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Economic Characterization of the Dietary Supplement Industry

Contract No. 223-96-2290: Task Order 3

Final Report

Prepared for

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PREFACE

The Food and Drug Administration (FDA) contracted with Research Triangle Institute (RTI) to collect information and report on the nature, size, and scope of the dietary supplement industry. This document is the final draft of the Dietary Supplement Industry Characterization Report provided under the contract.

The products that are the focus of the report are based on the definition of dietary supplements in the Dietary Supplement Health and Education Act of 1994 (DSHEA). They are the following:

- vitamins;
- minerals;
- herbals and other botanicals;
- amino acids;
- dietary substances used to supplement the diet by increasing its total daily intake; and
- concentrates, metabolites, constituents, extracts, and combinations of these ingredients.

In addition, these products must be intended for ingestion in pill, capsule, tablet, or liquid form; must not be represented as a food or sole item of a meal or diet; and must be labeled as a "supplement."

FDA requires the information contained in this report to aid in conducting regulatory impact analyses under DSHEA. According to Young and Bass (1994), DSHEA

- establishes dietary supplements as a new category of food,
- defines dietary supplements and ingredients,
- includes enforcement provisions for adulteration standards,
- excludes accompanying literature from the definition of labeling and thus allows it under certain conditions,
- allows for a claim of benefit and role of the product on its label,
- establishes labeling practices regarding ingredients and nutrition,
- requires pre-market notification of new dietary ingredients,
- authorizes the Secretary of Health and Human Services to issue regulations prescribing good manufacturing practices (GMPs),
- establishes a commission on dietary supplement labels, and
- establishes an office of dietary supplements within the National Institutes of Health.

Nearly all information contained in this report was obtained from secondary data sources. In addition to searching secondary data sources, RTI met with the following individuals in the course of obtaining information on the industry:

- Loren D. Israelsen, President, Utah Natural Products Alliance;
- Jill Ellis, Director of Science & Quality Assurance, National Nutritional Foods Association;
- John Hathcock, Director of Nutritional & Regulatory Science, and John Cordaro, President and Chief Executive Officer, Council for Responsible Nutrition;
- Jeffrey M. Morrison, President, American Herbal Products Association; and
- Patrice B. Wright, Director of Pharmacology and Toxicology, Nonprescription Drug Manufacturers Association.

Summaries of RTI's interviews with these individuals were provided previously to FDA in site visit summary reports.

CONTENTS

FIGURE

TABLES

SECTION 1
INTRODUCTION

The dietary supplement (DS) industry is made up a diverse set of products that are produced by a variety of manufacturers and distributed through a variety of channels. For these reasons, characterizing the industry is difficult. Furthermore, the industry has experienced tremendous growth recently due to increased consumer interest in these products, so information on the industry is continually being updated.

This report contains the most recent information available from secondary data sources on the size, scope, and nature of the DS industry. The products that are the focus of the report, which are based on the definition of a dietary supplement as contained in the Dietary Supplement Health and Education Act (DSHEA) of 1994, are:

Vitamins	Products that are organic (carbon-containing) nutrients that are essential in small quantities for normal metabolism, growth, and well-being. They must be obtained through the diet because they either are not synthesized in the body or are not synthesized in adequate amounts.
Minerals	Products that are chemical elements in their inorganic forms. "Minerals" are those that are required in amounts greater than 100 mg/day, and "trace minerals" are those required in lesser amounts.
Herbals & Botanicals (other than extracts)	Herbal or botanical products prepared by means other than extraction (i.e., dried, crushed, and encapsulated). These may include teas in addition to other product forms. The term *herbal* refers to the leaves and stems of the plant while *botanical* refers to these parts in addition to roots, seeds, and fruits.
Herbal and Botanical Extracts	Products that are extracts made from any part of a plant.
Animal Extracts	Products that are extracts made from animal parts (e.g., tissues and glands).
Amino Acids	Products that contain an amino group and an acidic function.
Proteins	Products with the complete set of amino acids to make up proteins.
Concentrates, Metabolites, Constituents	Products that are concentrated, are broken down into individual components, or are parts of other products.
Teas	Products infused in water that contain herbals, botanicals, or other DS products. Basic tea products have a standard of identity as a food product; however, many products are a combination of tea and dietary supplements.
Other Dietary Supplements	All other products meeting the criteria of dietary supplements that cannot be classified into the categories above. They include, for example, bee pollen, propolis, and royal jelly; coenzyme Q; spirulina and other algaes; and nucleic acids.

While some of these products (i.e., vitamins, minerals, and proteins) are taken because they are essential nutrients, others are taken for other reasons. In particular, herbal and botanical products are generally taken for reasons other than nutrition, although current FDA regulations restrict the types of claims allowed on the product. Products other than vitamins and minerals are only in the initial stages of standardization by members of the industry; thus, even a particular type may contain many heterogeneous products. As one would expect, the production processes vary greatly both between product types and within a product type.

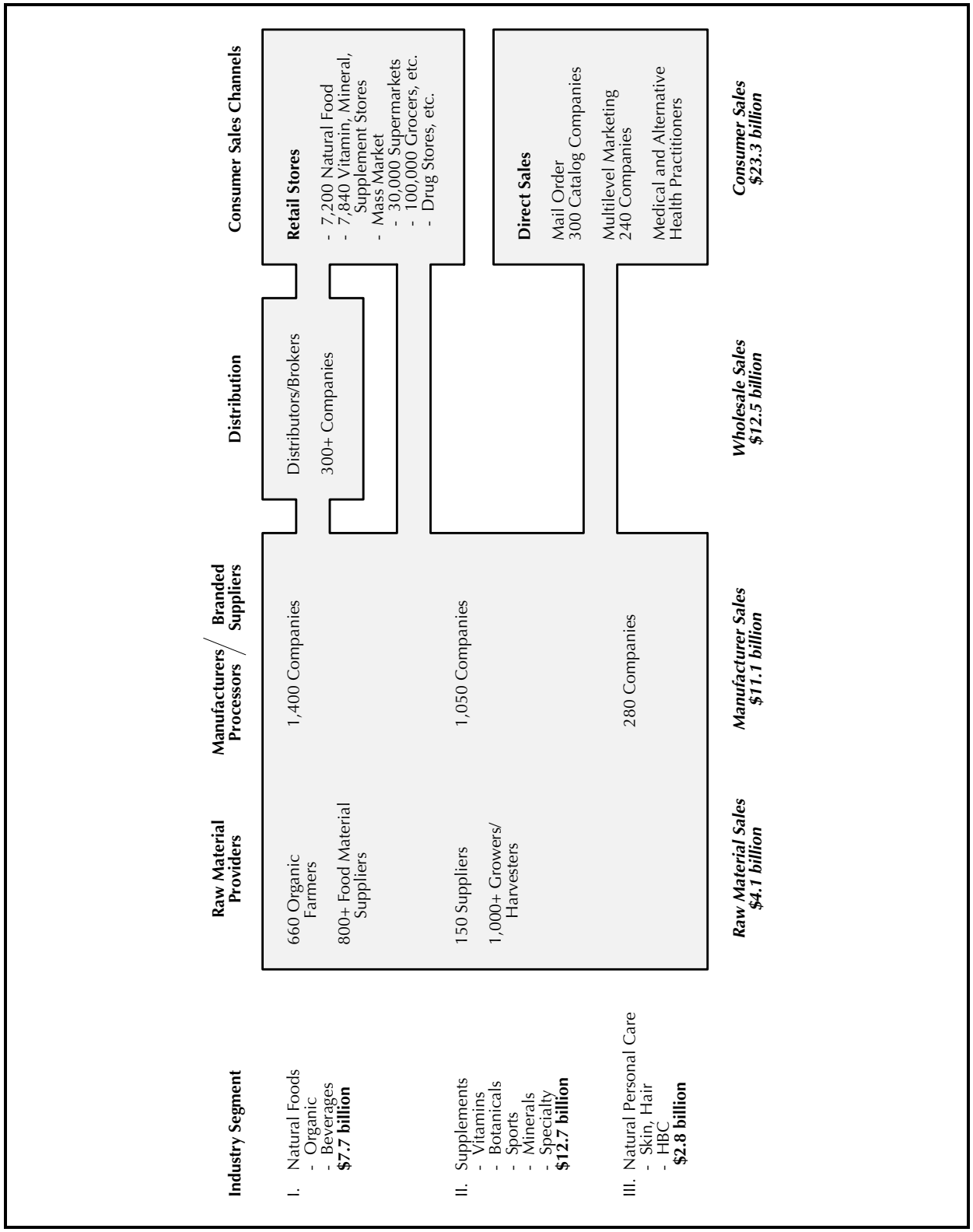
Industry statistics are difficult to come by because these products are scattered across at least eight different 4-digit Standard Industrial Classification (SIC codes) and nearly 80 different 6-digit international codes. In addition, different trade organizations cover varying aspects of the industry. These include the Council for Responsible Nutrition, which in the past concentrated primarily on vitamins and minerals but is now branching out into other DS products; the American Herbal Products Association, which contains primarily smaller herbal and botanical product manufacturers but is adding larger members over time; the Nonprescription Drug Manufacturers, which represents the larger over-the-counter pharmaceutical manufacturers, many of which produce vitamins and minerals; the Utah Natural Products Alliance, which represents eight large firms that are located in Utah but that have national distribution channels; and the National Nutritional Foods Association, which covers retailers in addition to manufacturers and is working on standardizing products. Many other smaller organizations represent various aspects of the industry as well.

The distribution channels for products are many and varied and include channels through which companies

- manufacture and sell their products within their own stores,
- manufacture products and private-label them for retail outlets, and
- manufacture products with a brand name label for sale in retail outlets.

In addition, a large volume of sales is through direct sellers such as mail order and multilevel marketing. Figure 1-1 reproduces from *Nutrition Business Journal* an outline of the distribution channels for all nutrition products. As represented, the raw material providers and manufacturers are distinct among the natural food, DS, and natural personal care lines, but the product lines share common distributors and retailers. However, this diagram does not clearly indicate the extent to which foreign firms are part of the distribution structure. International trade is a large component of the DS industry as many products sold in the U.S. are manufactured from imported raw ingredients or are imported as finished products.

Figure 1-1. Outline of the Distribution Channels for All Nutrition Products



Source: Nutrition Business International. September 1998. "$23 Billion and Counting: Nutrition Industry Braces for a Competitive Future." *Nutrition Business Journal* 3(9):1-5, 13, 18.

In the following sections, we provide more detailed information on the DS industry as a whole. In Section 2, we provide an overview of production practices for the different types of DS products. In Section 3, we summarize information on the facilities and firms as contained in the Dietary Supplement Enhanced Establishment Database (DS-EED), which is being created by RTI. In Section 4, we describe the uses and consumers of DS products and discuss substitution possibilities. Sales and marketing of DS products as well as industry structure are described in Section 5. Finally, we include information on SIC codes, international codes, and industry statistics, as well as projections, in Section 6.

SECTION 2
PRODUCTION AND SUPPLY OF DIETARY SUPPLEMENTS

Dietary supplements are made up of a diverse group of products, so production practices differ as much as the products themselves. Even within a particular category of DS products, there may be many different types of production processes. However, information on how the products are produced is necessary for characterizing the supply of DS products. In this section, we describe the production processes for vitamins, minerals, herbals and botanicals, amino acids, proteins, and other DS products, as well as the final dosage forms of all DS products. Good manufacturing practices (GMPs) and costs of manufacturing are also described briefly.

2.1 PRODUCTION PROCESSES FOR DS PRODUCTS

Within each DS product type are numerous different individual substances. For example, 11 vitamins and 13 minerals have been identified as essential nutrients for humans (Clayman, 1994), but additional nonessential vitamins and minerals have been identified as well (see Tables 2-1 and 2-2). Perhaps several hundred herbal and botanical products have been manufactured for human consumption. In this section, we summarize the production practices for each type of DS product for which we were able to obtain information. In addition to the primary DS product types, we also include information on algaes, bee products, and teas.

2.1.1 Production Processes for Vitamins

Vitamins are a group of organic (carbon-containing) compounds that must be consumed in the diet in small quantities for normal metabolism, growth, and health (Hendler, 1990). Thirteen substances have been identified as vitamins for humans. Vitamins A, D, E, and K are characterized as fat-soluble vitamins. Vitamins B_1, B_2, B_3, B_6, B_{12}, and C; biotin; folic acid; and pantothenic acid are water-soluble vitamins (Ullman's Encyclopedia of Chemical Technology, 1996). Table 2-1 lists these vitamins along with information on their presence in foods, methods used for commercial production, companies engaged in production, and quantities produced. There are three basic methods for producing vitamins on a commercial scale: (1) synthesis, (2) fermentation, and (3) extraction from natural products. Table 2-1 also indicates which of these three methods is used for each vitamin. The following is a brief description of each method.

Synthesis

Synthesis, which involves the production of vitamins through the combination of basic chemicals, is by far the most widely used method of production. First, scientists determine how to synthesize the compounds in a laboratory; then manufacturers scale up the processes to industrial volumes. As Table 2-1 indicates, vitamin B_{12} is the only one of the 13 vitamins that is not produced synthetically.

Table 2-1. Vitamins: Description, Occurrence, and Methods of Production

Vitamin	Other Designation	Occurrence	Production Method			Starting Materials for Extraction	Major Producers	Annual Production
			Synthesis	Fermentation	Extraction			
Fat Soluble:								
Vitamin A	Retinoids	Animal tissue, especially liver. Carotenoids, which are precursors, found in plants.	Most is synthetic. Must be stabilized with anitoxidants.	Commercially possible but not common.	Small quantities extracted.	Fish oils. Solvent extraction, distillation, and purification	Hoffman-LaRoche, BASF, Rhone-Poulenc	2,700 tons (1995)
Vitamin D	Calciferols vitamins D_1 through D_4	Formed in the body with exposure to sunlight. Present in cod liver oil or food oils exposed to UV light.	Most is synthetic.	No	Small quantities extracted.	Fish oils	Solvay-Duphar, Hoffmann-LaRoche, BASF, Synthesia	1.5×10^{15} I.U. (1995)
Vitamin E	Tocopherols, tocotrienols	Plant oils, especially wheat germ, corn, sunflower seed, rapeseed, soybean	Synthetically produced for animal and industrial purposes.	No	Extracted from natural sources for human consumption.	Deodorizer sludges from vegetable oil production	Natural source: ADM, Henkel. Synthetic: Hoffman-LaRoche, Rhone-Poulenc, Eisai	Synthetic: 20,000 tons; natural sources: 2,000 tons (1994)
Vitamin K	Phylloquinone, menaquinone, menadione	Higher plants, green and blue algae, liver, cheese, bacteria	Produced synthetically.	No	No	N/A	Roche, Merke, Eisai, and Nisshin Chemical	3,000-3,500 kg (1995)
Water-Soluble:[a]								
Vitamin B_1	Thiamine	Whole grains, meat products, vegetables, milk, legumes, fruit	Produced synthetically.	No	No	N/A	Hoffman-LaRoche, Takeda, Chinese State companies	4,200 tons (1993)
Vitamin B_2	Riboflavin lactoflavine	Milk, eggs, malted barley, liver, kidney, leafy vegetables, yeast	Produced synthetically.	Produced by fermentation mostly for animal feed.	No	N/A	Hoffman-La Roche, BASF, ADM, Takeda, Chinese State companies	2,400 tons (1995)
Vitamin B_3	Niacin, nicotinic acid, nicotinamide, Vitamin PP	Meats and fish	Produced synthetically.	No	No	N/A	Lonza, Vitachem, Nepera, Yuki Gosei	22,000 tons (1995)
Vitamin B_6	Pyridoxine hydrochloride	Most foods	Produced synthetically.	No	No	N/A	Roche, Takeda, Daiichi, Chinese State Companies	2,550 tons (1993)

(continued)

Table 2-1. Vitamins: Description, Occurrence, and Methods of Production (continued)

Vitamin	Other Designation	Occurrence	Production Method			Starting Materials for Extraction	Major Producers	Annual Production
			Synthesis	Fermentation	Extraction			
Water-Soluble:[a] (continued)								
Vitamin B_{12}	Cobalamins	Fish, dairy products, red meats, eggs, organ meats	No	Produced exclusively by fermentation.	Was done in the past, but no longer economical.	Residues from production of antibiotics	Over 80% made by Rhone-Poulenc; also Rousell Uclaf, Gedeon Richter, Nippon Petrochemicals, Merind	10 tons (1995)
Pantothenic acid	Vitamin B_5	Most foods	Produced synthetically.	No	No	N/A	Hoffman-La Roche, Daiichi, BASF, Alps, Terapia, Polfa	6,000 tons (1993)
Biotin	Vitamin H, coenzyme R	Most foods, especially milk and cheese. Synthesized by microorganisms in intestines.	Most produced synthetically.	Yes—methods are improving.	No	N/A	Hoffman-La Roche, Takeda, Sumica Fine Chemicals, Kongo, Changzhou Pharma and Changshu Huangang Pharma	25 tons (1995)
Folic Acid	Folates, Vitamin Bc, Vitamin M	Green leafy vegetables, liver, kidney, mushrooms, yeast	Produced synthetically.	No	No	N/A	Hoffman-La Roche, Tanabe, Sumitomo, Merck, Il Sung, Lonza, BASF	400 tons (1995)
Vitamin C	Ascorbic acid	Fresh fruits and vegetables, hip berries, fresh tea leaves	Produced synthetically from naturally occurring sugars.	Fermentation methods are being developed.	No	N/A	Hoffman-La Roche, Dalry, Belvidere, Takeda, Osaka, Wilmington, Merck, Darmstadt, BASF, Grenaa, Pliva, Zagreb, Chinese State companies	60,000 tons (1995)

[a]Choline, which is related to B-complex vitamins, is not truly considered to be a vitamin because of insufficient data on deficiency symptoms. The National Academy of Sciences has set Adequate Intake levels (AIs) but not RDAs for choline.

Sources: Ullmann's Encyclopedia of Industrial Chemistry. 1996. Vol. A27 1996 VCH Verlagsgesellschaft, pages 443-613.

Hendler, Sheldon Saul. 1990. *The Doctor's Vitamin and Mineral Encyclopedia.* New York, NY: Simon and Schuster, pages 37-109.

National Academy of Sciences. Institute of Medicine News. <http://www2.nas.edu/whatsnew/287e.html>. As obtained on April 7, 1998.

Budavari, S. (ed.). 1996. *The Merck Index: An Encyclopedia of Chemicals, Drugs, and Biologicals.* Whitehouse Station, NJ: Merck.

Fermentation

Fermentation is a process whereby bacteria are grown in tanks. The tanks, called "fermenters," are filled with a nutrient-rich medium and are inoculated with a strain of bacteria that will produce the desired vitamin. The fermenters are held at controlled temperatures to allow the bacteria to multiply at an optimum rate. Bacterial cells are then separated from the medium with filters or centrifuges, and the mass of cells is dried. Evaporation or spray drying can also be used to separate the cells from the medium. Various processes, which may include heating and the addition of chemicals, are then used to lyse, or break open, the cells, releasing the vitamin-rich cell contents. Further purification and concentration follows and may include solvent extraction. Several vitamins are produced through fermentation, and scientists are striving to improve techniques. Vitamin B_{12} is produced on an industrial scale exclusively through fermentation (Ullman's Encyclopedia of Chemical Technology, 1996).

