L-lysine
Serine	Glycine	L-methionine
Proline	L-histidine	Taurine
Asparagine	L-tyrosine	L-phenylalanine
L-arginine	Threonine	D-phenylalanine
L-ornithine	L-leucine	DL-phenylalanine
L-asparic acid	L-isoleucine	L-tryptophan
L-cysteine	L-valine	

Table 4-4. Examples of Animal Products

Adrenal	Pituitary	Ovary
Aorta	Prostate	Chondroitin sulfate
Kidney	Spleen	Shark cartilage
Liver	Thymus	Fish oils
Pancreas	Thyroid	Gelatin (check only if *active* ingredient)
Parathyroid	Testicular	

Table 4-5. Examples of Concentrates, Metabolites, and Constituents

Hormones	
DHEA	Melatonin
Pregnenolone	Anrostenediol
Androsterone	Gamma aminobutyric acid
Norandrostenedione	
Metabolites	
Creatine	Choline
Pyruvate	DMG or pangamic acid
Nicotinamide dinucleotide (NAD)	Inosine, adenine
Nicotinamide dinucleotine hydrogen (NADH)	Carnitine
Glucosamine	Alpha-ketoacids
Chondroitin sulfate	Inositol
Coenzyme Q	Lipoic acid
Lecithin	
Plant-Derived Substances	
Yohimbine	Ferulic acid
Ginsenoside	Gamma-oryzanol
Ginkoloids	Sitosterol
Ephedrine	Diosgenin, hecogenin
Psuedoephedrine	Isoflavones
Ecdysteroids, ecdysone	Phystostanols and phytosterols
Octacosanol	Glycosides

Table 4-6. Examples of Herbals and Botanicals

Garlic	Evening primrose	Gotu kola
Ginseng	Velarian root	Feverfew
Ginkgo biloba	Vegetable oils	Fiber supplements—psyllium
Echinacea	Saw palmetto	Wheat grass
St. John's wort	Cayenne	Ma Huang—Ephedra
Goldenseal	Ginger	

Table 4-7. Examples of Minerals

Boron, borate	Magnesium, dolomite
Calcium, dolomite, bone meal	Manganese
Chromium	Molybdenum, molybdenum-enriched yeast
Copper	Phosphorous, phosphates
Flourine, flouride	Potassium
Germanium	Selenium, selenite, organic selenium from Brewer's yeast
Iodine, iodide, iodate	Vanadium
Iron, ferrous, ferric	Zinc

Table 4-8. Examples of Teas

Green tea	Other herbal teas
Black tea	

Table 4-9. Examples of Proteins

Soy proteins	Whey	Collagen
Vegetable proteins	Casein	Gelatin
Milk protein	Egg protein	

Table 4-10. Examples of Vitamins

Vitamin A, beta carotene, retinol	Vitamin B-2, riboflavin	Choline
Vitamin D, calciferols	Vitamin B-6, pyridoxine	Folic acid, folate
Vitamin E, tocopherols	Vitamin B-12, cobalamin	Niacin, Vitamin B-3
Vitamin K, phylloquinone	Vitamin C, ascorbic acid	Pantothenic acid
Vitamin B-1, thiamin	Biotin	

4.6 COMPLETION

Once the data entry was complete, we reviewed the data to check for completeness and consistency in the selection of categories of claims and ingredients. We resolved any uncertainties by referring back to the product, catalog, or Internet site. All purchased dietary supplements as well as catalogs and printed Internet sites were shipped to FDA at the conclusion of the study.

5 Data Summary

The complete DSPD contains 2,997 records of label information from catalogs, Internet sites, and purchased products. In this section, we provide summary information on some of the key variables in the database. In particular, we summarize information on where the products were manufactured and sold, the ingredients in the products, the claims made on the labels, other labeling information, and the prices of the products. We also provide comparisons among the three sources of records.