Extraction from Natural Products

Scientists originally isolated each of the vitamins from some natural source. Vitamins A and D were originally isolated from fish liver oil; vitamin E from wheat germ oil; vitamin K from alfalfa; vitamins B_1 and B_6 from rice; vitamin B_2 from eggs; and vitamin B_{12}, niacin, folic acid, pantothenic acid, and biotin from liver. Although it is possible to extract all vitamins from natural products, it is generally infeasible on an industrial scale. An exception to this is vitamin E, which is produced in large quantities from a by-product of vegetable oil production. Relatively small quantities of vitamins A and D are also extracted from fish oils. Various processes are used for extraction, including distillation and solvent extraction (Ullman's Encyclopedia of Chemical Technology, 1996).

2.1.2 Production Processes for Minerals

Unlike vitamins, which are organic substances, minerals are inorganic compounds that are required in small quantities in the diet to maintain health. Inorganic substances that humans require in quantities greater than 100 milligrams per day are called "minerals," and those required in quantities less than 100 milligrams per day are called "trace elements" (Hendler, 1990). Table 2-2 lists 17 minerals that are commonly consumed in dietary supplements, along with the forms of the minerals used in supplements. Minerals, by their nature, come from the earth. They are derived from rocks or soils or may come from sea or lake water. Mineral supplements that are called "plant minerals" may actually be mined from deposits of sedimentary rock.

Chelated and Colloidal Minerals

Two forms of mineral supplements are marketed as being more easily absorbed by the body. These are chelated and colloidal minerals. A chelating agent is a molecule that binds to metal. Chelated minerals used in dietary supplements have been processed so that the metal

Table 2-2. Minerals Found in Dietary Supplements

Mineral	Occurrence in Foods	Forms Used as Supplements
Boron	Fruits and vegetables	Sodium borate
Calcium	Dairy products, salmon, leafy green vegetables, tofu	Calcium chloride, carbonate, glubionate, gluconate, lactate, phosphate, and citrate; dolomite; bone meal
Chromium	Whole grains, meats, cheeses, brewer's yeast	GTF chromium, chromium trichloride, chromium picolinate
Copper	Liver, shellfish, fruits, nuts, legumes	Copper gluconate, copper sulfate
Flourine	Drinking water, seafood, meat, tea	Sodium flouride
Germanium	N/A	Ge-132
Iodine	Seafood, seaweed, iodized salt	Iodide or iodate salts
Iron	Red meats, organ meats	Ferrous sulfate, fumarate, and gluconate; carbonyl iron
Magnesium	Meats, seafoods, green vegetables, dairy products	Magnesium oxide, carbonate, hydroxide, gluconate, aspartate, orotate, oxide and hydroxide; dolomite
Manganese	Whole grains and nuts, plants grown in manganese-rich soils, organ meats, shellfish, milk	Manganese sulfate, manganese gluconate
Molybdenum	Organ meats, grains, legumes, leafy vegetables, milk	Sodium molybdate, molybdenum-enriched yeast
Phosphorus	Dairy products	Sodium phosphate or potassium phosphate salts
Potassium	Fresh fruits and vegetables	Potassium chloride, bicarbonate, aspartate, and orotate
Selenium	Vegetables, brewer's yeast, grains, fish, organ meats (plants must be grown in soils that have selenium)	Sodium selenite, organic selenium derived from brewer's yeast
Silicon	Vegetables, whole grains, seafood	Magnesium trisilicate, silicon dioxide, symethicone
Vanadium	Black pepper, dill seeds, whole grains, seafoods, meats, dairy products	N/A
Zinc	Whole grains, brewer's yeast, seafood, meat	Zinc sulfate, acetate, gluconate, citrate, dipicolinate, aspartate, and orotate; amino acid chelates of zinc

Source: Hendler, Sheldon Saul. 1990. *The Doctor's Vitamin and Mineral Encyclopedia*. New York: Simon and Schuster.

atoms are surrounded by a chelating agent, in this case, amino acids (Reach 4 Life, 1998). A colloid is a suspension of extremely fine particles in a continuous medium. These particles do not settle out readily and are not readily filtered (The American Heritage Dictionary, 1985). Colloidal minerals used as dietary supplements are minerals that have been ground into very small particles and have been suspended in water. Colloidal mineral supplements come in liquid form (Reach 4 Life, 1998).

2.1.3 Production Processes for Herbals and Botanicals

Dietary supplements from plant sources are sometimes referred to as "phytopharmaceuticals." They are produced from fresh, dried or otherwise preserved plants or parts of plants. The active ingredients are usually not completely isolated but rather are obtained along with other naturally occurring components of the plant. (These other components are often believed to influence the efficacy of the active ingredient.) Sometimes the active ingredients are concentrated, and undesirable substances such as chlorophyll, tannins, or resins, are removed (List and Schmidt, 1989). The following sections discuss the various stages of production of dietary supplements of plant origin.

Cultivation and Collection of Plant Materials

Most of the plants used for dietary supplements or medicinal purposes are cultivated, that is, grown on farms. Some, however, may be collected from the wild (Wijesekera, 1991). The following section discusses both methods for obtaining botanicals or herbals.

Cultivation. Cultivation allows producers to have more control over quality and purity than does collecting plants from the wild. Cultivars (cultivated varieties) of a number of medicinal plant species have been developed to produce high yields of the desired constituents. Some plants that are grown commercially for medicinal purposes are propagated vegetatively. (This means that new plants are grown from cuttings of old plants. Plants grown in this way are genetically identical to the parent plant.) Some medicinal plants are grown from selectively bred hybrid seeds, while others are varieties of plants that are unchanged from their natural form (Wijesekera, 1991).

A number of medicinal plants are cultivated for use by the pharmaceutical industry. Some examples include yams, which are used in the production of steroids; foxglove, which is used for digitalis; belladona, which is used for atropine; and opium, which is used to make morphine. The following is a list of major, commercially cultivated medicinal plants, many of which are used in dietary supplements (Wijesekera, 1991):

Aconites	Costus	Ipecac	Rauvolfia
Aloe	Datura	Lemon grass	Senna
Anise	Dill	Liquorice	Smilax
Artemisia	Dioscorea	Male fern	Squill
Basil	Duboisia	Mints	Strophanthus
Belladonna	Ephedra	Opium poppy	Sweet flag
Buchu	Ergot	Papain	Thyme
Casara bark	Foxglove	Periwinkle	Valerian
Celery	Gentians	Podophyllum	Vinca
Chamomilla	Ginseng	Polygala	Withania
Cinchona	Henbane	Psyllium	
Colchicum	Hydrastis	Pyrethrum	

A number of countries commercially cultivate and export substantial quantities of medicinal plants. These countries include China, India, Thailand, South Korea, Brazil, Mexico, Egypt, Indonesia, Nepal, the Philippines, and Kenya. Eastern European countries cultivate medicinal plants as well, but mostly for their own consumption (Wijesekera, 1991).

As for any agricultural crop, producers of medicinal plants must provide plants with adequate moisture and nutrients and must control pests and diseases. Pesticides must be used cautiously to reduce the risk of harmful residues on plants (List and Schmidt, 1989). Production of medicinal plants is generally labor intensive. In many cases, only the portions of the plant that contain the active ingredients—not the whole plant—are used. Sometimes harvesting involves picking leaves and flowers by hand (Hornok, 1992). In the future, tissue culture may be used for producing plant material (List and Schmidt, 1989).

Collection from the Wild. Tropical forests are the source of a number of plants used for medicinal purposes. There are several disadvantages to collecting wild plants, however. This practice, along with deforestation, has caused some wild plant species to become endangered (Wijesekera, 1991). Also, when plants are collected from the wild, there is a risk that they have been incorrectly identified (List and Schmidt, 1989). One advantage to using wild plants, however, is that they are unlikely to contain any pesticide residues (Wijesekera, 1991).

Cleaning. After the plants are harvested or gathered, they must be cleaned. Cleaning may involve screening, washing, peeling, or stripping leaves from stems. Any unnecessary parts are removed prior to drying to avoid wasting time and energy. Cleaning is often done by hand (Hornok, 1992).

Drying. In some cases, botanicals are used for extraction while fresh, but generally, they are dried first. The purpose of drying is to reduce the water content so that the plant can be stored. Most plants contain 60 to 80 percent moisture when harvested and must be dried to within 10 to

14 percent moisture before storage. Plants must be dried or processed as soon as possible after harvest because they begin to deteriorate immediately. Processing up to this point is generally done by the producer of the plants (Hornok, 1992). Plants can be dried naturally or by a number of artificial methods. The type of plant or plant part being used will determine the appropriate drying technique (List and Schmidt, 1989).

Natural Drying. A practice that has been used since ancient times is sun-drying in the field. Although this method requires no drying equipment and uses solar energy, it requires large amounts of space, and plants can be damaged by the weather. Sometimes plants are placed by hand on drying frames or stands, to be air-dried in barns or sheds. This method of drying is labor-intensive and can take several weeks. The exact length of time for adequate drying depends on temperature and humidity (Hornok, 1992).

Artificial Drying. With the use of artificial dryers, drying time can be reduced to hours or minutes, and labor can also be greatly reduced. Fans that blow unheated air (cold-air drying) can reduce drying time to several days. Warm-air drying, which is the most widely used method for medicinal plants, uses a counter-current flow of warm air. There are several different types of systems for warm-air drying. One type is the plate chamber dryer, which blows warm air across plates on which plants have been placed. This method is useful for fragile flowers and leaves but requires large amounts of labor. Workers must load and unload the plants from the plates manually. The capacity of these dryers is relatively low, as well.

Conveyor dryers are a commonly used type of warm-air dryer. Fresh plants travel on a conveyor belt through a counter-current flow of warm air. These dryers can operate continuously, require relatively little labor, and have high throughput. However, they require a large capital investment and have high energy requirements. The drying time required for conveyor dryers ranges from 2.5 to 6 hours, and the temperature of the drying air ranges from 40 to 80ºC. Hot air dryers, which use very high temperatures (200 to 1,000ºC) for very short periods (2 to 5 minutes) are not commonly used for drying medicinal plants (Hornok, 1992).

Packaging of Dried Plants

Once drying is complete, plants are packaged in preparation for shipping and further processing. Dried herbaceous plants are generally compressed into bales weighing from 60 to 100 kg (13 to 220 pounds), which are then sewn into fabric bags or wrapped in plastic. Materials that cannot be baled, such as roots and bark, are placed in sacks. Smaller bags may be used for dense materials such as dried fruits or seeds. Very fragile materials, such as flowers, are packaged in crates. Dried plant materials tend to be hygroscopic (readily absorbing moisture) and must be stored under controlled humidity. Highly hygroscopic materials are generally packed in plastic (Hornok, 1992).

Cleaning and Sorting

When the sacks or bales arrive at the processing facility, processors open the packages and clean the dried plants to remove as many impurities as possible. Sand is removed pneumatically and iron-containing metals are removed magnetically. Next, processors sort the plant pieces by size, since different end-uses require different particle sizes. For example, finely shredded material may be used for tea bags and somewhat less finely shredded material for loose teas or infusions, while coarsely shredded material may be sold directly to consumers or used for extraction. Particles that are already the desired size can go directly into storage to await further processing. Particles that are too big undergo additional grinding, cutting or shredding, and sieving. Various methods are used to reduce particle size including hammer action, pressure, friction, impact cutting, and shredding (List and Schmidt, 1989). Some plant materials are packaged and sold at this point without any additional processing. Some proceed through an extraction process, which the following section describes.

Extraction

Extraction is a process whereby the desired constituents of a plant are removed using a solvent. The following section describes several methods used for preparing extracts, including organic solvent extraction, supercritical gas extraction, and steam distillation.

Organic Solvent Extraction. Organic solvent extraction is one process for separating the desired substance from plant material. As was previously mentioned, dried plants are usually used for extraction, although fresh plants are sometimes used. The plants are first ground and then thoroughly mixed with a solvent such as hexane, benzene, or toluene inside a tank. The choice of solvent depends on several factors including the characteristics of the constituents being extracted, cost, and environmental issues. If the end product will contain trace amounts of residual solvent, a nontoxic solvent must be used. Once the solvent dissolves the desired substances of the plant, it is called "miscella." The miscella is then separated from the plant material (Hornok, 1992). There are a number of techniques for solvent extraction, which include maceration, percolation, and countercurrent extraction. The following is a brief description of each.

- **Maceration:** This method involves soaking and agitating the solvent and plant materials together. The solvent is then drained off. Remaining miscella is removed from the plant material through pressing or centrifuging. This method does not totally extract the active ingredients from the plant materials.
- **Percolation:** With this method, the plant material is moistened with solvent and allowed to swell before being placed in one of a series of percolation chambers. The material is repeatedly rinsed with solvent until all the active ingredient has been removed. Solvent is reused until it is saturated. New solvent is used on plant material that is almost completely exhausted, and then re-used on subsequently less exhausted batches. This method is more effective at removing active ingredients than the maceration technique.

- **Countercurrent extraction:** This is a highly effective process whereby solvent flows in the opposite direction to plant material. Unlike maceration and percolation, which are batch processes, this method is continuous. Screw extractors and carousel extractors are two types of equipment used for countercurrent extraction (Wijesekera, 1991).

Purification and Concentration of Miscella. Miscella that has been separated from the plant material generally contains some unwanted substances such as tannins, pigments, microbial contaminants, or residual solvent. Methods such as decanting, filtration, sedimentation, centrifuging, heating, adsorption, precipitation, and ion exchange are used to separate impurities from the miscella. Sometimes the miscella resulting from solvent extraction is used as the final dosage form. This is known as a "fluid extract" (List and Schmidt, 1989).

The miscella is sometimes concentrated in order to increase the proportion of the desired substance. This is done through evaporation or vaporization. Solvent is generally recovered and reused (List and Schmidt, 1989). The degree of concentration depends on the desired end product. Equipment for concentrating the miscella may include descending film, thin layer or plate concentrators. Any method used to concentrate the miscella must avoid excessive heat because the active compounds may be subject to degradation (Wijesekera, 1991). Sometimes extracts are dried completely using vacuum freeze dryers, cabinet vacuum dryers, continuously operating drum or belt dryers, microwave ovens, or atomizers. The technique for drying depends on the stability of the product and the amount of moisture that must be removed. The resulting powdered extract is less subject to microbial contamination than are liquid extracts (Hornok, 1992).

Extraction with Supercritical Gases. This is a method for extracting active ingredients using gases. The plant material is placed in a vessel that is filled with a gas under controlled temperature and high pressure. The gas dissolves the active ingredients within the plant material, then passes into a separating chamber where both pressure and temperature are lower. The extract precipitates out and is removed through a valve at the bottom of the chamber. The gas is then reused. Gases suitable for supercritical extraction include carbon dioxide, nitrogen, methane, ethane, ethylene, nitrous oxide, sulfur dioxide, propane, propylene, ammonia, and sulfur hexafluoride. An advantage of supercritical extraction is that it can take place at low temperature, thus preserving the quality of temperature-sensitive components (List and Schmidt, 1989).

Steam Distillation. Steam distillation is another method for extracting active ingredients from medicinal plants. The plant material is loaded onto perforated plates inside a cylindrical tank or still, and steam is injected from below. The steam dissolves the desired substances in the plant, then enters a condenser where it is condensed back into a liquid. This condensate then passes into a flask, where the extract either rises to the top or settles to the bottom and is separated from the water. Distillation is complete when there is no more extract present in the condensate. The water may be reused, and the extract is purified through centrifuging and filtering (Hornok, 1992).

Other Minor Extraction Methods. Other minor methods for making extracts include cold pressing and the enfleurage process. Cold pressing is a process used to extract essential oils from citrus plants through pressing (Hornok, 1992). The enfleurage process is the same as the technique used to make perfume from flowers: purified fats are used to extract essential oils from plant parts. Plant material is spread onto sheets of purified fat, which dissolve the essential oils (List and Schmidt, 1989).

Sometimes practitioners of herbal medicine prepare extracts for immediate use. These include aqueous extracts known as decoctions, infusions, or macerations. Plant material is mixed, agitated, and soaked in water to dissolve the active ingredients. Controlling microbial contamination can be difficult in aqueous extracts. Oily drug extracts, also called "medicinal oils," may be prepared by soaking or macerating the plant material in an oil such as almond, peanut, olive, poppy seed, apricot kernel, or peach kernel oil. Vinegar is sometimes used to extract active ingredients as well. Plant materials are soaked in acetic acid, and the vinegar is consumed as the final dosage form (List and Schmidt, 1989).

Controlling the Quality of Extracts

Once an extract has been produced by one of the methods mentioned above, producers can use a number of tests to evaluate the quality and purity of their product. First, they may examine the physical characteristics of the extract. This may include evaluating its appearance, pH, solubility, total solids content, ash content, and in the case of dried extracts, particle size. Next, they may analyze the components of the extract to be certain it contains the appropriate quantities of desired ingredients. Chromatography (including thin layer, column, high pressure liquid, and gas chromatography) may be used for this. Finally, they may test the extract for impurities such as residual solvents, herbicides, and pesticides and for microbial contamination (Wijesekera, 1991).

Some extracts are labeled and sold as standardized extracts. According to industry sources, the desired constituents in standardized extracts are measured and are listed as a percentage of the total weight of the extract. For example, echinacosides are the desired compounds present in echinacea extract. A capsule containing 250 mg of echinacea extract standardized to 4 percent would contain 10 mg of echinacosides. In some cases, the desired constituent is a known active ingredient. In cases where the active ingredient has not been identified, another "marker " compound, or substance that is known to be present in the plant, may be measured for the purpose of standardization. Spectrophotometric testing and high pressure liquid chromatography may be used to measure standardized constituents (*Standardized Extract Product Guide*, 1997).

2.1.4 Production Processes for Amino Acids

Amino acids, which are the building blocks of proteins, are known as "chiral" compounds. This means that they exist in two forms that are mirror images of one another, like right and left hands. Amino acids are identified as either L or D, to indicate the chiral form of the molecule. Living organisms can only use the L form of amino acids, and are unable to recognize the D form. The

amino acids used in dietary supplements are generally the L form and are labeled as such (L-cystein, L-lysine).

Amino acids used in dietary supplements can be made through either synthesis or fermentation. The synthesis of an amino acid starts with basic chemicals and results in a 50-50 distribution of the L and D forms. Since the D form is useless to humans, it is generally removed. The fermentation process for producing amino acids uses yeasts that are fed nutrients from plant sources such as corn or soy. The yeasts are grown under controlled conditions and the amino acids are extracted from the yeast (see Section 2.1.1 on vitamins for a more detailed description of the fermentation process). Since yeasts are living organisms, this method results in 100 percent L-form amino acids (Heartland Lysine, 1998; Musashi USA, 1998).

2.1.5 Production Processes for Proteins

Various types of purified plant and animal proteins are sold as dietary supplements in the form of powders or granules. Soy is a major source of these proteins. The term *soy protein* refers to a processed, edible dry soybean product. The production of soy proteins for human consumption is generally a separate process from the production of vegetable oils or animal feeds. Soybeans that are rejected from the food-grade process are diverted to these other uses. Some general categories of soy proteins are full-fat soy flour, defatted soy flour, soy protein concentrates, and soy protein isolates. Full-fat soy flour, which is about 40 percent protein, is made by grinding whole, dried soybeans. Defatted soy protein is made from soybeans that have undergone solvent extraction to remove oil. It contains 52 to 54 percent protein. Soy protein concentrates are flours that have had all water or alcohol-soluble components removed. These are at least 65 percent protein. Soy protein isolates, which are 90 percent protein, are concentrates that have been rid of fiber. Soy concentrates and isolates often undergo additional processing, such as pH adjustment or hydrolysis, before drying. (Hydrolysis is the decomposition of a compound by reaction with water.) There are numerous options for further processing soy proteins, many of which are trade secrets (Erickson, 1995).

Whey and casein are two other types of protein used in dietary supplements. Both are products of the dairy industry. Whey is a by-product of the manufacture of cheese, and casein is the main protein found in milk and cheese. Other sources of protein used in dietary supplements include eggs, grains and other vegetable sources, and collagen, which is extracted from the cartilage and connective tissue of slaughtered animals.

2.1.6 Production Processes for Animal Products

Some dietary supplements of animal origin are compounds that have been purified from parts of animals, using techniques such as solvent extraction or column chromatography, while others are composed of whole concentrated animal tissue. For example, chondroitin sulfate, a dietary supplement used to relieve symptoms of arthritis, is extracted mainly from bovine trachea, or sometimes from shark cartilage (Sturtz, 1998). Dietary supplements known as “glandulars” are

raw animal glands such as the pituitary, prostate, or thyroid glands that have been lyophilized (freeze-dried) and placed in capsules or tablets (110% Products, 1998).

2.1.7 Production Processes for Other DS Products

A number of dietary supplements are not included in this section on production processes because information is not available from secondary sources. In addition, any available information on the dietary supplements referred to as "constituents, metabolites, and concentrates" has been included in one of the other categories. For example, concentrated extracts are discussed in the section on Herbals and Botanicals. Available information on several miscellaneous dietary supplements is presented below.

Algae

Single-celled algae, such as spirulina, have been consumed by humans throughout the world for centuries. The Aztecs harvested and consumed naturally occurring spirulina. At present, algae for human consumption is produced by various means, ranging from harvesting it from natural lakes and ponds to using sophisticated fermentation equipment to create it. Algae requires carbon, generally in the form of carbon dioxide, as well as nitrogen and phosphorus. It also needs small quantities of micronutrients. Water that is polluted with organic waste is ideal for growing algae. Algae can be raised outdoors in lakes, ponds and ditches. It is harvested by skimming with screens or cloths. Sometimes flocculating agents, such as lime, are added to the water to facilitate harvesting. After harvesting, the algae is dewatered through centrifuging and dried using sun drying, spray drying, or most often, drum drying (Encyclopedia of Food Science, Food Technology, and Nutrition, 1993).

Teas

As mentioned in the section on Herbals and Botanicals, plant materials that have been dried, cleaned, sorted, and shredded to the appropriate particle size may be sold as teas. Fine particles are used for tea bags, and coarser particles are used for loose teas. Green teas, which are said to have antioxidant qualities, are made from tea leaves that have been blanched or roasted to stop the process of fermentation that produces black teas (Best, 1996). Some teas may contain ingredients such as flavorings or extracts in addition to shredded plant materials (LEAVES Pure Teas, 1998).

Bee Products

Propolis, bee pollen, and royal jelly are all coproducts of honey production that are used in dietary supplements. Propolis is a sticky substance that is secreted by bees to seal cracks and spaces within the hive. Its antimicrobial properties help to control the growth of bacteria and fungus within the hive. Beekeepers can collect small quantities of propolis by hand by scraping it out of the crevices and corners of the hive. Those who collect it commercially may place a fine-

mesh plastic screen about an inch above the hive. In the fall, the bees attempt to seal the space between the screen and the hive with propolis. The beekeeper later removes the screen along with the propolis. A healthy hive can produce about 200 grams of propolis in a season.

To collect pollen from bees, beekeepers construct pollen traps. These are screens that the bees must crawl through in order to enter the hive. As they crawl through the mesh, about 10 percent of the pollen that they are carrying is scraped off and falls into a clean tray below. Beekeepers can collect 2 to 3 kg of pollen from a single hive in one season without causing a shortage for the bees.

Royal jelly is a substance that bees produce in minute quantities to feed larvae that are to become queen bees. It is collected by hand with either a special spoon or a suction device. Royal jelly degrades easily and should be refrigerated in air-tight brown glass containers.

Many beekeepers collect propolis, pollen, and royal jelly for their own use and do not sell it commercially. Only large beekeeping operations produce enough of these substances for commercial marketing (Schech, 1998).

2.2 FINAL DOSAGE FORMS

Although the production practices for DS products differ, the final dosage forms among them are similar in many cases. In this section we describe how products are put into the form in which they are purchased by consumers.

2.2.1 Capsule Dosage Forms

Gelatin capsules were invented in the 1830s by a pharmacist who wanted to make unpalatable medicines easier to swallow. Both hard and soft capsules have similar ingredients, which include gelatin and water, and possibly colorants, preservatives, opacifying agents, flavors, and sweeteners. Soft capsules also contain plasticizers such as glycerin or sorbitol to keep them pliable. The following is a brief description of the production processes for hard and soft capsules.

Hard Capsules

The process for manufacturing hard capsules is highly automated. Rows of mold pins that are shaped like either the body or cap of a capsule are lowered into tanks containing a gelatin solution. The gelatin coats the pins and hardens. After drying, the capsule bodies and caps are removed from the pins and cut to the correct length. The caps are placed on the bodies, and the empty capsules are sealed in moisture-proof containers for shipping and storage until use (Swarbrick and Boylan, 1990).

Hard gelatin capsules can be filled with many types of materials, including powders, granules, pastes, oily liquids, suspensions, and solutions. Gelatin capsules cannot be used for substances

that have a high water content because water will soften or dissolve the gelatin. Substances that must be consumed in large volume are not well suited for capsules either, since there is a limit to the size of capsule that can be easily swallowed. Substances that react with gelatin, such as formaldehyde, should also be avoided (Swarbrick and Boylan, 1990).

Various types of machines are used for filling hard capsules. They all automate the same basic steps. The empty shells are first all pointed in the same direction, with the bottoms pointing down. The cap is removed from the bottom using suction. A dosing head places the correct amount of material into the capsule, and the cap is replaced. For powders and dry solids, there are direct and indirect filling machines. Machines that use the capsule itself to measure the correct volume of material are known as direct filling machines. Indirect filling machines have a separate chamber that premeasures the correct quantity to be placed in each capsule. Machines for filling capsules with liquids use volumetric pumps to measure the correct dose (Swarbrick and Boylan, 1990).

The equipment used to make hard gelatin capsules is very costly. For this reason, these capsules are manufactured in large quantities by only a few companies (Swarbrick and Boylan, 1990).

Soft Capsules

Soft capsules, which are also called "softgels," are one-piece, hermetically sealed, soft gelatin shells that contain a liquid or semiliquid substance. They are formed, filled and sealed in one continuous operation. As with hard capsules, substances that dissolve or react with the gelatin are not suitable for encapsulation in softgels.

Softgels are produced as follows: Melted gelatin flows from two tanks in thin streams onto two rotating cooling drums, forming two thin ribbons of gelatin. These ribbons, which are lubricated with mineral oil, pass over guide rolls and are brought together through rotating die rolls. These die rolls pinch the two ribbons together to form the capsule. Before the two ribbons are completely pinched together, a pump injects the fill material into the pocket that has been formed between the two ribbons. The die then seals off the pocket to form a capsule and stamps it out of the ribbons. The filled capsules pass through a solvent to remove the lubricant and are dried. The equipment used to produce softgels also requires a large capital investment and is generally performed by large manufacturers on a contract basis (Swarbrick and Boylan, 1990).

2.2.2 Tablet Dosage Forms

Tablets are a solid dosage form that come in various shapes and sizes. They are formed by compression and generally contain additives to aid in their manufacture, as well as various colorants and coatings. The additives used to make tablets are called "adjuncts." These may include diluents or fillers to add bulk; binders, or adhesives to help hold tablets together; disintegrating agents to aid in the breakup of the tablet after swallowing; and lubricating agents to allow the material to flow freely through the tablet-making equipment. The machines used to

make tablets use punches or dies that apply tremendous pressure to powdered or granular material, compressing it into tablets. Tablets can be made through a single compression, or layered tablets may be made using multiple compressions (Ansel, Popovich, and Allen, 1995).

Once tablets are formed, they may be coated with a sugar, film, or enteric coating. Sugar coatings protect the active ingredients in the tablet from air and humidity and cover bad flavors. They also can be used to make tablets larger and easier to handle. Film-coated tablets are covered with a thin layer of a polymer that protects the tablet and makes it easier to swallow. This film breaks apart in the stomach. Enteric coatings remain intact until the tablet reaches the intestines. Chewable tablets, which have no coating, are also made by compression. This type of tablet is commonly used for children's vitamins. They are generally made from a mannitol base with added colors and flavors (Ansel, Popovich, and Allen, 1995).

Dissolution of Capsules and Tablets

Both hard and soft capsules and tablets can be tested to determine how readily they dissolve. The rate of dissolution is an important characteristic of capsules and tablets since it is indicative of the substance's absorption and availability within the body. A fairly simple apparatus is used to measure the rate of dissolution for these dosage forms. The equipment consists of a series of wells or containers with the dissolution solvent kept at a constant temperature by a water bath. The tablets are introduced directly into the dissolution solvent and stirred with a paddle or are introduced in a basket attached to a shaft that is rotated. The capsules and tablets are mixed with the dissolution solvent until the dissolution time has expired. Then the solvent is analyzed for dissolved constituents to determine the dissolution rate (Hines, 1998).

2.2.3 Liquid Dosage Forms

Liquid dosage forms include solutions, syrups, and elixirs. Solutions contain active ingredients plus a solvent, which is generally water. They are prepared on an industrial scale in large, thermostatically controlled mixing vats with openings for mechanical stirrers (Ansel, Popovich, and Allen, 1995). Syrups are concentrated aqueous preparations that generally contain sugar or a sugar substitute, flavorings, colorings, and preservatives, along with the active ingredient. They may also contain additional solvents, solubilizing agents, thickeners, or stabilizers. Most syrups contain 60 to 80 percent sugar because of its sweetness, viscosity, and stability. Syrups can be prepared using heat to dissolve the sugar and active components or without heat, using agitation to dissolve the ingredients. Sometimes sugar syrup is prepared separately and cooled before mixing with a fluid extract. Elixirs are similar to syrups except that they contain some alcohol and less sugar. They are useful for delivering substances that are not soluble in water alone (Ansel, Popovich, and Allen, 1995).

2.2.4 Powder and Granule Dosage Forms

Powders are fine particles of material in dry form. Powders used for medicinal purposes must be a homogeneous blend of all desired components and must be of an appropriate particle size. Various types of mills and pulverizing equipment are used to reduce particle size, and standardized sieves are used to measure particle size. Granules are agglomerates of smaller particles. They are made by blending a liquid with a powder, then passing the mixture through a sieve to produce the desired granule size. The granules are then dried (Ansel, Popovich, and Allen, 1995).

2.2.5 Lozenge Dosage Forms

Lozenges are made to dissolve slowly in the mouth for local effect. They can be made by compression with a tableting machine, or if the active ingredient is heat resistant, lozenges can be produced with hard-candy-making equipment. The active ingredients are added to a hot, concentrated sugar syrup that is molded and cooled (Ansel, Popovich, and Allen, 1995).

2.2.6 Packaging of Dietary Supplements

The purpose of packaging is to provide protection, presentation, identification, information, and convenience from the time a product is manufactured until it is consumed. The type of packaging used will depend on the characteristics of the product, such as its sensitivity to moisture, oxygen, or light or its reactivity with the packaging material. The form of the product is also important. Whether the product is a tablet, capsule, liquid, or granule will determine the appropriate packaging. Plastic bottles and jars are commonly used to package dietary supplements. Other types of packaging include glass bottles, jars, vials, and ampules, as well as bags or pouches made of plastic film, laminates, aluminum foil, or paper. Some types of packaging, such as blister packs, are a combination of several materials. Packaging is sometimes performed on a contract basis (Lockhart and Paine, 1996).

2.3 GOOD MANUFACTURING PRACTICES

A draft report prepared by representatives of several trade associations for FDA in 1995 outlines good manufacturing practices (GMPs) for the dietary supplement industry (U.S. Dept. of Health and Human Services, 1997). These practices are modeled after GMPs for food, not those for pharmaceuticals. The majority of the GMPs in this report are identical to those for food. However, in some instances the report provides more detailed recommendations for the manufacture of dietary supplements than for foods. For example, the section of the report on production and process controls contains detailed guidelines for quality control, maintenance of laboratory records, and specification of expiration dates. It calls for manufacturers to keep master production and control records, as well as individual production and control records for each batch produced. The report also specifies that raw materials should be examined, identified, and tested prior to use. It recommends that manufacturers establish procedures for ensuring the

quality and composition of the final product. Instructions on appropriate packaging and labeling are included, as are procedures for handling complaints (Council for Responsible Nutrition, 1995).

2.4 PRODUCTION COSTS FOR DIETARY SUPPLEMENTS

Data on production costs for DS products are not readily available from secondary data sources. However, some information can be obtained on the relative costs of labor and materials at the 4-digit Standard Industrial Classification (SIC) level from the U.S. Bureau of the Census. Table 2-3 presents the number of employees, payroll expenses, costs of materials, and value of industry shipments for each of the six SIC codes that encompass the majority of the DS industry. DS products fall predominately in SIC 2833, Medicinal Chemicals and Botanical Products, and 2834, Pharmaceutical Preparations; however, other types of firms are also included in these SICs.[1]

The percentages of payroll expenses and cost of materials relative to value of shipments are calculated in Table 2-3 for each SIC. For most of the SIC codes, the cost of materials is half or more of the value of shipments, and payroll expenses are much less. For SIC 2833, the cost of materials made up about 48 percent of the value of shipments in 1996. For 2834, in comparison, cost of materials made up only 30 percent of the value of shipments in 1996. The percentages of labor expenses for each were 9 percent and 10 percent, respectively, in 1996. In general, from 1994 to 1996, it appears that labor expenses were falling and costs of materials were rising relative to value of shipments.

[1]SIC codes are discussed in greater detail in Section 6 of this report.

Table 2-3. Labor and Materials Expense for SIC Codes that Contain Dietary Supplement Products: 1994-1996

SIC	Year	Description	Total Employees (thousands)	Total Payroll Current Dollars (million $)	Cost of Materials Current Dollars (million $)	Value of Shipments Current Dollars (million $)	Payroll as a % of Value of Shipments	Cost of Materials as a % of Value of Shipments
2099	1994	Food Preparations, NEC	64.3	1,546.5	6,781.7	13,314.9	11.61%	50.93%
	1995		66.8	1,602.4	7,122.7	14,021.6	11.43%	50.80%
	1996		69.5	1,681.8	7,326.4	14,971.2	11.23%	48.94%
2819	1994	Industrial Organic Chemicals, NEC	64.6	2,751.9	6,267.2	16,032.2	17.16%	39.09%
	1995		58.9	2,681.5	6,787.3	17,133.7	15.65%	39.61%
	1996		57.0	2,744.8	7,461.1	17,861.9	15.37%	41.77%
2833	1994	Medicinal Chemicals and Botanical Products	13.9	613.7	2,953.0	6,189.3	9.92%	47.71%
	1995		14.1	685.8	3,298.5	7,027.2	9.76%	46.94%
	1996		16.8	840.1	4,238.0	8,883.8	9.46%	47.70%
2834	1994	Pharmaceutical Preparations	134.2	5,753.8	14,497.3	56,960.5	10.10%	25.45%
	1995		143.0	6,268.2	16,825.5	58,404.5	10.73%	28.81%
	1996		136.9	6,196.7	18,555.7	61,554.3	10.07%	30.15%
2869	1994	Industrial Organic Chemicals, NEC	89.3	4,501.0	33,449.2	57,670.5	7.80%	58.00%
	1995		92.6	4,814.4	35,399.0	63,493.3	7.58%	55.75%
	1996		100.3	5,589.9	39,189.6	62,739.3	8.91%	62.46%
2899	1994	Chemicals and Chemical Preparations, NEC	36.5	1,364.6	5,683.2	11,370.4	12.00%	49.98%
	1995		38.1	1,445.8	6,092.8	12,088.7	11.96%	50.40%
	1996		35.1	1,389.1	6,012.3	11,872.2	11.70%	50.64%

Source: U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census. 1994 and 1996 Annual Survey of Manufactures: Statistics for Industry Groups and Industries M94(AS)-1 and M96(AS)-1.

SECTION 3
FACILITIES AND FIRMS

Currently available estimates of the number of facilities and firms that supply raw materials and manufacture DS products cover a broad range.[2] The *Nutrition Business Journal* estimates that in 1997, 150 raw material manufacturers and over 1,000 growers and harvesters supplied raw materials to the industry and 1,050 manufacturers produced finished DS products (see Figure 1-1). The Council for Responsible Nutrition (CRN) estimates that between 800 and 1,400 raw material suppliers and manufacturers serve the market. These estimates are similar to the estimate of over 1,100 DS raw material and manufacturing firms that are members of the five major DS trade organizations.[3] This may be an overstatement to the extent that some firms belong to multiple organizations but an understatement to the extent that some firms belong to none of the organizations.

RTI compiled information on plants and firms in the DS industry in the Dietary Supplement Enhanced Establishment Database (DS-EED). To the extent that data are available, the records contain information such as name and location of facilities, DS product type, facility type (manufacturer, ingredient supplier, repackager/relabeler/encapsulator, importer, exporter), other product types manufactured, sales, employment, SIC codes, NAICS and international codes. The sources of this information include the following:

- American Herbal Products Association 1998-1999 Membership Directory and Resource Guide;
- Council for Responsible Nutrition 1998 Membership Directory;
- Natural Food Merchandiser's Retailer Purchasing Guide, August 1998;
- InfoSeek Company Capsules (Hoover's Corporation), downloaded February 1998;
- Natural Products Expo West, Show Directory, March 1998;
- FDA's Official Establishment Inventory;
- Harris InfoSource, Inc.'s U.S. Manufacturers Database, electronic file received February 1998; and
- Thomas Food Industry Register on the Internet, downloaded January-February 1999.

After deleting duplicate records from these sources, 2,026 facilities remained in the DS-EED. Of these 2,026 facilities, 1,978 are located in the United States, 42 are located in Canada, and 6 are located in Puerto Rico.

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[2]In this section, the term *facility* is synonymous with *establishment* or *plant* and the term *firm* is synonymous with *company*. Firms may own a single facility or multiple facilities.

[3]Based on its interviews with the major trade organizations, RTI learned that the Council for Responsible Nutrition has 94 members; American Herbal Productions Association has approximately 200 members; the Nonprescription Drug Manufacturers Association has 15 members who produce DS products; the Utah Natural Products Alliance has 8 members; and the National Nutritional Foods Association (NNFA) has 800 raw material and manufacturing firm members. NNFA's numbers include some firms that produce natural products other than dietary supplements.

In Section 3.1, we describe the characteristics of the facilities in the DS-EED. In Section 3.2, we describe financial data for the DS industry.

3.1 FACILITY CHARACTERISTICS

The facilities in the DS-EED are characterized by facility type, product type, and other products produced. Each of these characteristics is described below.

The facility type indicates whether a facility manufactures, distributes, imports, exports, repackages, relabels, or encapsulates DS products or whether a facility provides raw ingredients to the industry. Table 3-1 provides frequencies for each facility type. Because a facility may be involved in more than one activity, the frequencies add up to greater than the total number of facilities in the database.

Table 3-1. DS Facility Type Frequencies

Facility Type	Number of Facilities	Percentage of Facilities
Manufacturer	1,555	78.6%
Input supplier	316	16.0%
Repackager, relabeler, or encapsulator	347	17.5%
Distributor	268	13.5%
Importer	209	10.6%
Exporter	340	17.2%

Source: Dietary Supplement Enhanced Establishment Database (DS-EED), as obtained March 24, 1999.

More than 78 percent of the facilities in the DS-EED are manufacturers of DS products. Sixteen percent of the facilities provide raw ingredients; 17 percent repack, relabel, or encapsulate products; and 13 percent distribute products. More plants export products (17 percent) versus import products (11 percent).