5.1 SOURCE OF PRODUCTS IN THE DSPD

As described in Sections 2 and 3, we purchased or selected approximately 3,000 dietary supplement products from three different sources. Table 5-1 provides the final breakdown from each source in the DSPD. By design, we obtained approximately the same number of products from each source and ultimately ended up with slightly more catalogs than Internet sites and more Internet sites than product labels.

Table 5-1. Source of Dietary Supplement Records Included in the DSPD

	Product Label	Catalog	Internet Site	Total
Total	970	1,020	1,007	2,997
Percent	32.37%	34.03%	33.60%	100%

Records in the DSPD were obtained from a total of 32 states, as indicated in Table 5-2. We obtained the greatest number of records across all three record sources from California (526), followed by New York (268) and Pennsylvania (186).

By design, purchased products came from ten PSUs. Three of these PSUs were in California, reflecting the high population density of the state. The remaining PSUs were in Florida, Illinois, Massachusetts, Maryland, Missouri, New York, and Pennsylvania. Ten stores were sampled in each PSU. The product totals reflect that we expected to average ten products per store, but the actual number varied depending on the number of herb and botanical stores (15 products purchased in each) versus food or drug stores (five products purchased in each) that we sampled as well as whether we reached our budget limit for the store with fewer products.

We obtained the largest number of catalogs from California and New York (seven each) followed by Colorado and Florida (five each). Only one catalog, which carries one product, did not identify a state.

For Internet sites, it was often difficult to determine the state in which the site was located. For 35 Internet sites, which account for more than half (555) of the Internet sites' products, we could not identify the site's location. Of those for which we could identify the state, the most were from California (eight), followed by Pennsylvania (five) and Oregon (four).

The distribution of products by the state of manufacturer is quite different as indicated in Table 5-3. Based on the location of the manufacturer, the products came from a total of 47 states as well as Mexico and China. However, products may have been manufactured in other states or other countries than the one indicated on the label. For example, a company may contract with a repacker, encapsulator, or relabeler to prepare ingredients or products from another source. The company indicated on the label may be the company that distributes but does not manufacture the product.

Nearly all purchased and catalog products indicated the state of the manufacturer but only one Internet site did. For the purchased

Table 5-2. Dietary Supplement Products, Catalogs, Internet Sites, and Stores in the DSPD by State

	Source of Record							
	Product Label		Catalog		Internet Site		Total	
State	# Stores	# Products	# Catalogs	# Products	# Sites	# Products	# Sources	# Products
AR	0	0	1	24	0	0	1	24
CA	30	327	7	120	8	79	45	526
CO	0	0	5	63	2	40	7	103
CT	0	0	0	0	1	1	1	1
FL	10	96	5	47	3	25	18	168
GA	0	0	0	0	1	4	1	4
HI	0	0	0	0	1	5	1	5
IL	10	84	1	24	2	2	13	110
IN	0	0	3	54	0	0	3	54
KY	0	0	0	0	1	11	1	11
MA	10	96	1	24	1	1	12	121
MD	10	100	0	0	2	20	12	120
ME	0	0	0	0	1	1	1	1
MI	0	0	2	48	1	2	3	50
MN	0	0	2	24	0	0	2	24
MO	10	88	0	0	0	0	10	88
NC	0	0	0	0	1	13	1	13
NE	0	0	1	24	1	21	2	45
NJ	0	0	4	96	1	7	5	104
NV	0	0	1	24	0	0	1	24
NY	10	100	7	168	0	0	17	268
OH	0	0	1	24	1	20	2	44
OR	0	0	1	21	4	40	5	61
PA	0	0	4	96	5	89	9	186
SC	10	79	0	0	0	0	10	79
TN	0	0	2	12	0	0	2	12
TX	0	0	2	31	2	34	4	65
UT	0	0	1	10	0	0	1	10
VA	0	0	2	25	0	0	2	25
VT	0	0	1	24	0	0	1	24
WA	0	0	0	0	3	37	3	37
WI	0	0	2	36	0	0	2	36
State Totals	100	970	56	1,019	42	452	198	2,441
State Unknown	0	0	1	1	35	555	36	556
Database Totals	100	970	57	1,020	77	1,007	234	2,997