The product type indicates the type of DS produced or handled by each facility. Table 3-2 provides frequencies for each facility type. Vitamins and minerals, which are grouped together because facilities nearly always produce both in combination, are produced or handled by more than half (54 percent) of the facilities. Facilities that produce or handle herbals and botanicals follow at 43 percent. Herbal and botanical extracts, which are a subset of herbals and botanicals, are produced or handled by 14 percent of facilities. Teas follow at 10 percent, amino acids at 9 percent, proteins at 4 percent, and animal extracts at 2 percent. Concentrates, metabolites, and constituents are produced or handled at 4 percent of plants, but this figure may not represent the true total because the industry directories used to compile the DS-EED did not provide sufficient

Table 3-2. DS Product Type Frequencies

Product Type	Number of Facilities[a]	Percentage of Facilities
Vitamins and Minerals	1,066	53.9%
Herbals and Botanicals	850	43.0%
Herbal and Botanical Extracts	273	13.8%
Animal Extracts	34	1.7%
Amino Acids	186	9.4%
Proteins	87	4.4%
Tea	200	10.1%
Concentrates, Metabolites, and Constituents	80	4.0%
Other Supplements	602	30.4%

[a]The record source for 372 facilities did not indicate any product types.

Source: Dietary Supplement Enhanced Establishment Database (DS-EED), as obtained March 24, 1999.

detail to identify these products. Similarly, nearly 19 percent of facility records indicate no product types, which is also due to insufficient detail in the industry directories. Table 3-3 further breaks out product type by facility type for comparison across facility types.

Other products produced indicates whether a facility produces foods and/or drugs in addition to dietary supplements. Table 3-4 provides frequencies of facilities producing each of these other product types. Approximately 21 percent of facilities also produce foods and 17 percent also produce drugs.

3.2 DS FINANCIAL DATA

Future versions of the DS-EED will likely contain more information on sales and employment at individual facilities than is available from industry directories. Once this information becomes available, it will be possible to characterize DS facilities based on sales volumes and employment. In addition, parent company information can be used to categorize DS companies as small or large.

The U.S. Small Business Administration (1997) size definitions for the most relevant SIC codes are the following:

- 2075 Soybean Oil Mills: < 500 employees
- 2099 Food Preparations, Not Elsewhere Classified: < 500 employees
- 2819 Industrial Organic Chemicals, Not Elsewhere Classified: < 1,000 employees
- 2833 Medicinal Chemicals and Botanical Products: < 750 employees

Table 3-3. Frequencies of DS Product Types Produced at Each Facility Type[a]

	Manu-facturer	Input Supplier	Repackager/ Relabeler/ Encapsulator	Distributor	Importer	Exporter	Number of Facilities
Vitamins and Minerals	857	147	198	171	98	197	1,066
Herbals & Botanicals	647	184	237	186	140	198	850
Herbal and Botanical Extracts	209	115	85	53	59	71	273
Animal Extracts	28	3	5	6	5	8	34
Amino Acids	153	32	39	28	23	49	186
Teas	156	46	53	43	41	43	200
Proteins	80	14	16	12	10	19	87
Concentrates, Metabolites, and Constituents	67	17	26	11	8	17	80
Other Supplements	528	88	106	53	61	108	602
Number of Facilities	1,555	316	347	268	209	340	

[a]Facilities may be of multiple types and may produce multiple products.

Source: Dietary Supplement Enhanced Establishment Database (DS-EED), as obtained March 24, 1999.

Table 3-4. Frequencies of Other Products Produced at DS Facilities

Other Products	Number of Facilities	Percentage of Facilities
Foods	414	20.9%
Drugs	339	17.1%

Source: Dietary Supplement Enhanced Establishment Database (DS-EED), as obtained March 24, 1999.

- 2834 Pharmaceutical Preparations: < 750 employees
- 2869 Industrial Organic Chemicals, Not Elsewhere Classified: < 1,000 employees
- 2899 Chemicals and Chemical Preparations, Not Elsewhere Classified: < 500 employees

Based on these definitions, it is likely that the majority of firms in the DS industry will be considered small.

The *Nutrition Business Journal* provides sales information for the largest DS manufacturers. These sales data include only supplements rather than sales of all products produced by each company. Table 3-5 lists supplement sales for the top 15 manufacturers. Additional information on the facilities owned by these companies is available in the DS-EED.

Table 3-5. Top 15 Dietary Supplement Manufacturers, 1997

Manufacturer	Location	Supplement Sales ($ million)
Leiner Health Products	Carson, CA	425
Pharmavite	San Fernando, CA	340
American Home Products	Madison, NJ	325
Rexall Sundown	Boca Raton, FL	291
NBTY	Bohemia, NY	281
General Nutrition Companies	Pittsburgh, PA	260
Weider Nutrition Group	Salt Lake City, UT	219
Twin Laboratories	Hauppauge, NY	213
Abbott Labs	Columbus, OH	170
Perrigo	Allegan, MI	152
Solgar Vitamin & Herb Company	Hackensack, NJ	120
Bayer Corporation	Pittsburgh, PA	110
IVC Industries	Freehold, NJ	109
Experimental & Applied Sciences	Golden, CO	108
Nature's Way Products	Springville, UT	100

Source: Nutrition Business International. September 1998. "$23 Billion and Counting: Nutrition Industry Braces for a Competitive Future." 3(9):1-5, 13, 18.

SECTION 4
DEMAND FOR DIETARY SUPPLEMENTS

Consumers use DS products for a wide variety of reasons. Some products are taken because they are essential nutrients (e.g., vitamins and minerals at recommended dosages). Others are taken because they are expected to have some pharmacological effect (e.g., herbals and botanicals). In this section, we identify the uses of major DS products, describe the consumers of DS, and describe substitution possibilities.

4.1 DS PRODUCT CHARACTERISTICS AND USES

DS products are desired by consumers based on, among other things, the actual, perceived, or suggested health benefits that they yield to consumers. Consumers learn of the beneficial effects of DS products from

- ➤ product labels,
- ➤ merchandise catalogs,
- ➤ media advertisements (radio, newspaper, magazines, television),
- ➤ the Internet,
- ➤ product literature,
- ➤ books and pamphlets, and
- ➤ physicians and other practitioners (e.g., chiropractors).

The claims made by DS manufacturers and retailers are regulated by DSHEA. They are allowed to make structure/function claims that describe the role of a nutrient or dietary ingredient in affecting part of the structure or a function of the human body or that describe the way a nutrient or dietary ingredient acts to maintain body function and structure. In order to make these claims, DS retailers must back their claims with sufficient data (substantiation) and must also place on the product a disclaimer stating that the "product is not intended to diagnose, cure, treat, or prevent a disease" (Raubucheck, 1997).

Some health claims that have been approved for use on conventional food products can be used on DS products as well. These include claims linking

- ➤ calcium and osteoporosis,
- ➤ folate and neural tube defects,
- ➤ soluble fiber from whole oats and coronary heart disease,
- ➤ soluble fiber from psyllium husks and coronary heart disease, and
- ➤ sugar alcohols and dental caries [cavities].

(see Table 2 in Commission of Dietary Supplement Labels, 1997).

This section provides information on the perceived or actual health benefits of dietary supplements in the following categories: vitamins, minerals, herbal and botanicals, amino acids, proteins, and animal extracts. Within each category, commonly purchased products are detailed as to the perceived or actual health benefits consumers receive by ingesting them, some common claims that are made, and any scientific evidence backing the validity of these claims. Metabolites, constituents, and concentrates and other supplement products not elsewhere classified are discussed at the end of this section.

4.1.1 Vitamins

Vitamins are essential for normal health, metabolism, growth, and the proper functioning of cells. Vitamins are divided into two categories: fat-soluble, which can be stored in the body, and water-soluble, which are not stored in significant quantities in the body. Vitamins must be obtained from the diet because they are either not synthesized in the human body or are not synthesized in large enough amounts. Table 4-1 lists 13 vitamins and their health benefits and whether or not a particular vitamin is toxic or has a deficiency disease associated with it.

Vitamin supplements may be purchased as single vitamin products, multivitamin preparations, or combined with other DS products (e.g., some St. John's wort products contain B-complex vitamins). Dietary supplement product vitamin preparations come in many forms, including capsules, tablets, sprays, liquids, candies and lozenges, and chewable tablets (Hendler, 1990).

4.1.2 Minerals

Minerals are chemical elements required by our bodies for numerous biological and physiological processes that are necessary for the maintenance of health. Like vitamins, minerals are also divided into two categories. Those that are required in our diets in amounts greater than 100 milligrams per day are called "minerals" and those that are required in amounts less than 100 milligrams per day are "trace elements." Minerals include compounds of the elements calcium, magnesium, phosphorus, sodium, potassium, sulfur, and chlorine. Trace elements that are necessary for human health include iron, iodine, copper, manganese, zinc, molybdenum, selenium, and chromium (Hendler, 1990). Table 4-2 describes the role of minerals and trace elements in the body and lists claims made for particular minerals, any scientific evidence that exists to support these claims, and deficiency symptoms and toxicity. Some minerals that may have positive effects on human health are also included in the table. Sulfur, chlorine, and sodium, which are sometime included in DS products, are not included in the table because they are found in food via the soil it is grown in, in our water supply, and in the case of sodium, in numerous food products. Minerals are prepared in a variety of forms including, but not limited to, tablets, capsules, multivitamin-multimineral preparations, and liquids (Hendler, 1990).

Table 4-1. Health Benefits, Deficiency, and Toxicity of Vitamin Dietary Supplement Products

Vitamin	Health Benefit	Deficiency	Toxicity
Fat-Soluble Vitamins			
Vitamin A (beta-carotene or retinol)	Maintenance of normal vision and night vision Essential for immune system Necessary for growth; induces differentiation of cells	Fairly common; results in night blindness and eye disease, dry pimply skin, increased infections, and kidney stones	Unlikely from diet alone, but supplements and excessive fish oil may produce toxic symptoms such as increased skull pressure, hair loss, and blurred vision
Vitamin D (calciferols)	Helps to maintain constant levels of calcium in the blood Important in insulin and prolactin secretion, muscle function, immune and stress response, melanin synthesis, and cellular differentiation Vital for kidney and parathyroid gland function Necessary for healthy bones	Disease is rickets, not a major problem in U.S.; symptoms include soft bones and teeth	Most people do not take in supplemental form since the body produces its own via exposure to the sun Toxic in doses larger than 1,000-1,500 I.U.s daily for a month or longer; produces nausea, weakness, and irritability May lead to brain or liver damage, jaundice, and the destruction of red blood cells
Vitamin E (tocopherols)	Protects vitamin A from oxidation during digestion Enhances immune response Inhibits carcinogens from reaching target sites Can stop neurological problems associated with cystic fibrosis, liver disease early in disease process Detoxifies free radicals, prevents damage to cell membranes Prevents LDL cholesterol from turning into damaging oxidized LDL, which initiates buildup of arterial plaque which can lead to heart disease	No disease; may produce vague symptoms and anemia	Unlikely, although high doses increase the action of anticoagulant medications High doses also interfere with the absorption of other fat-soluble vitamins, particularly vitamin K
Vitamin K (phylloquinone)	Helps blood coagulate In conjunction with vitamins A and D helps body build bone protein Given as injection to newborns to help blood clot, sometimes to women before labor or to patients before and after surgery	Rare	From food it is rare; can occur with medical treatment Not sold as a supplement

(continued)

Table 4-1. Health Benefits, Deficiency, and Toxicity of Vitamin Dietary Supplement Products (continued)

Vitamin	Health Benefit	Deficiency	Toxicity
Water-Soluble Vitamins			
Vitamin B-1 (thiamin)	Vital for healthy nervous system and nerve transmission Essential in converting glucose to energy	Disease is beriberi Symptoms of a deficiency include depression, irritability, attention deficit Severe deficiency leads to edema, paralysis, and heart failure	No toxicity has been reported by those taking large doses over prolonged periods of time
Vitamin B-2 (riboflavin)	Essential for metabolizing carbohydrates, fats, and lipids and for the degradation of fatty acids and the synthesis of ATP Acts as an intermediary in the transfer of electrons in oxidation-reduction reactions Necessary for the function of vitamins B-6, folic acid, and niacin Involved in formation of red blood cells and maintenance of body tissues, particularly the skin and eyes	Symptoms are dry, scaly skin on face, oral swelling, and cracking at the corners of the mouth	No evidence that high doses have toxic effects
Vitamin B-6 (pyridoxine)	Necessary for immune system function, hormone modulation, gluconeogenesis Essential in making certain amino acids and turning others into hormones Involved in metabolizing polyunsaturated fats and proteins Used to build red blood cells and maintain nerve tissue Formation of niacin	Not common; symptoms include mouth sores, nausea, nervousness, anemia, convulsions	High doses over prolonged periods are very toxic and can cause temporary or permanent nerve damage
Vitamin B-12 (cobalamin)	Works with folic acid to produce red blood cells Helps build and maintain protective nerve sheaths Needed for RNA and DNA synthesis	Pernicious anemia, muscle and nerve paralysis	None reported

(continued)

Table 4-1. Health Benefits, Deficiency, and Toxicity of Vitamin Dietary Supplement Products (continued)

Vitamin	Health Benefit	Deficiency	Toxicity
Water-Soluble Vitamins (continued)			
Vitamin C (ascorbic acid)	Activates liver-detoxifying systems Antioxidant to inactivate highly reactive oxygen species; protects against damage to lipids and other molecules Inhibits formation of carcinogenic compounds Protects cellular functions Enhances function of key white blood cells involved in the destruction of bacteria Protects vitamin E Integral to maintenance and building of collagen, a protein that holds the body's cells in place Vital to bones and teeth, blood vessels, healing of wounds, and iron absorption Helps metabolize several amino acids and hormones	Scurvy is the deficiency disease	Mostly nontoxic; diarrhea is a side-effect High doses not recommended for those with genetic conditions that cause iron overload
Biotin	Key role in metabolizing fats, carbohydrates, and proteins Part of a number of enzymes in which it functions as a carboxyl carrier Manufactured in lower digestive tract by bacteria	Not common; symptoms include baldness, a rash around the mouth and nose, and dry, flaky skin	No evidence of toxicity at high doses
Choline	Helps maintain central nervous system Precursor to acetylcholine, a neurotransmitter Involved in production and metabolism of fats and cholesterol Protects liver from fatty deposits	Increased fatty deposits in liver, memory loss, poor muscle coordination	Nontoxic, but excess consumption may result in tension headache

(continued)

Table 4-1. Health Benefits, Deficiency, and Toxicity of Vitamin Dietary Supplement Products (continued)

Vitamin	Health Benefit	Deficiency	Toxicity
Water-Soluble Vitamins (continued)			
Folic acid (folate, B vitamin)[a]	Used by body to break down and synthesize amino acids Helps synthesize nucleic acids, which are needed to build new cells, particularly red blood cells Involved in a variety of reactions in amino acid and nucleotide metabolism Recommended for women of childbearing age; helps prevent neural tube birth defects	Leads to anemia similar to that caused by B-12 deficiency Can exist without anemia with broad signs including generalized weakness, easy fatigability, irritability, and cramps	Can mask B-12 deficiency (which causes neurologic problems) at high doses and interfere with some seizure and cancer drugs
Niacin (sometimes called vitamin B-3)	Enables body to use carbohydrates, fats, and proteins (to provide energy), and amino acids Influences metabolism of DNA, NAD, NADP Aids nervous system and digestive tract function and promotes healthy skin	Disease is pellagra, rare in U.S. Symptoms of deficiency: digestive upsets, insomnia, headaches, fatigue, sore and swollen tongue (disease is much worse)	Symptoms may include itching, skin flushing, and gastrointestinal distress Time-released capsules have caused impaired liver function, reported jaundice, and liver failure Toxic in high doses May produce skin discoloration and dryness, decrease glucose tolerance, produce high uric acid levels, aggravation of peptic ulcers, and symptoms that accompany hepatitis
Pantothenic Acid	Necessary for adrenal cortex function Part of chemistry of coenzyme A, which is vital to metabolism of carbohydrates, fats, and proteins and involved in making fatty acids, cholesterol, acetylcholine, steroid hormones, and nerve regulators	Can result in abdominal distress, vomiting, cramps, burning in heels, fatigue, and insomnia	No known toxicity, but research has been inadequate

[a]Health claims can be made regarding folic acid's reduction of a woman's risk of having a child with a brain or spinal cord defect.

Source: Anderson, Jean, and Barbara Deskins. 1995. *The Nutrition Bible.* William Morrow & Company. Information for table from <http://www.phys.com/a_home/01home/home.htm>. As obtained on January 30, 1998.

Brody, Jane E. October 26, 1997. "In Vitamin Mania, Millions Take a Gamble on Health." *The New York Times.* pp. 1, 20, 21.

Hendler, Sheldon Saul. 1990. *The Doctors' Vitamin and Mineral Encyclopedia.* New York: Simon & Schuster. pp. 37-111.

Smart Basics Inc. 1997. "Smart Basics Glossaries—Choline." <http://www.smartbasics.com/frameshome.html>.

Table 4-2. Health Benefits, Claims, Deficiency, and Toxicity of Leading Mineral Dietary Supplement Products

These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

Mineral	Health Benefit	Claims	Support for Claims	Deficiency	Toxicity
Calcium[a]	Developing and maintaining healthy bones and teeth	Reduces the risk of osteoporosis	Effect against osteoporosis proven	If severe, may lead to abnormal heartbeat, dementia, muscle spasms, and convulsions	High doses may cause constipation and interfere with kidney function and iron absorption
	Assists in blood clotting, muscle contraction, nerve transmission	Prevents cancer	Studies suggest may help prevent cancer	Brittle, thinning bones (osteoporosis)	Causes tissue calcification
	Involved in production of energy and maintenance of immune function	Useful in treating high blood pressure; lowers cholesterol; helps prevent cardiovascular disease	Studies say it helps reduce high blood pressure and CVD; mixed results for lowering cholesterol		May cause magnesium deficiency
		Helps alleviate cramps in the legs	Anecdotal evidence it is used for leg cramps and as a tranquilizer		
		Useful in treating and preventing arthritis	No evidence for treating arthritis or healthy skin		
		Helps keep skin healthy			
Chromium	Aids in glucose metabolism and regulates blood sugar; essential trace element	Treatment and prevention of diabetes	No evidence that it prevents diabetes, although there is evidence that it may increase glucose tolerance	Possibly glucose intolerance, impaired growth, elevated blood cholesterol, and fatty deposits in the arteries	Hexavalent chromium is toxic and carcinogenic, but the dietary form (trivalent) has very low toxicity
		Protects against cardiovascular disease and high blood pressure	Contradictory evidence for protecting against CVD and high blood pressure		Trivalent form not associated with any type of cancer
		Useful in treating hypoglycemia	Aid re: hypoglycemia unclear		
Copper	Essential trace element; one of the factors in hemoglobin formulation; helps stimulate the absorption of iron; plays a role in respiration	Anticancer substance	No evidence for anticancer claims	Second most common trace metal deficiency occurring during intravenous feeding	Relatively nontoxic
	Helps maintain cell membranes; part of enzyme that protects against cellular damage; prevents peroxidation of polyunsaturated fatty acids	Protective against cardiovascular disease	Studies done, need more re: protection against CVD	Symptoms include anemia that is unresponsive to iron, lowered white blood cell count, and loss of bone density (osteoporosis)	
	Involved in production of collagen, elastin, melanin, and the neurotransmitter noradrenalin	Anti-inflammatory and useful against some forms of arthritis	Promising studies as an anti-inflammatory agent; need more work		
		Immune booster	Role in human immune system needs clarification		

(continued)

Table 4-2. Health Benefits, Claims, Deficiency, and Toxicity of Leading Mineral Dietary Supplement Products (continued)

These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

Mineral	Health Benefit	Claims	Support for Claims	Deficiency	Toxicity
Iodine	Integral part of the thyroid hormones that have important metabolic roles; factor in the thyroid gland's regulation of energy production	Protects against toxic effects from radioactive materials Relieves pain and soreness from fibrocystic breasts Good for loosening up clogged mucus in the breathing tubes Good antiseptic	Does protect from toxic effects of radioactive materials More research needed for fibrocystic breast relief Iodine containing drugs (need prescription) are useful for loosening coughs Effective in purifying back-country water (not elemental)	Major cause of hypothyroidism in the world Symptoms include chronic fatigue, apathy, dry skin, intolerance to cold, weight gain, and enlargement of the thyroid	High doses may aggravate acne (rare from diet or typical supplement consumption) High doses may lead to a temporary block of hormone synthesis and temporary hyperthyroidism Over prolonged periods, high doses may result in hyperthyroidism High doses greater than 50 milligrams/day may lead to inflammation of the salivary glands, which is easily reversed
Iron	Necessary in red blood cell formation and function Protection from oxidant damage; maintenance of the immune system Backbone of energy-producing process Involved in the production of carnitine, collagen, elastin, several brain neurotransmitters	Prevents and cures iron-deficiency anemia Anticarcinogenic Boosts physical performance Prevents learning disorders in children	Prevents iron-deficiency anemia Anticancer evidence is meager; appears to play an important role in cellular immunity More research needed for muscular performance claim Evidence says may help prevent learning disorders in kids	Iron-deficiency anemia (significant decrease in number of red blood cells), which means decreased oxygenation of tissues and symptoms of fatigue and muscle weakness *(Note: iron is the treatment for this deficiency)* Associated with Plummer-Vision Syndrome, when there is difficulty in swallowing solid food because a web-like membrane grows across the esophagus *(Note: supplementation has been found to eliminate this condition)*	Toxic after prolonged usage; reports are rare Some concern that unbound iron can generate free radicals and be destructive to cells, but usually occurs just with certain genetic disorders Oversupplementation may cause abdominal pain, diarrhea, or constipation

(continued)

Table 4-2. Health Benefits, Claims, Deficiency, and Toxicity of Leading Mineral Dietary Supplement Products (continued)

These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

Mineral	Health Benefit	Claims	Support for Claims	Deficiency	Toxicity
Magnesium	Activates nearly 100 enzymes; helps nerves and muscles function; necessary for every major biological process (e.g., glucose metabolism, production of cellular energy, and the synthesis of protein and nucleic acids) Regulator of calcium flow within cells; collaborates with calcium in the production of biologic energy	Protects against cardiovascular disease and helps in treatment of high blood pressure	Conflicting findings about role in CVD, but have found that magnesium plays an important role in the maintenance of the electrical and physical integrity of the heart muscle	Loss of appetite, nausea, vomiting, diarrhea, confusion, tremors, loss of coordination, and occasionally fatal convulsions Sometimes associated with calcium and potassium deficiencies at the same time Marginal deficiency is common	People with impaired kidney function can accumulate magnesium, which can be fatal Those with high-grade atrioventricular blocks or bifascicular blocks should not take (could slow heart rate) No evidence it is harmful other than in these two instances
		Helps in treating PMS	Insufficient research in helping PMS		
		Helps prevent kidney and gallstones	No evidence that is helpful in treating gallstones, but evidence exists that it is helpful in preventing calcium oxalate kidney stones in people who have this recurrent problem		
		Treats prostate problems	No evidence to support this		
		Useful in treating polio, postpolio syndrome	No evidence to support this		
		Helps fight depression	No evidence to support this		
		Helps in treating neuromuscular and nervous disorders	Intravenous magnesium used to treat this		
		Good for treating convulsions in pregnant women to prevent premature labor	No evidence of benefit for those with these symptoms unless symptoms are due to magnesium deficiency		
		Helps with diarrhea, vomiting, and indigestion	Early symptoms of deficiency; products on market containing magnesium actually cause diarrhea, and it is used in laxatives		

(continued)

Table 4-2. Health Benefits, Claims, Deficiency, and Toxicity of Leading Mineral Dietary Supplement Products (continued)

These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

Mineral	Health Benefit	Claims	Support for Claims	Deficiency	Toxicity
Manganese	Essential part of several enzyme systems, involved in protein and energy metabolism	Antioxidant	Not clear; needs more research	Not documented in humans; only one report of man who was on a manganese-deficient diet for 4 months	Dietary form has low toxicity, inhaled dust can cause serious neurologic disease
		Important for normal function of the brain, effective in treating schizophrenia and other nervous disorders	Appears to be involved in synthesis of neurotransmitters in brain, anecdotal reports that it works on schizophrenia, but no scientific reports		
		Necessary for reproduction	Not demonstrated in humans		
		Needed for normal bone structure and helpful in treating osteoarthritis	Need more research		
		Necessary for normal glucose metabolism and beneficial in treating diabetes mellitus	No evidence in humans nor for treating diabetes		
Molybdenum	Necessary for several enzymes	May be an antioxidant, protect against cancer	No evidence supplementation protects against cancer	Only one report of deficiency, from a patient fed intravenously	Noted in animals due to antagonism of copper
		May be a detoxifier of potentially hazardous substances (sulfiting agents for preserving drugs and food)	No evidence supplementation protects against cancer		
		Protects teeth	No clinical support		
		Prevents sexual impotence	No evidence		
		Prevents anemia and mobilizes iron	Role not thought to be significant		
Phosphorous	Works with calcium to develop and maintain strong bones and teeth; enhances use of other nutrients	Increases endurance in athletes	If adequate phosphate intake, supplementation will not boost energy—only if suffering from depletion (if alcoholic, antacid user, various medical conditions)	Rare, although severe deficiency could lead to seizures, coma, and death	Toxic; treatment of deficiency should be administered by physician
	Component of cell membranes			Depletion has been reported in those taking antacids between 2 and 12 years because antacids contain magnesium and aluminum, both of which prevent the absorption of phosphate into the body	
	Important in vital biologic processes (storage and processing of biological information, cellular communication, energy production, and integrity of tissue)	Fights fatigue, overall good tonic	Homeopathic remedies claim this, no adequate research on its effectiveness		

(continued)

Table 4-2. Health Benefits, Claims, Deficiency, and Toxicity of Leading Mineral Dietary Supplement Products (continued)

These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

Mineral	Health Benefit	Claims	Support for Claims	Deficiency	Toxicity
Potassium	Major component of our cells; regulates heartbeat; maintains fluid balance; helps muscles contract; role in nerve conduction Involved in production of energy, synthesis of nucleic acids and proteins	Useful in preventing and treating high blood pressure	Diets rich in potassium appear to protect against hypertension (epidemiologic studies indicate); as for supplementation lowering hypertension, differs across individuals: more work needs to be done	Produces broad physical problems from fatigue, weakness, muscle pains, to death if untreated	Unlikely to have adverse effects unless person has kidney failure, in which case it may accumulate to high levels and be fatal
		Protective against stroke-related death	One 12-year study did find a link between increased potassium intake and lower risk of stroke-related death, but findings need confirmation		
		Helpful in prevention and treatment of cancer	No evidence		
		Enhances athletic performance	Not known to improve performance of someone who is not deficient in potassium		
Selenium	Role in immune system, enhances cellular immunity; essential component of a key antioxidant enzyme Necessary for normal growth and development	Anticarcinogenic	Not well understood; studies have shown it does have anticancer properties	Linked to heart disease Supplementation: Useless with concurrent intake of vitamin C—may convert selenium to nonabsorbable form	Highly toxic even in tiny doses, although we may be able to tolerate in higher doses than previously believed May cause changes in hair and nails, slower mental function, and gastrointestinal distress Capable of producing harmful mutations in cells (in form of sodium selenite, but at doses much higher than normally consumed) Carcinogenic; early studies claimed this, but National Research Council said the studies were faulty
		Enhances immune system	Has been observed in animal studies		
		Protective against heart and circulatory diseases	Some evidence that it may inhibit free-radicals linked to tissue damage related to restricted blood flow or oxygen supply		
		Increases male potency and sex drive	Anecdotal		
		Useful against arthritis, autoimmune diseases (anti-inflammatory)	Injectable and oral forms used in animals; no scientific work done on humans		
		Capable of detoxifying heavy metals, various drugs, alcohol, cigarette smoke, peroxidized fats	Detoxifies mercury and cadmium; results are mixed on drugs and alcohol and more work needs to be done on protection against damage from smoking		
		Beneficial to skin	Shown to reduce skin tumors in mice (oral); not reliably investigated (oral and topical)		

(continued)

Table 4-2. Health Benefits, Claims, Deficiency, and Toxicity of Leading Mineral Dietary Supplement Products (continued)

These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

Mineral	Health Benefit	Claims	Support for Claims	Deficiency	Toxicity
Zinc	Essential part of more than 200 enzymes involved in digestion, metabolism, reproduction (sperm formation), and wound healing	Treats common cold	Based on preliminary findings, dissolve in throat; if swallowed, it is ineffective	Common among patients fed intravenously, so it is added to the IV solution	High doses may cause copper deficiency, gastrointestinal distress, and impaired immune function
	Involved in sense of taste	Boosts immunity	Some findings, need more research	Moderate deficiency symptoms include growth retardation, poor appetite, mental lethargy, delayed wound healing, abnormalities of taste, smell and vision, skin changes	Large doses for long periods of time depress "good" HDL cholesterol
	Role in function and structure of cell membranes	Prevents cancer	Contradictory findings		
	Major part of the immune system	Prevents blindness as people age	Promising findings in double-blind clinical study		
	Component of insulin	Accelerates wound healing	Conflicting studies, needs more work	Mild deficiency leads to low sperm count	
		Increases male potency and sex drive	Useful in combating male impotence only when he has moderate to severe zinc deficiency	Moderate to severe deficiency in males leads to decreases sexual interest, mental lethargy, emotional problems	
		Useful in treatment and prevention of infertility	Needs more research		
		Prevents prostate problems	No evidence that it prevents and treats enlarged prostate		
		Useful in treating acne	More research needed on oral supplementation; topical use may treat acne effectively		
		Prevents hair loss	No evidence		
		Helpful in diabetics	More research is needed		
		Useful in treating rheumatoid arthritis	Little recent work, needs more research		
		Restores taste, smell	No evidence age-related disturbances can be improved with supplementation		
Boron	Essentiality in humans has yet to be proven	Prevents osteoporosis in postmenopausal women	Needs more study re: osteoporosis	Essentiality in humans has yet to be proven	None reported
		Beneficial in treating arthritis	No evidence for arthritis treatment		
		Builds muscle	No evidence for building muscle		

(continued)

Table 4-2. Health Benefits, Claims, Deficiency, and Toxicity of Leading Mineral Dietary Supplement Products (continued)

These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

Mineral	Health Benefit	Claims	Support for Claims	Deficiency	Toxicity
Fluorine	Yet to be established as nutritionally essential	Protects against dental cavities	Evidence that it does protect against cavities	Yet to be established if nutritionally essential	Supplements must be prescribed by a dentist or doctor
		Protects against osteoporosis and useful in its treatment	Need more information about role in osteoporosis (if any)		Is toxic in high doses, can be fatal
					High doses may cause abnormal hardening of bones, leading to arthritic pain, joint stiffness, occasional nerve damage and paralysis
Germanium	No evidence has any nutritional, biological or biochemical role in humans	Useful in treatment of ARC and AIDS	Effects on AIDS patients being studied, don't know if has beneficial effects	No known role in humans	Appears to be low
					Small percentage reported skin eruptions and stool softening
		Stimulates the immune system	Further research is needed on effects on immune system		Some reports of kidney failure
		Useful in treating cancer	Human studies for cancer prevention are needed		
		Useful in treating chronic Epstein-Barr virus syndrome	Clinical anecdotes on its effects on Epstein-Barr virus		

[a]Health claims regarding osteoporosis disease prevention can be made on calcium products.

Sources: Council for Responsible Nutrition. February 3, 1997. "Baby Boomers Fuel Trends in Vitamins." *Chain Drug Review* 19(3):20-22.

Hendler, Sheldon Saul. 1990. *The Doctors' Vitamin and Mineral Encyclopedia.* New York, NY: Simon & Schuster, pp. 112-207.

Day, Kathleen. January 11, 1997. "Cold Sufferers Find Zinc as Good as Gold." *The Washington Post.* pg. D1.

Brody, Jane E. October 26, 1997. "In Vitamin Mania, Millions Take a Gamble on Health." *The New York Times.* pp. 1, 20, 21.

4.1.3 Herbals and Botanicals

Herbal products are those made from the leaves and stems of plants, and botanical products are those made from any part of the plant. They are both becoming increasingly valued by some consumers for their perceived medicinal properties; however, FDA regulations prevent statements that these products are intended to diagnose, treat, cure, or prevent disease. In addition to the more familiar herbs, Chinese traditional herbs and Ayurvedic (traditional Indian) medicinal herbs are becoming available in the United States. An estimated 2,500 herbs have been used for medicinal purposes at one time or another throughout history (Griffith, 1988). Table 4-3 lists some of the common conditions and symptoms and the herbal products that are used to treat them. The active ingredients within herbal products vary depending on the plants' growing conditions and degree of maturity when harvested as well as the drying process used and the type and duration of storage. Herbals and botanicals are available in many forms including teas, powders, tinctures, extracts, and liquids (Hendler, 1990).[4]

4.1.4 Amino Acids

Amino acids are compounds that include an amino group (NH_2) and an acidic function. Twenty amino acids are the chief components of proteins and are the building blocks of all living structures. They are divided into two categories: essential and nonessential. Table 4-4 lists the essential amino acids, which are not synthesized in the body, and the nonessential amino acids, which are.[5] Children require the eight essential amino acids plus histidine and arginine for physical well-being. Essential amino acids must be obtained from the diet while the nonessential amino acids can be made by the body from other substances. There are other amino acids which are found in the human body but are not involved in the synthesis of proteins. Table 4-4 includes two of these, ornithine and taurine. Amino acids come in a variety of forms such as tablets, capsules, powders for oral solution, and as a constituent of multivitamin/mineral preparations. Injectable forms are also available but must be administered by a doctor (Griffith, 1988; Hendler, 1990; HealthWorld Online, 1998a).

4.1.5 Proteins

In the human body, proteins are antibodies as part of the immune system; an energy source; important in fetal formation, during pregnancy and in children's growth; essential in the replacement of all the body's cells; involved in maintaining the proper sodium, water and potassium balance inside cells which enables the heart, lungs, and nervous system to function properly; and important in regulating blood pH. There are specific dietary requirements for proteins although the exact amounts are not known. The Recommended Daily Allowance is 0.8 grams per kilogram of ideal body weight for the adult. Protein deficiency is not common in the Western world, but it does occur in Third World countries.

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[4]Although DS products can be prepared as teas, not all teas are DS products. Teas have a Standard of Identity (SOI) as a food product and are considered as such unless the manufacturer labels them as dietary supplements.

[5]Information on benefits and claims not listed in Table 4-4 was not readily available from secondary sources.

Table 4-3. Herbs Used to Alleviate Conditions and Symptoms

These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

Condition/Symptom	Herbs Used
Angina	**Hawthorn** (*Crataegus laevigata, C. monogyna*)
Anxiety and Sleep Disorders	**Valerian** (*Valeriana officinalis*)
	Passion flower (*Passiflora incarnata*)
	Hops (*Humulus lupulus*)
	Catnip (*Nepeta cataria*)
	L-Tryptophan (natural amino acid, occurs in concentrations of 1%-2% in plant and animal proteins)
Appetite Loss	
Significant bitter herbs	**Gentian** (*Gentiana lutea*)
	Centaury (*Centaurium erythraea*)
Minor bitter herbs	**Bitterstick** (*Swertia chirata*)
	Blessed Thistle (*Cnicus benedictus*)
	Bogbean (*Menyanthes trifoliata*)
	Wormwood (*Artemisia absinthium*)
Arteriosclerosis	**Garlic** (*Allium sativum*)
Arthritis	**Willow bark** (*Salix alba, S. purpurea, S. fragilis*)
Bronchial Asthma	**Ephedra** or **ma huang** (*Ephedra* species, particularly *E. sinica, E. equisetina, E. gerardiana*)
Burns, Wounds, and Infections	**Calendula** (*Calendula officinalis*)—tea for putative and antispasmodic effects
	Comfrey (*Symphytum officinale*)
Cancer	**Apricot pits** (*Prunus armeniaca*)
	Pau d'arco (*Tabebuia*) also called **lapacho**, or **taheebo**
	Mistletoe (*Viscum album*)
Colds and Flu	
Demulcent antitussives	Cough suppressants
	Coltsfoot (*Tussilago farfara*)—however, it contains toxic pyrrolizidine alkaloids
	Iceland moss (*Cetraria islandica*)
	Marshmallow root (*Althaea officinalis, Malva sylvestris*)
	Mullein flowers (*Verbascum thapsus, V. densiflorum, V. phlomoides*)
	Plantain leaves (*Plantago lanceolata*)
	Slippery elm (*Ulmus rubra*)

(continued)

Table 4-3. Herbs Used to Alleviate Conditions and Symptoms (continued)
These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

Condition/Symptom	Herbs Used
Colds and Flu (continued)	
Expectorants	Treat irritative, nonproductive coughs associated with a small amount of secretion
Nauseant-expectorants (caution given about safe consumption)	**Lobelia** (*Lobelia inflata*)
	Ipecac (*Cephaelis ipecacuanha, C. acuminata*)
Local irritants	**Anise** (*Pimpinella anisum*)
	Fennel (*Foeniculum vulgare*)
	Thyme (*Thymus vulgaris, T. zygis*)
	Eucalyptus leaves (*Eucalyptus globulus*)
Surface tension modifiers	Increase gland secretion of mucous
	Licorice, also known as **glycyrrhiza** (*Glycyrrhiza glabra*)
	Seneca snakeroot (*Polygala senega*)
Communicable Diseases and Infections	**Echinacea** (*Echinacea angustifolia, E. pallida, E. purpurea*)
Congestive Heart Failure	**Adonis** (*Adonis vernalis*)
	Oleander (*Nerium oleander*)
	Apocynum or black Indian hemp (*Apocynum cannabinum, A. androsaemifolium*)
	Black hellebore (*Helleborus niger*)
	Cactus grandiflorus (*Selenicereus grandiflorus*)
	Convallaria or **lily of the valley** (*Convallaria majalis*)
	Squill (*Urginea maritima*)
	Strophanthus (*Strophanthus kombe, S. hispidus*)
Control Hypertension	**Garlic**
Depression	**St. John's wort** (*Hypericum perforatum*)
Diarrhea	**Blackberry leaves** (*Rubus fruticosus*)
	Blueberry leaves (*Vaccinium corymbosum* or *V. Myrtillus*)
	Raspberry leaves (*Rubus idaeus*)
Digestion	**Ginger** (*Zingiber officinale*)
Gastric and Duodenal (Peptic) Ulcers	**Licorice**, also known as **glycyrrhiza** (*Glycyrrhiza glabra*)
	Ginger (*Zingiber officinale*)

(continued)

Table 4-3. Herbs Used to Alleviate Conditions and Symptoms (continued)
These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