Table 5-3. Dietary Supplement Manufacturers in the DSPD by State

State	Product Label	Catalog	Internet Site	Total Number of Products
AR	1	24	0	25
AZ	5	0	20	25
CA	182	126	0	308
CO	35	67	0	102
CT	17	0	0	17
DE	2	0	0	2
FL	52	47	0	99
GA	1	0	0	1
HI	2	0	0	2
IA	4	0	0	4
ID	2	0	0	2
IL	44	23	0	67
IN	2	54	0	56
KS	1	0	0	1
MA	7	19	0	26
MI	3	48	0	51
MN	1	24	0	25
MO	10	0	0	10
MT	3	0	0	3
NC	5	0	0	5
NE	0	24	0	24
NH	1	2	0	3
NJ	89	83	0	172
NM	3	0	0	3
NV	3	24	0	27
NY	139	147	0	286
OH	3	24	0	27
OR	20	21	0	41
PA	79	96	0	175
RI	10	0	0	10
TN	0	12	0	12
TX	9	31	0	40
UT	150	11	0	161
VA	2	25	0	27
VT	6	24	0	30
WA	9	0	0	9
WI	11	36	0	47
Total US	913	992	20	1,925
Mexico	2	0	0	2
China	12	0	0	12
Total Foreign	14	0	0	14
Total Unknown	43	28	987	1,058
Total Database	970	1,020	1,007	2,997

products and catalog products, the highest number listed a manufacturer in California, followed by New York, New Jersey, Utah, and Colorado. These rankings are similar for both catalogs and purchased products with the exception that nearly all of the Utah products were purchased rather than catalog products.

5.2 LABELING AND PRICE INFORMATION FOR PRODUCTS IN THE DSPD

One of the reasons for compiling the DSPD was to examine information on ingredients in dietary supplement products and claims made about the products. In this section, we summarize information on the categories of ingredients and claims on the products. We also provide information on other label attributes and the prices of the products in the database.

5.2.1 Product Ingredients in the DSPD

As described in Section 4.5.2, the product ingredients were categorized into ten categories (e.g., amino acids, herbals and botanicals, and vitamins). Table 5-4 indicates the frequency of ingredients for each record source. Because the ingredients in products may fall into multiple categories, more than one category may be indicated for an individual product. Percentages within each category are calculated relative to the number of products with ingredients indicated. Overall, 42 percent of products with identified ingredients contained herbals and botanicals, followed by vitamins at 32 percent and minerals at 25 percent.

Nearly all of the purchased products listed at least one ingredient, but 5 percent of catalog products and 8 percent of Internet products did not identify a single ingredient and did not identify the primary ingredient(s) in the name of the product. Of the products with ingredients indicated, the frequencies of ingredient categories are similar for all three record sources (see Figure 5-1) with the exception of vitamins and minerals. For each of these categories, purchased products contained these ingredients at somewhat greater frequencies than catalog or Internet products.