Condition/Symptom	Herbs Used
Gynecological Disorders	
Menopausal symptoms, PMS, dysmenorrhea, female sex hormone imbalances or deficiencies	**Black cohosh** (*Cimicifuga racemosa*)
	Chaste tree berry (*Vitex agnus-castus*)
	Evening primrose oil (*Oenothera biennis*)
	Black currant oil (*Ribes nigrum*)
	Raspberry leaves (*Rubus idaeus, R. strigosus*)
	Borage seed oil (*Borago officinalis*)
PMS	**Evening primrose oil** (*Oenothera biennis*)
Hyperthyroidism	**Bugle weed** (*Lycopus virginicus, L. europaeus*)
Indigestion—Dyspepsia	
Carminatives	Carminative effects (to eruct air from stomach, increase stomach secretions, relax intestine to enable gas passage, limit development of undesirable microorganisms, promote bile flow to facilitate nutrient absorption)
Significant carminative herbs	**Peppermint** (*Menthax piperita*)
	Chamomile (*Matricaria recutita, M. chamomilla, Chamomilla recutita, Chamaemelum nobile*)
Minor carminative herbs	**Anise** (*Pimpinella anisum*)
	Caraway (*Carum carvi*)
	Coriander (*Coriandrum sativum, C. vulgare, C. microcarpum*)
	Fennel (*Foeniculum vulgare*)
	Calamus (*Acorus calamus*)
	Rosemary (*Rosmarinus officinalis*)
Cholagogues	Act to empty the gall bladder or to stimulate the production of bile or both
	Turmeric (*Curcuma domestica, C. longa, C. zanthorrhiza, C. zedoaria*)
	Boldo (*Peumus boldus*)
	Dandelion (*Taraxacum officinale*)

(continued)

Table 4-3. Herbs Used to Alleviate Conditions and Symptoms (continued)
These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

Condition/Symptom	Herbs Used
Infections and Kidney Stones	
Significant aquaretic-antiseptic herbs	Enhance fluid and electrolyte excretion, increase blood flow in the kidneys. Useful for: local infection of renal tissue (pyelonephritis); inflammation of urethra (urethritis); inflammation of urinary bladder (cystitis); preventing kidney stones
	Goldenrod (*Solidago virgaurea, S. serotina, S. canadensis*)
	Parsley (*Petroselinum crispum*)
	Juniper (*Juniperus communis*)
Minor aquaretic herbs	Used in diuretic teas
	Birch leaves (*Betula verrucosa, B. pubescens*)
	Lovage root (*Levisticum officinale*)
Antiseptic herbs	**Bearberry** (*Arctostaphylos uva-ursi*, two varieties: *coactylis, adenotricha*)—antibacterial herb for urinary tract infections
Anti-infective herbs	**Cranberry** (*Vaccinium macrocarpon*), most useful for preventing and treating urinary tract infections
Prostate enlargement	**Saw palmetto** (**sabal**) (*Serenoa repens)*
	Nettle root (*Urtica dioica, U. urens*)
Laxative	
Bulk-producing laxative	**Plantago**, also known as **psyllium seed** (*Plantago psyllium, Plantago indica, Plantago ovata*)
Significant stimulant laxatives	**Cascara sagrada** (*Rhamnus purshiana*)
	Buckthorn (frangula) bark (*Rhamnus frangula*)
	Senna (*Cassia acutifolia*—known in commerce as **Alexandria senna**, or *Cassia angustifolia*—known in commerce as **Tinnevelly senna**, or these two grouped into *Senna alexandrina*)
Other stimulant laxatives	**Aloe** (*Aloe barbadensis, A. vera, A. ferox, A. africana, A. spicata*)
	Rhubarb (*Rheum officinale, R. palmatum, R. emodi, R. webbianum*)
Minor laxatives	
Drastic purgatives	**Jalap**
	Podophyllum
	Colocynth
Mild and uncertain inaction	**Dandelion root**
	Manna

(continued)

Table 4-3. Herbs Used to Alleviate Conditions and Symptoms (continued)

These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

Condition/Symptom	Herbs Used
Liver Damage	**Milk thistle** (*Silybum marianum*)
	Schizandra (*Schisandra chinensis*)
Lower Cholesterol	**Garlic**
	Plantago, also known as **psyllium seed** (*Plantago psyllium,* or *Plantago indica, Plantago ovata*)
Migraine or Vascular Headache	**Feverfew** (*Tanacetum parthenium*)
Nausea and Vomiting	**Ginger** (*Zingiber officinale*)
Pain (General)	**Willow bark** (*Salix alba*)
Performance and Endurance Enhancers	**The ginsengs** (*Panax ginseng, P. quinquefolius, P. pseudo-ginseng*)
	Eleuthero (*Eleutherococcus senticosus*)
	Sarsaparilla (*Smilax aristolochiaefolia, S. febrifuga*)
	Ashwagandha (*Withania somnifera*)
	Sassafras (*Sassafras officinalis*)
Peripheral Vascular Disease	
Cerebrovascular disease	**Ginkgo** (*Ginkgo biloba*)
Other peripheral arterial circulatory disorders	**Rosemary** (*Rosmarinus officinalis*)—questionable effectiveness
Varicose vein syndrome	**Horse chestnut seed** (*Aesculus hippocastanum, A. glabra*)
	Butcher's broom (*Ruscus aculeatus*)
Sexual Impotence	**Yohimbe** (*Pausinystalia yohimbe*)—not recommended for self-treatment, not for OTC sale in US
	Ginkgo (*Ginkgo biloba*)

Source: Tyler, Varro E. 1994. *Herbs of Choice: The Therapeutic Use of Phytomedicinals.* Binghamton, NY: Pharmaceutical Products Press. 209 pp.

Table 4-4. Health Benefits and Claims of Amino Acids and Amino Acid Supplement Claims

These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

Amino Acid	Health Benefits	Claims	Notes
Nonessential (synthesized in the body)			
Alanine	Inhibitory neurotransmitter in the brain; component of cell walls; glucose can be made from alanine in the liver or from muscles when energy is needed; part of some intestinal bacteria	Increases excitation (i.e., in epilepsy); maintains blood sugar level; helpful in treating hypoglycemia; helps those with suppressed immune systems	No scientific evidence supporting these claims
Serine	Component of nerve coverings and brain proteins; involved in metabolism of purines and pyrimidines (part of RNA and DNA); important information of cell membranes and creatine synthesis		
Proline	Major amino acid in collagen; involved in formation of bone, skin, and cartilage	Aids in tissue repair after injury, wound healing, and maintaining joints and tendons	
Asparagine	Formed from aspartic acid; helps in the metabolic function of brain and nervous system cells		
L-arginine	Effects on several major endocrine hormones; plays a large role in muscle growth and healing; helps regulate and support key components of the immune system; important in male fertility (is essential in children)	Boosts immunity; fights cancer; builds muscle and burns fat; promotes healing of burns and wounds; protects liver and detoxifies harmful substances; enhances male fertility	Effects on several major endocrine hormones; plays large role in muscle growth and healing; helps regulate and support key components of the immune system; important in male fertility (is essential in children)
L-ornithine	Shares arginine's properties; is also capable of stimulating growth hormone release	Can increase the weight and activity of the thymus gland, possibly enhancing the immune system response; shown to have liver-regenerating effects in animals	
L-aspartic Acid	Involved in formation of ammonia and urea for disposal; excitatory function in the brain	Treatment of chronic fatigue, "aerobic enhancers" to boost energy; may be helpful in overcoming opiate withdrawal	Suggestions that it works in this way are preliminary; used clinically to treat fatigue and depression

(continued)

Table 4-4. Health Benefits and Claims of Amino Acids and Amino Acid Supplement Claims (continued)

These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

Amino Acid	Health Benefits	Claims	Notes
Nonessential (synthesized in the body) (continued)			
L-cysteine	Precursor of glutathione, a major antioxidant in the body	Said to inactivate free radicals and therefore protect and preserve cells; extends lifespan via DNA repair; burns fat; builds muscle; protects against various toxic substances; combats arthritis	More work needs to be done re: extending lifespan; need more research on protection from toxins and pollutants; preliminary study on arthritis claim but needs more study
L-glutamine and L-glutamic Acid	Glutamine is a derivative of glutamic acid; important in brain function; precursor of important neurotransmitters in nervous system	Glutamine may help curb alcohol craving, speed healing of peptic ulcers, energize the mind, inhibit senility, counter depression; glutamic acid is claimed to boost IQs of mentally retarded people	Studies have consistently contradicted one another; recent animal work on alcohol claim and its possible favorable effects—more work is needed; used in alcoholism clinics as it decreases the craving for alcohol—may do so for sugar as well, not proven yet though
Glycine	Helps save glucose for energy by facilitating glycogen storage; involved in brain metabolism; necessary for synthesis of hemoglobin and collagen	May help dampen overactive brain processes that produce certain forms of spastic movement; helps heal wounds; reduces gastric acidity	More work is needed
L-histidine	Essential in children for growth; involved in production of blood cells and histamine	May be helpful in treating arthritis, rheumatoid arthritis	More work is needed
L-tyrosine	Synthesized from phenylalanine; involved with important brain neurotransmitters; can cause large short-term increase in levels of dopamine, epinephrine and norepinephrine in the blood	Psychic energizer and stress reliever; antidepressant; effective in treating PMS; addictive drug detoxifier; diminishes pain; improves memory; increases sexual interest; appetite suppressor; treats Parkinson's disease	Studies suggest that it may be an energizer and antidepressant; anecdotal evidence and accumulating clinical data for PMS relief; favorable reports on detoxifying addictive drugs

(continued)

Table 4-4. Health Benefits and Claims of Amino Acids and Amino Acid Supplement Claims (continued)

These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

Amino Acid	Health Benefits	Claims	Notes
Essential (not synthesized in the body)			
Threonine	Important constituent in many proteins; essential in formation of elastin, collagen, and tooth enamel protein; minor role in controlling fat buildup in the liver	Helps some cases of depression	No evidence that it treats depression
L-leucine, L-isoleucine, L-valine		Promoted as potent anabolics (muscle builders) and energizers; help restore muscle mass in those who have liver disease or who have had trauma; useful in treating liver damage; helpful in some neurologic disorders and Lou Gehrig's disease	Little scientific evidence to support claims of muscle building and energy enhancing; appears useful for effects of chronic liver disease
L-lysine	Promotes tissue repair and growth; involved in production of hormones, enzymes and antibodies	Inhibits herpes; builds muscle	Studies have reported positive and negative findings; only anecdotal evidence on building muscle
L-methionine and Taurine	Taurine and cysteine, important amino acids, depend on methionine for biosynthesis in the body; helps regulate nervous system and muscle system	Help eliminate fatty substances that might otherwise clog the arteries; may be essential for growth of adolescents, children and infants	Shown to have a depressant effect on the central nervous system and may impair short-term memory; otherwise, little research has been done
L-phenylalanine, D-phenylalanine, DL-phenylalanine	Involved in a number of biochemical processes related to brain synthesis of various neurotransmitters	Claimed to increase mental alertness; help control addictive substance abuse; promote sexual arousal and releases hormones to control appetite; alleviate chronic pain; treats Parkinson's disease	DL- no scientific support for pain relief, analgesic, and anti-inflammatory effects shown; some anecdotal, experimental evidence that L-increases alertness; no evidence on appetite suppression or sex stimulation; preliminary evidence re: addictive behavior
L-tryptophan	Important in the biosynthesis of serotonin, a brain neurotransmitter thought to be an inducer and regulator of certain stages of sleep	Natural sleeping aid; mood regulator; may reduce sensitivity to pain and have tranquilizing effects; appetite suppressor and reduces cravings for alcohol and some other drugs; helps prevent panic attacks	Appears to work well for sleeping and jet lag; in preliminary studies, acts as a mood regulator and prevents panic attacks; some studies say does relieve pain; results in humans re: appetite suppression mixed; alcohol craving suppression not directly investigated

Sources: Hendler, Sheldon Saul. 1990. *The Doctors' Vitamin and Mineral Encyclopedia.* New York, NY: Simon & Schuster. pp. 208-234.

HealthWorld Online. 1998b. <http://www.healthy.net/hwlibrarybooks/haas/amino/his.htm> and <http://www.healthy.net/hwlibrarybooks/haas/amino/thr.htm>. As obtained on March 19, 1998.

Proteins are taken as DS products because they are believed to aid in the maintenance of a positive nitrogen balance in muscles, post-exercise recovery, building of muscles, and to increase energy. Proteins do not have specific medical or biological names; therefore they are marketed simply as "protein" supplements and the name attached to the label is the company's choice. They come in a variety of forms from powdered drink mixes and energizing shakes to capsules and tablets (HealthWorld Online, 1998c).

4.1.6 Animal Extracts

Animal extracts are the tissue extracts from animals of specific tissues or glands. The term *glandulars* refers to the concentrated extracts of various animal glands. These products can be found as tablets, powders, capsules, as constituents of multivitamin/mineral preparations and oils. The following are commonly found animal extract and glandular supplement products (110% Products, 1998; Sequential Healing Health Services, 1998):

Adrenal	Prostate
Aorta	Spleen
Fish oils (Omega-3 fatty acids)	Thymus
Gelatin	Thyroid
Kidney	Testicular
Liver	Pituitary
Pancreas	Ovary
Parathyroid	Chondroitin sulfate (from cartilage of most mammals)
Pituitary	Shark cartilage

Companies are marketing glandular products with claims that they revive and rejuvenate glands that are not functioning as well as they once were due to the aging process. In other words, glandular products are claimed to restore health and function to the tissue that is targeted (e.g., consumers' adrenal glands will work better if they take adrenal extracts). Glandulars are claimed to be effective in treating cancer and hypoglycemia, in lowering cholesterol, boosting sex drive and building muscle, and preventing and reversing aging. There is no legitimate scientific evidence that any of these claims are valid, and glandulars can be dangerous due to the fact that some of the organ concentrates may contain chemicals that livestock come in contact with, such as antibiotics, growth hormones, pesticides, herbicides, and fertilizers.

4.1.7 Metabolites, Constituents, and Concentrates

As mentioned in Section 2, these are alternative forms of products classified in the other categories. Thus they are not specifically addressed here.

4.1.8 Other Supplement Products Not Elsewhere Classified

A variety of other products are marketed as DS products and claim to have numerous beneficial impacts on human health and physical well-being.[6] They may be available as capsules, liquids, tablets, powders, and as constituents of multivitamin/mineral preparations. A few of the more widely available products are described below (HealthWorld Online, 1998d).

- *Acidophilus*—bacterium found in yogurt and other products. It helps maintain bacteria balance in the lower intestines.
- *Algae*—green or blue-green freshwater, one-celled organisms. The three main algae products are chlorella, spirulina, and blue-green manna. All these products are high in protein and contain large amounts of vitamins and minerals. Blue-green algae products contain all the amino acids and are marketed as body rejuvenators, which improve energy levels, decrease appetite, and increase mental energy. These products are commonly used for weight loss and fasting and are sold in powdered or tablet form.
- *Bee pollen*—microscopic male seed of flowering plants. No beneficial effects have been proven.
- *Bioflavinoids*—chemical constituent of pulp and rind of citrus fruits, green pepper, apricots, cherries, grapes, papaya, tomatoes, and broccoli. Intake of these treats a rare bioflavinoid deficiency and prevents vitamin C and adrenalin from being oxidized.
- *Brewer's yeast*—supplies B vitamins, proteins, and minerals and is a good source of enzyme-producing vitamins. It helps regulate sugar metabolism via the chromium it contains and provides bulk to prevent constipation.
- *Coenzyme Q*—part of mitochondria of cells. It is found in beef, sardines, spinach, and peanuts and helps control the flow of oxygen within individual cells.
- *Dietary fiber*—makes up cell walls of plants. Because it passes through the digestive tract without being absorbed, it lessens the chances of constipation, helps to control blood-sugar levels in diabetics, and helps reduce cholesterol and triglycerides in the blood.
- *Gamma-linolenic acid*—an oil found in evening primrose plant (see Herbals and Botanicals).
- *Inositol*—(also called myo-inositol) made synthetically and found in beans, nuts, oats, pork, rice, veal, wheat germ, whole-grain products, cantaloupe, calves' liver, citrus fruits, chickpeas, lentils, and lecithin. It helps move fats out of the liver.
- *Lecithin*—made synthetically and also found in all animal and plant products and in cabbage, eggs, green beans, lentils, rice, and split peas, among other natural sources. It protects cells from damage by oxidation, is a major source of choline, and is found in chemicals that aid the passage of nutrients into cells from the bloodstream.
- *Nucleic acids*—large molecules that are encoded with genetic instructions and are part of each living cell. Nucleic acids taken orally are not effective and have no impact, as they are changed or destroyed in the intestinal tract before they can be absorbed. There is no deficiency for nucleic acids, and the oral tablet and capsule forms are nontoxic (Griffith, 1988; HealthWorld Online, 1998d).
- *Royal jelly*—substance secreted by salivary glands of worker bees. It has no known effects in the human body.

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[6]These claims have not been evaluated by the Food and Drug Administration. DS products may not include statements that they diagnose, treat, cure, or prevent disease.

- *Spirulina*—(*Spirulina geitler, S. maxima, S. platenis*) algae. It has no known or proven effects.
- *Superoxide dismutase*—enzyme associated with copper, zinc, and manganese. The oral forms have no effect, as they are destroyed in the intestines before being absorbed.

4.2 CONSUMERS OF DS PRODUCTS

To construct a demand curve for a DS product, one would include characteristics of the population that consumes the product. These demographic characteristics (e.g., income, gender, age) are the factors that shift the demand curve for a particular product. However, information on the demographic characteristics of DS users is scarce. Most of the large-scale studies on DS use were conducted several years ago and did not contain information on nontraditional DS products (i.e., products other than vitamins and minerals). However, a new survey of 43,000 households that was conducted by Hartman and New Hope includes information on the use of nontraditional DS products (Wingate, 1998).

In general, studies indicate that gender, age, race, income, educational level, and body weight are related strongly to DS use. Most studies found that whites, women, individuals over 30, and individuals living in the western United States are more likely to consume DS products. One study also found that other health habits and occupation are also strongly related to DS use. In comparison, studies that considered smoking and tobacco use, alcohol use, exercise level, and marital status found no correlation with DS use.

In this section, we summarize the large-scale studies and briefly describe some of the small-scale studies that have been conducted on DS use.

4.2.1 Major Studies of DS Use

Stewart et al. (1985): This survey assessed vitamin and mineral supplement usage via a national telephone interview survey of an age-stratified random sample of 2,991 people age 16 and over. This survey revealed that, excluding pregnant or lactating women, 39.9 percent of the population consumed one or more supplements daily. Of these, 52.4 percent consumed only one supplement and 10.9 percent consumed five or more supplements daily. The most any person consumed was 14 products daily. However, the percentage of people taking at least one supplement in the past year declined from 51.1 percent in 1987 to 46.2 percent in 1992. Use of supplements by women was greater than used by men for each age group (16 to 24, 25 to 64, 65+). Women ages 25 to 64 had the highest supplement usage (46.8 percent), and men ages 25 to 64 had the lowest usage (33.3 percent). The most widely used supplements were single vitamin/miscellaneous supplements, with vitamin/mineral combinations as the second most common and multivitamin/minerals as the third most common supplement product consumed. Use was more common in the West census region than in the rest of the country. Those with higher incomes and those who had at least finished high school were more likely to use supplements than those who had lower incomes and those who had not finished high school.

Block et al. (1988): The data used for this assessment came from the first National Health and Nutrition Examination Survey, 1971-1974, in which 21,000 people were sampled. Because the information is outdated, we give just a brief overview of the data. This paper presented detailed information on the use of nine specific vitamins and minerals for a broad range of behavioral and demographic characteristics. More women were found to consume supplements than men, at 26.1 percent vs. 19.4 percent. Consumption of supplements was much more common for whites, with 24.1 percent using supplements, than for blacks, with 11.7 percent using supplements. Overall, those older than 65 consumed the most supplements. Consumption was found to be highest in the West and lowest in the South. Educational level was found to correlate with supplement consumption, although no significant correlation could be found between income and usage. Body weight, however, was found to have a significant negative relation to use of vitamin and mineral supplements.