Table 5-4. Dietary Supplement Ingredients by Source of Record in the DSPD

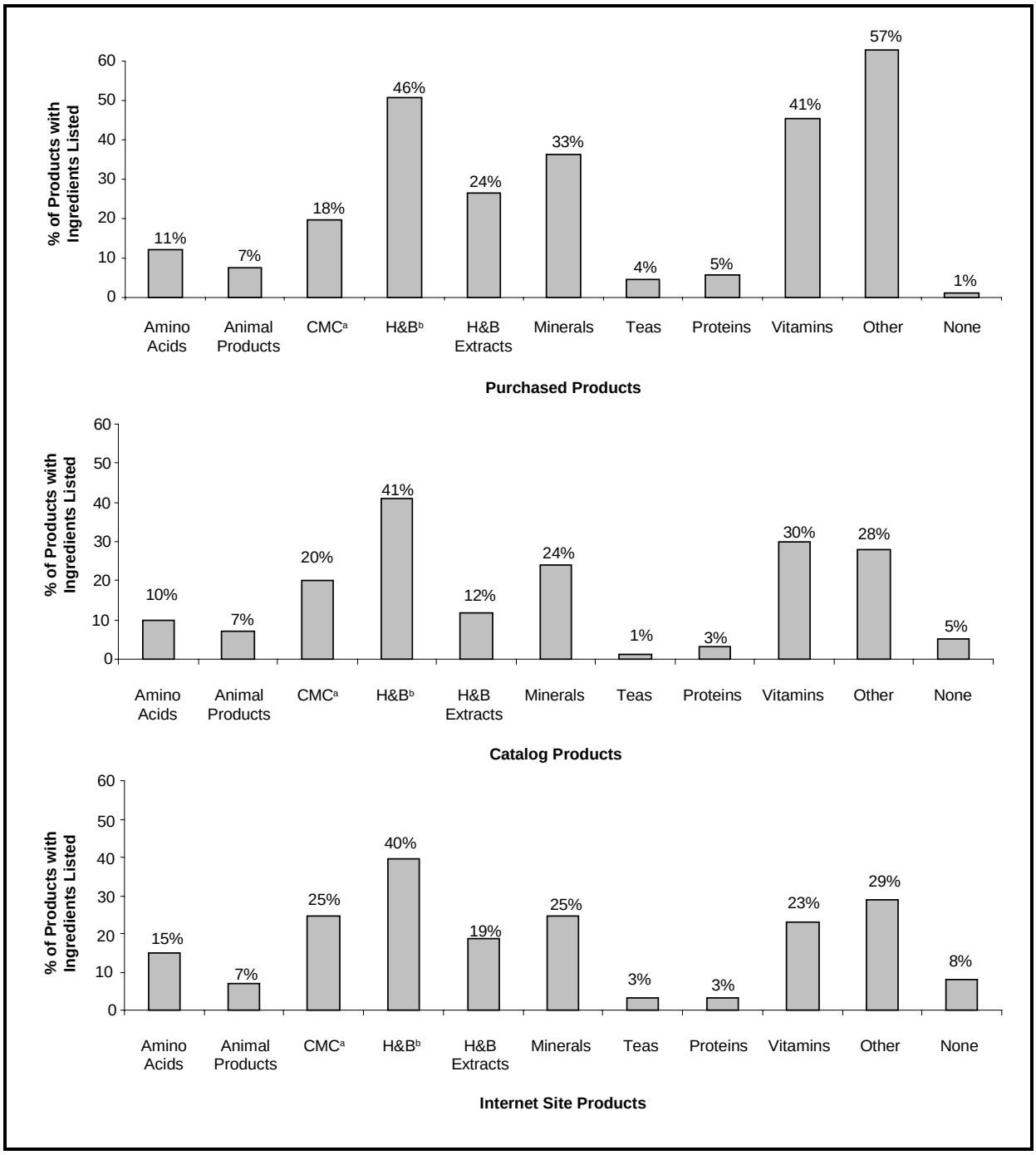
	Source of Record							
	Product Label		Catalog		Internet Site		Total	
Ingredients	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Amino acids	104	11%	98	10%	136	15%	338	12%
Animal products	65	7%	66	7%	64	7%	195	7%
Concentrates, metabolites, and constituents	172	18%	192	20%	231	25%	595	21%
Herbals and botanicals	445	46%	400	41%	369	40%	1,214	42%
Herbal and botanical extracts	231	24%	121	12%	173	18%	525	18%
Minerals	321	33%	237	24%	232	25%	790	25%
Proteins	47	5%	31	3%	27	3%	105	4%
Teas	38	4%	14	1%	28	3%	80	3%
Vitamins	396	41%	288	30%	213	23%	897	31%
Other ingredients	552	57%	273	28%	271	29%	1,096	38%
Number of Products in Each Category with Ingredients Listed	968	100%	973	95%	925	92%	2,866	96%
Number of Products with No Ingredients Listed	2	0%	47	5%	82	8%	131	4%
Total Number of Products in Each Category	970		1,020		1,007		2,997	

Note: Because each product may have multiple ingredients, a product may appear in multiple categories. Percentages are calculated relative to the number of products from each source with ingredients listed with the exception of products with no ingredients listed. For products with no ingredients listed, the percentages are calculated relative to the total number of products.

5.2.2 Product Claims in the DSPD

As described in Table 4-2, the claims made on products were categorized into 18 categories (e.g., antioxidant, energy/alertness, and pain relief). Table 5-5 indicates the frequency of claims in each category for each record source. In addition, we note the frequency of use of three FDA-approved claims, including the links between calcium and prevention of osteoporosis, fiber consumption and prevention of coronary heart disease, and folic acid and the prevention of neural tube defects. As with ingredients, products may list multiple claims; thus, multiple claim categories may be indicated for a particular product. Percentages within each

Figure 5-1. Dietary Supplement Ingredients by Source of Record



[a]CMC = Concentrates, Metabolites, and Constituents.

[b]H&B = Herbals and Botanicals.

Table 5-5. Dietary Supplement Claim Categories by Source of Record in the DSPD

	Source of Record							
	Product Label		Catalog		Internet Site		Total	
Claim Category	**No.**	**%**	**No.**	**%**	**No.**	**%**	**No.**	**%**
Allergy	2	0%	8	1%	15	2%	25	1%
Anti-aging	7	1%	22	3%	55	7%	84	4%
Antioxidant	92	17%	88	12%	148	18%	328	16%
Bones and skeleton	62	12%	57	8%	91	11%	210	10%
Circulatory system	95	18%	133	18%	199	25%	427	21%
Diet supplementation	131	24%	150	21%	129	16%	410	20%
Digestive system	56	10%	91	13%	105	13%	252	12%
Energy/alertness	89	17%	112	16%	158	20%	359	17%
Fitness	30	6%	84	12%	171	21%	285	14%
Immune system	62	12%	73	10%	162	20%	297	14%
Mental health	71	13%	84	12%	163	20%	346	17%
Other organs	36	7%	45	6%	95	12%	176	9%
Pain relief	13	2%	35	5%	65	8%	113	5%
Respiration	3	1%	16	2%	49	6%	68	3%
Sexual function	6	1%	31	4%	41	5%	78	4%
Skin/hair/nails	46	9%	49	7%	83	10%	178	9%
Urinary tract	23	4%	19	3%	43	5%	85	4%
Weight loss	18	3%	59	8%	120	15%	197	10%
Other	79	15%	137	19%	404	50%	620	30%
FDA-Approved Claims								
Calcium/osteoporosis	10	2%	4	1%	4	0%	18	1%
Fiber/heart	0	0%	3	0%	0	0%	3	0%
Folic acid/birth defects	3	0%	6	1%	1	0%	10	0%
Number of products in each category with claims	539	56%	720	71%	809	80%	2,068	69%
Number of products with no claims	431	44%	300	29%	198	20%	929	31%
Total number of products in each category	970		1,020		1,007		2,997	

Note: Because each product may have multiple claims, a product may appear in multiple categories. Percentages are calculated relative to the number of products from each source with claims listed. For products with no claims, the percentages are calculated relative to the total number of products.

category are calculated relative to the number of products with claims indicated.