Moss et al. (1989): This study provides estimates from the National Center for Health Statistics' 1986 survey of adults and young children who use nonprescription vitamin and mineral products. A vitamin and mineral user was defined as anyone who had taken a nonprescription vitamin, mineral, or fluoride product in the 2-week period before the interview was conducted. This report estimated that 36 percent of all adults took vitamin and mineral supplements in 1986 and that women were more likely than men to consume supplements (41 percent to 31 percent). An estimated 40 percent of whites used supplements versus 20 percent of blacks. This racial difference was found in both sexes and among all age groups. This study estimated that 29 percent of Hispanic adults take supplements. Both family income and educational level were found to be directly related to supplement usage. Those in the West were found to be more likely to consume supplements, as were those who live in a metropolitan statistical area. Most people take just one supplement, and it is a multivitamin, according to this report. For those over 45, the percentage of adults using two products or more (45 percent) was higher than for those under 45 (36 percent). More women than men used more than one vitamin and mineral product. Differences in the types of products taken were also reported, with only 16 percent of adults who took any vitamin product taking a single vitamin product, and 86 percent of adults who purportedly took three products or more taking a single vitamin product. The paper also indicates that supplement use is frequent, with 70 percent of all adults and children who use supplements taking them every day.

Slesinski, Subar, and Kahle (1995): This study detailed the trends in the use of vitamin and mineral supplements in the United States. Information is based on the 1987 and 1992 National Health Interview Surveys, making this paper relatively current. This study found that multivitamin use increased from 17.4 percent to 19.3 percent from 1987 to 1992. In general, more women than men took supplements, and far more whites than either blacks or Hispanics consumed supplements, although the percentage of blacks taking supplements increased 2 percent while white and Hispanic use increased by only 0.3 percent and 0.1 percent, respectively. Also, those with higher incomes and educational levels were more likely to consume supplements in both

1987 and 1992. Those age 55 and older had the highest percentage of supplement consumption in both 1987 and 1992. Overall, supplement usage did not change much between 1987 and 1992.

Subar and Block (1990): This study used data from the 1987 National Health Interview Survey which was collected from 22,080 adults age 18 to 99. Only 23.2 percent of the adults interviewed used DS products daily, although 51.1 percent said they had used a supplement within the year before the interview. Whites, women, and older people were found to be much more likely to consume supplements on a regular basis than blacks, men, and younger adults. Multivitamins were the most common supplements consumed, followed by vitamin C, calcium, and vitamins E and A. Daily usage was highest among both men and women in the 55 to 64 age range (32.2 percent) and declined slightly with age. White women age 55 to 64 had the highest percentage consuming supplements (39.9 percent); this number declined slightly with age. Within other sex-race categories, use increased with age. Whites consumed the most supplements within age-sex categories, followed by Hispanics and then blacks.

This study also looked at other demographic and behavioral characteristics. Those completing high school and college were significantly more likely to consume supplements than those who did not finish high school. Supplement use was also shown to increase with income. As in other studies, consumption was highest in the West and lowest in the South. Individuals with the highest body mass index were the least likely to take supplements. Former smokers were the heaviest supplement users, followed closely by those who never smoked. People in the highest alcohol consumption category used supplements the least, although use of supplements was relatively similar for all other drinking categories. Those who believe that diet affects disease prevention were found to be significantly more likely to consume supplements than those who did not believe there was a link between diet and disease prevention. This study included a variable not found in the other major studies—occupation category. The category with the highest daily supplement use (27.5 percent) was "not in the labor force," which includes women working in the home and retired persons. Close behind are white-collar workers, 24.6 percent of whom use supplements regularly. The highest rates among white-collar workers were for senior executives and those with a professional specialty. Less than 20 percent of blue-collar workers and those in the military regularly use supplements.

Wingate (1998): This study, conducted in December 1997, is the most recent large-scale survey undertaken. A sample of 43,000 households with a member who had used vitamins, minerals, or herbal supplements in the past 6 months was asked about usage of 97 different vitamin, mineral, herbal, and other supplement products. This survey was unique in that it addressed the use of supplement products not typically asked about in other surveys, like herbs and amino acids.

Overall, 68 percent of the 43,000 households responding to the survey reported that they had used vitamins, minerals, or herbal supplements in the past 6 months. The study found that women age 21 to 40 are the most educated consumers, while those over 50 tend to use more

products and use them more frequently than younger consumers. Almost half the people using saw palmetto and glucosamine sulfate are over age 60. Pygeum, chondroitin sulfate, and bilberry are also popular among those over age 60. The largest percentage of households with a member who used a vitamin, mineral, or herbal product (30 percent) was in the 60+ age group. The 40-49 age group followed, with 22 percent, and the 30-39 group, 21 percent.

Geographic region and specific product purchases were also addressed. The highest concentration of garlic and ginseng users/buyers was in the southern Atlantic states, followed by the Pacific states. Eighteen percent of households had a member who had used a supplement in the past 6 months in the southern Atlantic states, followed by 16 percent in the central Northeast and 15 percent each in the Pacific and mid-Atlantic regions, the survey found. Garlic was used by 19 percent of those surveyed, followed by ginseng (10 percent), ginkgo (9 percent), echinacea (7 percent), and antioxidants (7 percent). The survey found that 32 percent buy their supplements at a pharmacy or drug store, 23 percent purchase them at a supermarket, 17 percent buy them from network marketing and 11 percent buy them at health food stores.

4.2.2 Smaller Studies

Thomsen, Terry, and Amos (1987): A study of 163 adolescent students in a rural Iowa town found that 16 percent took a supplement daily and that 64 percent had taken one during the past month. The teens' use of supplements was correlated with their parents' use of supplements.

Zive et al. (1996): Young adults were the focus of another survey that used 24-hour diet recalls from 1988 to 1991 on a sample of 504 19- to 28-year-olds in Bogalusa, Louisiana. Nine and one-half percent of the participants reported taking a DS product in the prior 24-hour period. About 11 percent said they took supplements daily, 17 percent said they took them "once in a while," and 72 percent said they had never taken a DS product.

Medeiros et al. (1991): People in seven western states were surveyed in the spring of 1986, and by telephone in the winter of 1986/1987 and again, in the fall of 1987. Forty percent used supplements at the baseline and in both telephone surveys. Those who used supplements long-term (in all three surveys) did not differ from nonusers by income or educational level, but they did have a slightly higher mean age. Women represented 55 percent of long-term users, and 60 percent of the nonusers were men.

Eliason et al. (1997): This survey of 136 patrons of two health food stores had findings contrary to the major studies and to some of the smaller studies as well. Respondents took an average of 5.9 supplements a day. Patrons took a total of 805 supplements, 50 of which had reported toxicities. Herbal products were the most commonly used supplements, followed by multivitamins. The most popular herbal products were garlic, ginseng, ginkgo biloba, evening primrose oil, alfalfa, and echinacea. Like the other studies, the typical supplement user was a white, middle-aged woman with an education beyond high school.

Eliason et al. (1996): Two hundred consecutive patients over age 18 attending a family medical practice were surveyed. Of these, 53 percent reported taking supplements. This study reported higher usage of more than one supplement product than other studies had (18 percent took 2 to 5 supplements). Their average estimated expenditure was $6.60 per month, and 84 percent of the products they purchased were vitamins and minerals, 8 percent herbals, and 3 percent amino acid and protein supplements. No tissue or organ extracts were taken. Only educational level was found to correlate significantly with supplement use.

Oakland and Thomsen (1990): The use of supplements by the elderly was investigated in this 1990 study of 24 males and 78 females in seven Iowa counties. Forty-nine percent had used vitamin and mineral supplements within the last 6 months. According to this study, 25 percent of men and 27 percent of women regularly used supplements.

Merkel, Crockett, and Mullis (1990): In another study, 340 surveys were collected from randomly selected women age 26 to 51 with school-age children. Fifty-two percent of the women reported using DS products. Only 11 percent said they had never used a DS product. Over two-thirds of the supplement users took only one or two products, and only 7 percent regularly used more than six supplements. Multivitamins (78 percent), followed by calcium and vitamin C, were the most commonly consumed supplements.

Applied Biometrics (1996): According to information provided by Applied Biometrics in a 1996 presentation to the Food and Drug Law Institute, 67 percent of supplement users do not have any children under age 18 living with them and 7 out of 10 have had some college education. Fifty-one percent of supplement users have incomes between $20,000 and $50,000, according to Applied Biometrics, and 19 percent have incomes greater than $50,000. The majority exercise at least three times a week and 23 percent exercise daily. Eighty percent do not smoke and 60 percent drink only occasionally. Applied Biometrics also notes that 30 percent of all women and 23 percent of the total take only one supplement, most likely a multivitamin. Only about 11 percent of women and 12 percent of men take two supplements.

4.3 SUBSTITUTION POSSIBILITIES FOR DS PRODUCTS

In addition to the demographic characteristics described in Section 4.2, the price of substitute products shifts the demand curve for DS products as well. If products can substitute for one another, then an increase in the price of one product will increase the demand for its substitutes. However, DS products are so heterogeneous that either (1) no substitutes will exist or (2) if substitutes do exist, consumers will have strong preferences for one product over another. For example, zinc, echinacea, and vitamin C are all consumed because individuals believe they will prevent colds, but they are dissimilar enough that even large price changes in one will probably have little effect on the demand for the others. In other words, the cross-price elasticity of demand is small.

For traditional vitamin and mineral products, an obvious source of substitution is food products that contain the vitamin or mineral. Consumers could obtain adequate amounts through the diet. However, nontraditional DS products are taken for reasons other than nutritional supplementation. For these products, the substitute product may be conventional medical care. In the section below, we review some of the information that is available on both forms of substitution for DS products.

4.3.1 DS Products as Substitutes for Nutrients in Conventional and Fortified Foods

Dietary supplements are imperfect substitutes for both conventional foods and fortified foods. While consumers can get all the nutrients they require from foods, the opposite is not true—they cannot get all the nutrients they require from supplements. At most, dietary supplements can replace a small portion of the diet. Substitution possibilities for both conventional and fortified foods are described briefly below.

Conventional Foods

Some consumers of DS products, particularly vitamins and minerals, may be using them as substitutes for the nutrients available in foods. For example, consumers who wish to increase their intake of calcium may prefer to take a calcium pill rather than eat more dairy products. Or, an individual may prefer taking an iron supplement to eating red meat. If the price of the supplement were to increase, it is possible that some consumers would respond by taking less of the supplement and eating more of the foods that are rich in that nutrient. Conversely, an increase in the price of the nutrient rich-food could cause some consumers to rely more heavily on supplements. Price may be a very small factor in determining the consumer's choice, however. Many consumers have compelling reasons for avoiding certain foods. Individuals with lactose intolerance would not eat more dairy products as a source of calcium, nor would vegetarians eat red meat as a source of iron. Consumers' strong preferences regarding food limit the extent to which supplements and food can act as substitutes for each other.

Fortified Foods

In some cases, fortified foods and DS products may act as substitutes for each other. For example, an individual may choose a breakfast cereal that contains 100 percent of the RDAs for vitamins instead of taking a daily vitamin supplement. The same manufacturers who produce vitamins for the dietary supplement industry also supply the food industry. Major manufacturers including Hoffmann LaRoche, BASF, Rhone-Poulenc, and ADM produce vitamins for the food industry as well as the DS and animal feed industries. In terms of value, the food industry accounts for about 20 percent of vitamins consumed, compared to 30 percent used in supplements and 50 percent used in animal feeds worldwide (Ullman's Encyclopedia of Industrial Chemistry, 1996). If consumers switch from a fortified food to a supplement, or vice versa, they may still be

consuming vitamins from the same manufacturer that have been prepared and packaged in a different form. Although the demand for vitamins from the manufacturer might remain unchanged, such a shift would affect businesses involved in the later stages of processing, packaging, or marketing either fortified foods or DS products.

4.3.2 DS Products as Substitutes for Conventional Medical Care

Alternative medicine has become mainstream in its popularity as Americans increasingly turn to self-medication for treatment and prevention of disease. In 1996, $94 million was spent in the United States for books on herbs and related topics (Cuthbert, 1998). Unconventional medicine is sometimes more accessible than traditional medicine to health care consumers, and a large segment of the population is disgruntled with traditional medicine. Thus, some consumers are taking a more proactive role in their health care and are looking to prevent illness to avoid the need to see a doctor. Studies also show that consumers substitute herbal remedies and supplements for traditional medical intervention. However, only a very small percentage of consumers rely completely on unconventional therapies. Most people who use alternative medicine do so in conjunction with traditional medicine and generally use alternative therapies for long-term, chronic conditions; for secondary health problems; or for general well-being and disease prevention. Most of those faced with serious conditions requiring medical treatment still consult a medical physician rather than pursuing unconventional therapies (Taylor, 1997).

In a survey of 1,539 adults nationwide, one-third of respondents reported using at least 1 of 16 possible unconventional therapies, defined as medical interventions not taught widely in U.S. medical schools nor generally available in U.S. hospitals and including herbal medicine and megavitamin therapy. Rates of use of unconventional therapies ranged from 23 to 53 percent, and use was more common among those 25- to 49-years-old, white, with some college education, and who lived in the West and had an annual income above $35,000 (Eisenberg et al., 1993). *Comprehensive Therapy* also reports that one in three Americans uses an unconventional therapy at some time (Taylor, 1997).

The majority of those using nontraditional therapies to treat their principal medical problem use them to treat chronic medical conditions. In particular, patients with cancer, arthritis, chronic back pain, AIDS, chronic renal failure, eating disorders, and gastrointestinal problems frequently use unconventional therapies. Of these conditions, megavitamin therapy is most commonly used because individuals believe it will treat digestive difficulties. Those using megavitamin therapy to treat their ailments reported out-of-pocket expenditures averaging $203 per person per year (Eisenberg et al., 1993).

Women are also using alternative medicine as a substitute for hormone replacement therapy after menopause. Supplements containing calcium, magnesium, boron, DHEA (a hormonal supplement), and phytoestrogens, or naturally occurring plant sterols that may exhibit effects similar to estrogen are taken to mimic the effects of estrogen therapy in mitigating the symptoms

of menopause as well as to provide benefits beyond the treatment of menopausal symptoms (stronger bones, lower cardiovascular disease and cancer risk). Botanicals commonly used in menopause treatment are angelica, black cohosh, chamomile, damiana, evening primrose, ginseng, saw palmetto, and licorice. Women are choosing such natural alternatives because they believe they will avoid the possible side effects of synthetic estrogen replacement therapy, such as breast cancer, weight gain, and breakthrough bleeding.

Supplementation and herbal healing are also being considered by some insurance companies and health maintenance organizations (HMOs) as possible avenues by which to offset some of the skyrocketing costs of medical care by substituting some traditional care with less costly unconventional therapies. Oxford Health Plans Inc. became the first network provider for alternative medicine, according to *Nutrition Business Journal* (Nutrition Business International, October 1996a). Oxford plans to establish a network of 1,000 holistic providers, include alternative medicine coverage, and establish a mail order service for purchasing vitamins, remedies and alternative medicine products (Nutrition Business International, October 1996a). Indeed, Eisenberg's study does touch on the growing interest in insurance providers in this area; 83 percent of those using the services of herbal therapists were reimbursed by third parties, as were 30 percent of those using megavitamin therapies. Also, 70 percent of respondents in a survey of HMOs reported an increase in the number of members asking for the provision of alternative care therapies (Nutrition Business International, October 1996a).

However, Eisenberg's study found that serious, life-threatening medical conditions are still generally treated by conventional doctors. Among people who did use an alternative therapy to treat a serious medical problem, 83 percent also sought treatment from a medical doctor for that condition. Of the 1,279 respondents reporting at least one principal medical condition, only 3 percent saw an unconventional provider and not a medical doctor. Seven percent saw both a medical doctor and a provider, and 58 percent saw just a traditional medical doctor. These numbers illustrate the rarity of visits to unconventional providers in the absence of a consultation with a medical doctor (Eisenberg et al., 1993).

A study conducted by the Medical College of Wisconsin of customers of two health food stores supports the Eisenberg study regarding use of unconventional therapies for overall wellness and disease prevention and not as the preferred method of medical care. Of the 805 different supplements taken by the 136 persons surveyed, 84.3 percent were taken to prevent disease and health problems, and only 15.7 percent of those surveyed took supplements to treat health problems. Both studies found the use of unconventional therapy was not supervised by a physician the majority of the time these therapies were used. As in the Eisenberg study, most users of these unconventional therapies did have health insurance and had a regular physician (Eliason et al., 1997).

The use of unconventional therapies is also reflected in developments in alternative health law. In 1996 alone, Utah, Maine, and Vermont licensed all their naturopaths; Washington State's King

County established a natural health clinic; University of California at San Francisco created an Integrative Medicine Program and more than 30 other medical schools planned courses in alternative medicine; and medical freedom bills were active in 12 states (Nutrition Business International, January/February 1997).

SECTION 5
DIETARY SUPPLEMENT MARKETS, DISTRIBUTION CHANNELS, AND INDUSTRY STRUCTURE

Estimates of retail sales of DS products vary widely from Frost & Sullivan's 1997 estimate of $5.8 billion to F-D-C Reports, Inc.'s 1996 estimate of $10.3 billion. However, most sources agree that the industry has grown rapidly and will continue to do so in the near future. In addition, the distribution channels for these products are changing as grocery stores, drugstores, and mass marketers are increasing the range of DS products they carry. Because consumer demand has increased greatly, larger pharmaceutical companies are entering the market, often by buying supplement firms (Stewart, 1998). As a result, the structure of the market is changing and will continue to change as the DS market matures.

In this section, we first provide information on the size of vitamin, mineral, and herbal and botanical markets as reported in secondary sources. We then describe the marketing of DS products by the following outlets: supermarkets, drugstores, mass merchandisers, natural food stores, mail order and Internet, health care practitioners, and specialty shops. Finally, we describe the structure of the industry including market concentration and vertical and horizontal integration.

5.1 SALES OF DIETARY SUPPLEMENT PRODUCTS

Growth of DS product sales has been fueled in particular by increases in sales of herbal and botanical products and mineral products. However, vitamins are still the largest component of DS product sales. Table 5-1 breaks out sales of DS products by category, as reported in the F-D-C Tan Sheet (F-D-C Reports, 1997b). Vitamins account for 48 percent of sales, minerals for 6 percent, and herbals and botanicals for 28 percent, with sports nutrition (much of which is dietary supplements), meal supplements, and specialty supplements making up the remainder. As indicated in Table 5-2, the leading brands of DS products in 1994 (the most recent year available) were Centrum (9 percent market share), Nature Made (8.7 percent), and Your Life (8.4 percent). However, nearly a third of sales are private label brands. In the following sections we describe sales of the major DS product categories.

5.1.1 Vitamin Supplement Sales

Vitamins are the largest supplement category, with $4.9 billion in sales in 1996 and 48 percent of the supplement market (see Table 5-1). Since vitamins are the most mature supplement category, they experienced growth of about 8 percent from 1995 to 1996, which is slower than the other DS products (Nutrition Business International, September 1997b). Multivitamin preparations continue to make up the majority of vitamin sales. Among single-category vitamins, vitamins E, D, B_6, and folic acid led sales growth in 1996.

Table 5-1. Dietary Supplement Sales and Market Share, 1996

Product	Sales ($ millions)	Percent of Dietary Supplement Market
Vitamins	4,900	48%
Herbal and Botanicals	3,000	28%
Sports Nutrition Products	927	9%
Meal Supplements	618	6%
Minerals	618	6%
Specialty Supplements	309	3%
Total	$10,372	100%

Source: F-D-C Reports, Inc. 1997b. "The Tan Sheet: Nonprescription Pharmaceutical and Nutritionals." Chevy Chase, MD: F-D-C Reports, Inc.