While 80 percent of Internet products included claims, only 71 percent of catalog products and 56 percent of purchased products did so. Overall, the top claim categories are circulatory system (21 percent), diet supplementation (20 percent), mental health (17 percent), energy/alertness (17 percent), and antioxidant (16 percent). FDA-approved claims were infrequent across all three record sources at 0 to 2 percent. The frequency of rankings of claim categories across the record sources is presented in Figure 5-2. "Diet supplementation" was the top category for catalog and purchased products, with nearly one-quarter of products including this claim, while "circulatory system" was the top category for Internet products, with more than one-fifth of products including this claim.

5.2.3 Other Labeling Information in the DSPD

Other label information that may be included on dietary supplement products includes the following:

- the term "supplement" used in conjunction with a modifier such as "dietary supplement," "herbal supplement," or "vitamin supplement";
- the FDA disclaimer "These statements have not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease"; and
- the Supplement Facts box or the Nutrition Facts box.

FDA labeling regulations require that products manufactured after March 23, 1999, must include the term "supplement," the FDA disclaimer, and the Supplement Facts box. Because most of our product information was obtained prior to this date, the products in the database were not yet required to comply with the regulations. In addition, many products carry the Nutrition Facts box because their labels where designed before manufacturers had information on the labeling requirements or because manufacturers are marketing what are essentially dietary supplements as food products.

As indicated in Table 5-6, we found overall that 43 percent of products were labeled "supplement." However, while 73 percent

Figure 5-2. Top Ten Claim Categories by Source of Record in the DSPD

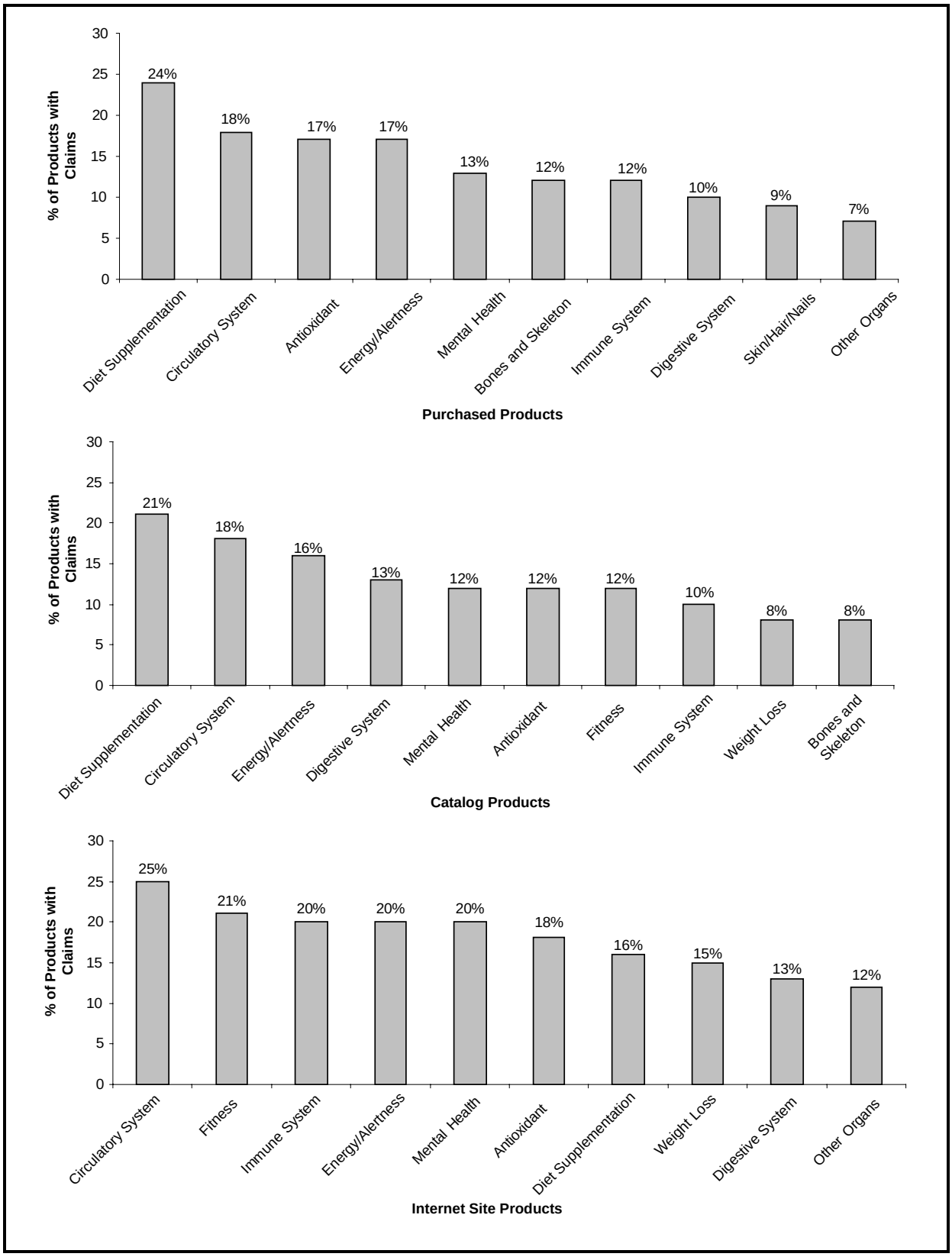


Table 5-6. Other Dietary Supplement Information by Source of Record in the DSPD

	Source of Record							
	Product Label		Catalog		Internet Site		Total	
	No.	%	No.	%	No.	%	No.	%
Labeled "Supplement"	711	73%	282	28%	288	29%	1,281	43%
Includes FDA Disclaimer	196	20%	137	13%	242	24%	575	19%
Includes Nutrition Facts Box	161	17%	1	0%	18	2%	180	6%
Includes Supplement Facts Box	190	20%	1	0%	24	2%	215	7%
Total Number of Products in Each Source	970		1,020		1,007		2,997	

of purchased products were labeled "supplement," fewer than 30 percent of either catalog and Internet products were. The FDA disclaimer appeared on 19 percent of all products combined, most frequently on Internet sites at 24 percent and the least frequently on catalog products at 13 percent. While 20 percent of purchased products included the Supplement Facts box, only a handful of Internet and catalog products did so. However, the Supplement Facts box is only required on the package; therefore, it is not expected to appear on Internet sites or catalogs. Finally, 17 percent of purchased products included the Nutrition Facts box, and a few catalog and Internet products did as well.

5.2.4 Product Price Information in the DSPD

Table 5-7 provides summary statistics for dietary supplement product prices in the DSPD. The average product in the database costs $17.15. Overall, Internet products were most expensive, followed by catalog and purchased products. The least expensive product in the database is a vitamin and mineral supplement, which costs $0.35 for a single dose and is to be taken two or more times per day. The most expensive product in the database is shark cartilage supplement, which costs $335.00 for 1,400 grams (daily dose is not indicated) and is offered for sale on the Internet.

Table 5-7. Dietary Supplement Product Prices in the DSPD by Source of Record

	Source of Record			
	Product Label	**Catalog**	**Internet Site**	**Overall**
Mean	$11.62	$16.40	$23.34	$17.15
Minimum	$0.35	$0.38	$2.49	$0.35
Maximum	$59.99	$100.00	$335.00	$335.00
Missing	0	9	18	

Differences in package sizes may account for part of the differences in average prices. For purchased products in particular, budget limitations prevented us from purchasing the most expensive products. Thus, a more relevant price comparison across products would be based on per-day dosages. However, a large number of the products did not provide sufficient information to calculate the number of daily dosages within the package.

Reference

Chromy, J.R. 1979. "Sequential Sample Selection Methods." Proceedings of the *American Statistical Association Section on Survey Research Methods*, pp. 401-406.