F-D-C Reports, Inc. 1997a. "The Tan Sheet: Dietary Supplement Sales up 16% to Approximately $10.3BIL." Chevy Chase, MD: F-D-C Reports, Inc.

Table 5-2. Market Shares of Leading Dietary Supplement Product Brands, 1994

Brand	Manufacturer	Market Share[a]	Sales ($ millions)	Percentage Dollar Change from Previous Year
Centrum	Lederle	9.0%	67.2	17%
Nature Made	Pharmavite	8.7%	64.7	6%
Your Life	Leiner	8.4%	63.1	48%
Nature's Bounty	Nature's Bounty	5.0%	37.7	243%
Theragran	Squibb	3.0%	22.6	3%
One-A-Day	Miles	2.6%	19.3	89%
Ginsana	SunSource	2.5%	18.5	-8%
Os-Cal	SmithKline-Beecham	2.1%	15.4	1%
Flintstones	Miles	1.3%	9.5	19%
Lederle	Lederle	1.1%	8.0	8%
Private Label	(various)	33.8%	252.6	N/A
Other	(various)	22.5%	168.0	N/A
Total		100.0%	$746.6	

[a]Market share is based on product movement from distribution centers among Towne-Oller reporting retailers for the 12 months through December 1994.

Source: *Chain Drug Review.* February 27, 1995. "Drug Chains Adopt New Tactics to Meet Competition in Vitamins." *Chain Drug Review* 17(5):30, 32. Values for other products and total are inferred.

5.1.2 Mineral Supplement Sales

Minerals experienced the second largest growth in sales in the DS category from 1995 to 1996, trailing only herbals and botanicals (see Table 5-1). In 1996, sales reached $600 million, an increase of 18 percent over 1995. Calcium and selenium were two of the best-selling mineral products; both benefited from reports of positive clinical trials on their usage and from media stories (Nutrition Business International, September 1997a).

5.1.3 Herbal and Botanical Supplement Sales

As illustrated in Table 5-1, herbal and botanical products totaled $3 billion in sales for a 28 percent share of the DS market. Their growth rate of 20 percent from 1995 to 1996 was the highest of all DS products. However, sales volumes of specific products are relatively concentrated in a few products. Specifically, garlic, ginseng, ginkgo biloba, and echinacea were the best-selling herbal products in 1995 and 1996 (Table 5-3). The leading herbs in terms of sales growth in 1996, each with greater than 50 percent growth (in sales), were ginkgo biloba, echinacea, and saw palmetto. St. John's wort, a relative newcomer to the industry, has experienced phenomenal sales growth as well.

Table 5-3. Market Shares of Leading Herbal Dietary Supplement Products, 1995 and 1996

Herb	Market Share	
	1995[a]	1996[b]
Garlic	40.6%	29.6%
Ginseng	36.9%	29.3%
Ginkgo biloba	1.9%	13.7%
Echinacea	3.2%	5.4%
Goldenseal	1.8%	2.0%
Evening primrose	1.4%	2.0%
Valerian root	0.7%	1.2%
Saw palmetto	0.1%	1.1%
Cayenne	0.7%	0.8%
Ginger	0.4%	0.5%
Gotu kola	0.2%	0.4%
Feverfew	0.1%	0.3%

[a]Annual average market share from November 6, 1994, to November 5, 1995.

[b]Annual average market share from November 4, 1995, to November 3, 1996.

Source: Information Resources Inc., 52 weeks ending November 5, 1995, vs. 52 weeks ending November 3, 1996, as found in: Troy, Mike. February 17, 1997. "Herbals: Strong Growth, Powerful Potential." *Drug Store News* 19(4):19.

While most of these products are sold in tablet, capsule, or powdered form, some are sold as tea products. However, not all teas are dietary supplements; they are considered DS products only if their label indicates that they are. Table 5-4 lists the types of tea products sold as well as their market shares and growth rates.

Table 5-4. Herbal Teas Dollar Share and Sales Growth[a] by Subcategory, January – August 1997 Compared to January – August 1996

Tea	Dollar Share	Growth
Medicinal Blend Teas	37.5%	28.1%
Herbal Beverage Teas	20.9%	4.5%
Medicinal Single Teas	13.3%	9.7%
Green Teas	12.3%	50.9%
Black Teas	6.7%	25.2%
Chai	5.3%	170.6%
Diet Teas	1.6%	-1.0%
Iced Teas	1.5%	-25.3%
Bulk Teas	1.0%	40.5%
Total Tea Category		25.5%

[a]Growth measured January through August 1997 vs. January through August 1996.

Source: Cuthbert, Lauren. 1998. "Tantalizing Tea Sales." *Natural Foods Merchandiser* 19(1):48. From SPINS Distributor Information, "The Tea Report."

5.2 SALES AND MARKETING BY DISTRIBUTION CHANNEL

This section describes the sales and marketing practices for the various distribution channels for dietary supplements, as well as the marketing techniques used by manufacturers and distributors. Sales of DS products by sales channel are listed in Table 5-5 for 1995, 1996, and 1997. DS products in this table include vitamins, herbals and botanicals, sports nutrition, meal supplements, minerals, and specialty supplements.[7] Percentages of sales by distribution channel for herbals and botanicals in particular are included in Table 5-6. While multilevel marketing and natural food stores each have high market shares of 38 percent and 37 percent, respectively, mass merchandisers trail at only 10 percent.

The market share of natural food/health chain stores has been steadily increasing at the expense of the market share of multilevel marketing firms. From 1996 to 1997, natural food and health chain stores sales increased 55 percent while multilevel marketing firm sales were unchanged. The market shares of the other distribution channels have remained fairly constant.

[7]"Mass merchandisers" refers to mass merchandise outlets, supermarkets, and drugstores.

Table 5-5. Dietary Supplement Product Sales and Market Share by Distribution Channel, 1995 and 1996

Outlet	1995 Supplement Sales ($ billion)[a]	1995 Supplement Market Share[b]	1996 Supplement Sales ($ billion)[a]	1996 Supplement Market Share[c]	Percentage Growth from 1995 to 1996	1997 Supplement Sales ($ billion)[a]	1997 Supplement Market Share[d]	Percentage Growth from 1996 to 1997
Natural Food and Health Chain Stores	2.3	26%	2.9	28%	26%	4.5	35%	55%
Mass Merchandisers	2.8	31%	3.2	31%	14%	3.8	30%	19%
Multilevel Marketing Firms	2.7	30%	2.9	29%	7%	2.9	23%	0%
Mail Order	0.6	7%	0.7	7%	17%	0.8	6%	14%
Health Care Practitioners	0.5	5%	0.6	5%	20%	0.7	6%	17%
Total	$8.9	100%	$10.4	100%	—	$12.7	100%	—

[a]Consumer sales.

[b]Supplements accounted for 52 percent of sales in the $17.2 billion nutrition products industry in 1995.

[c]Supplements accounted for 52 percent of sales in the $19.8 billion nutrition products industry in 1996.

[d]Supplements accounted for 55 percent of sales in the $23.2 billion nutrition products industry in 1997.

Sources: Nutrition Business International. September 1997a. "$20 Billion and Counting: Nutrition Industry Momentum Builds." *Nutrition Business Journal* 2(9):1-5.

Nutrition Business International. August 1996. "$17 Billion and Counting: Defining the Nutrition Industry." *Nutrition Business Journal* 1(1):1,4-5.

Nutrition Business International. September 1998. "$23 Billion and Counting: Nutrition Industry Braces for a Competitive Future." *Nutrition Business Journal* 3(9):1-5, 13, 18.

Table 5-6. Distribution Channels for Herbal and Botanical Products, 1996

Distribution Channel	% of Total Sales
Multilevel Marketing	38%
Natural Food Stores	37%
Mass Merchandisers	10%
Mail Order	9%
Health Care Practitioners/Herbalists	4%
Specialty Shops	2%

Source: F-D-C Reports, Inc. 1997b. "The Tan Sheet: Nonprescription Pharmaceutical and Nutritionals." Chevy Chase, MD: F-D-C Reports, Inc.

F-D-C Reports, Inc. 1997a. "The Tan Sheet: Dietary Supplement Sales up 16% to Approximately $10.3BIL." Chevy Chase, MD: F-D-C Reports, Inc.

5.2.1 Food Store Sales and Marketing

Of the types of mass merchandisers, which had a 30 percent share of the dietary supplement market in 1997 (see Table 5-5), food stores trailed drugstores in every category of vitamin and mineral product sales while surpassing mass merchandisers in sales of some products and trailing in others. Table 5-7 breaks out the values and quantities of sales by mass market stores for each of these products.[8] At the specific brand name level (see Table 5-8), food stores led the other mass market stores in sales of some brands, such as One-A-Day, Flintstones, Bugs Bunny, and Nature Made and trail in the others. DS product sales in food stores have recently been erratic, as DS sales increased 24 percent in 1993, increased 6 percent in 1994, decreased by 7 percent in 1995, and then increased 4 percent in 1996 (Nutrition Business International, October/November 1997b).

As more consumers are purchasing supplements at food stores and supplements are becoming an important part of the Health and Beauty Care (HBC) section, food stores are responding by increasing the product mix and the variety and selection they offer. In particular, multivitamin and vitamin shelf space has been increased as has space for children's vitamins. Food stores are also adding other DS items, especially herbal products, to their product list.

In addition to expanding their product mix, food stores are also working to educate consumers and make them aware of supplement product offerings. Educational pamphlets and shelf talkers, which provide information on the shelf about the specific items sold on that shelf, can be found in food stores across the country. Price discounts, coupons, and products with "25% More Free" are also common marketing techniques used in supermarkets for supplement products. Food stores

[8]The source of these data, *Supermarket News*, did not include the other dietary supplements.

Table 5-7. Dollar and Unit Volume of Vitamin and Mineral Sales at Food, Drug, and Mass Merchandise Retail Outlets[a]

Retail Outlet	Multivitamins		1& 2 Letter Vitamins		Mineral Supplements		Liquid Vitamins/Minerals		Total	
	Annual $ Volume (millions)	Annual Unit Volume (millions)	Annual $ Volume (millions)	Annual Unit Volume (millions)	Annual $ Volume (millions)	Annual Unit Volume (millions)	Annual $ Volume (millions)	Annual Unit Volume (millions)	Annual $ Volume (millions)	Annual Unit Volume (millions)
Food Stores	197.2	30.3	153.6	28.8	130.4	23.3	9.5	1.6	490.7	84.0
Drugstores	307.6	43.0	314.9	58.9	375.8	58.2	26.8	3.5	1,025.1	163.6
Mass Merchandisers	165.2	26.7	156.6	35.1	197.2	38.1	8.4	1.7	527.4	101.6

[a]For the year September 9, 1995, through September 8, 1996.

Source: *Supermarket Business*. November 1996. "Vitamins." *Supermarket Business* 51(11):72.

Table 5-8. Mass Market Share of Leading Brands in Multivitamins, 1996

Brand	Manufacturer or Brand Parent	Food Stores ($ thousands)	Drugstores ($ thousands)	Mass Merchandisers ($ thousands)	Total Mass Market ($ thousands)	Mass Market Share
Centrum	Lederle	37,377	46,509	30,022	113,908	16.9%
Centrum Silver	Lederle	16,760	28,499	17,504	62,763	9.3%
One-A-Day	Bayer	18,445	16,423	12,894	47,762	7.1%
Flintstones	Bayer	16,400	9,213	9,749	35,362	5.2%
Theragran M	BM Squibb	6,636	16,474	4,985	28,095	4.2%
Ocuvite	Lederle	2,175	10,575	4,711	17,461	2.6%
Bugs Bunny	Bayer	5,500	2,775	4,567	12,842	1.9%
Geritol Complete	Warner Lambert	3,059	5,102	3,891	12,052	1.8%
Centrum Jr	Lederle	4,131	3,750	3,287	11,168	1.7%
Stresstabs	Lederle	2,608	5,060	3,330	10,998	1.6%
Nature Made	Pharmavite	4,208	5,317	627	10,152	1.5%
Sundown	Rexall Sundown	1,370	4,757	2,630	8,757	1.3%
Sesame Street	J&J	3,711	2,074	2,057	7,842	1.2%
Protegra	Lederle	1,249	3,146	1,386	5,781	0.9%
Your Life	Leiner	1,897	3,182	612	5,691	0.8%
Your Life Daily Pack	Leiner	866	2,273	2,124	5,263	0.8%
Icaps Plus	Icaps	512	2,983	1,312	4,807	0.7%
Nature Made Essential Balance	Pharmavite	1,261	1,904	1,567	4,732	0.7%
Your Life Max Pack	Leiner	518	1,637	1,868	4,023	0.6%
Theragran M	BM Squibb	883	2,437	583	3,903	0.6%
Other Brands		18,413	44,823	14,885	78,121	11.6%
Private Label		51,883	84,688	46,971	183,542	27.2%
Total Category		$199,862	$303,601	$171,562	$675,025	

Source: Nutrition Business International. December 1996a. "Dominant Brands Still Up for Grabs in the Nutrition Industry." *Nutrition Business Journal* 1(5):1-3.

are also using manufacturers' point-of-purchase displays to generate interest in the products, educate consumers, and explain the uses of products. These displays are generally arranged by product attribute without making any health claims; for example, *energy*, *digestion*, and *the immune system* are terms that are used. These displays enable retailers to move the display unit around in the store to get supplement products into high-traffic areas without rearranging existing shelf space, a bonus considering the shortage of shelf space in nutrition products aisles.

In addition, some food stores are developing a "store within a store" concept for nutrition products, including supplements, to build category awareness. Other ways in which food stores are trying to increase supplement product visibility, include placing vitamins near the checkout counter to increase impulse purchases, placing them more prominently in stores, and cross-merchandising supplements with other food categories (e.g., children's vitamins in the cereal aisle, other supplements mixed in with incontinence care).

The attention given to expanding product offerings, educating consumers, and giving supplements prominent store location is not a surprise considering the large profits food stores make on DS products. The profit margin for most products in food stores ranges from 1 to 3 percent. Dietary supplements, however, yield profit margins near 40 percent (Gaseau, 1995). A buyer from a large East Coast supermarket chain said that pricing is not an issue and that food stores can "… price [supplements] competitively and make a ton of money" (Gaseau, 1995).

5.2.2 Drugstore Sales and Marketing

Although drugstores are experiencing increased business in the overall supplement category, their market share is declining. Drugstores maintained a 49 percent market share in sales of dietary supplements and had sales of $1.1 billion, according to AC Neilsen (Nutrition Business International, October/November 1997c). Drugstores lead the way relative to food stores and mass merchandisers in sales of multivitamins, minerals, one- and two-letter vitamins, and liquid vitamins/minerals (see Table 5-7). In addition, they lead sales of the majority of individual brands listed in Table 5-8. However, there is evidence that this share is being eroded by mass merchandisers, who experienced a 60 percent increase in vitamin sales in 1994, and natural food stores (*Chain Drug Review*, 1995).

To slow the flow of supplement sales toward other retail outlets, drugstores are working to educate consumers and to leverage their unique competitive advantage—the in-house pharmacist—to attract consumers. DS products are intentionally positioned in most drugstores near their pharmacies to capitalize on the advantage of having a knowledgeable, accessible health care provider located nearby to educate and help guide consumers in their purchase decisions. Monthly newsletters, manufacturer–supplied informational brochures, and educational programs are also being offered by chain drugstores as a means to educate consumers.

In addition to trying to educate consumers, drugstores are also increasing the number of products they offer in response to rising demand and are using the media to highlight their larger product

mix. The expanded shelf space is likely to be filled with herbal products, as drugstores increase the number of herbal products they carry. Advertisements inform consumers that the drugstores carry these herbal products. In general, West Coast drugstore chains have larger stores and generally devote more shelf space to the supplement category than those east of the Mississippi, although East Coast stores are trying to turn the supplement section into a destination department for shoppers. Some drug chains also use secondary display locations in the store to drive impulse sales.

As in food stores, manufacturers are also using point-of-purchase displays in drugstores to educate consumers about their products. Information Delivery Systems of California is taking this approach one step further in chain drugstores across the country. They are providing these stores with a point-of-purchase audio system that allows customers to ask about and receive information on over 60 key nutrients, botanicals, and related products. Manufacturers benefit from this system as they receive feedback on the number of times an inquiry was made about a product each week, a feature that provides them with quantitative data on how well their marketing and public relations activities are working. Several major retailers are also working to develop CD-ROM touch screen technology to allow consumers to determine which products best fit their needs. Drugstores also advertise price discounts in flyers and in other media to generate sales.

5.2.3 Mass Merchandiser Sales and Marketing

Mass merchandise outlets accounted for approximately $665 million in sales of dietary supplements in 1996, giving these mass retailers a 26 percent market share (Nutrition Business International, October/November 1997c). Over 40 percent of these sales were vitamin products, for a total of $266.6 million in sales (F-D-C Reports, Inc., 1997b; F-D-C Reports, Inc., 1997c).

Mass merchandisers carry a broad mix of private label and brand names, although most of the major advertising expenditure is on national brands. The presentation and mix that mass merchandisers offer consumers is more streamlined and mainstream than that found in health food stores, meaning that their product lines are similar to those in supermarkets and drugstores. Mass merchandisers carry what may be viewed as "commodity products." Product lines of national-brand multivitamins, in particular, are better represented in mass merchandise outlets than in health food stores. Mass merchandisers make buying decisions on the national level and therefore wield large buying power. This enables them to be very price sensitive in choosing which products to carry and to refrain from getting locked into long-term contracts with manufacturers and distributors. Therefore, mass merchandisers have great flexibility in determining which products to present to consumers and the power to obtain these products at low prices.

Like drugstores and supermarkets, mass merchandisers are struggling to educate their consumers. Those that have pharmacies in the store position DS and nutrition products near the pharmacy. Mass merchandisers are also making an effort to educate their pharmacists by offering them

continuing education programs, newsletters, and seminars. Point-of-purchase displays, common in drugstores and supermarkets, are also used extensively in mass merchandise retail outlets. In addition, targeted couponing, shelf promotions, and pricing strategies are also used by mass merchandisers to generate supplement sales.

5.2.4 Natural Food Store Sales and Marketing

Natural and health food stores commanded $4.5 billion in DS sales in 1997 for an overall market share of 35 percent (see Table 5-5). Sales increased 55 percent from 1996 to 1997, making natural food stores the fastest growing DS distribution channel. Sales of herbal and botanical products are more concentrated in natural food stores and multilevel marketing firms than in the overall supplement category with 37 percent and 38 percent, respectively, of the herbal and botanical market (see Table 5-6).

Of the natural food stores, General Nutrition Centers (GNC) stands out with $1.2 billion in sales in 1996, or 20 percent of the $6.2 billion retail market for supplements (Nutrition Business International, October/November 1997d). Large natural food store companies, such as GNC, produce their own products and may manufacture private-label products for supermarkets and drugstores as well. Other natural food stores carry both national brands and private label brands manufactured by other companies.

In the past, many natural foods stores concentrated on sports nutrition. Now they are focusing on sales strategies that are science-based and concentrating on good nutrition and care of the body to lure consumers. GNC in particular is also trying to appeal to mainstream consumers via advertisements on network television. In addition, stores are taking steps to customize their service as well. Some natural foods stores are creating nutrition profiles for customers to fit their own lifestyles and needs and others are packaging the DS regime, which is tailored to an individual, right in the store. At Great Earth stores, the sales staff must pass a unique 5-week training course. In addition to the more scientific and individualized approach, health food stores are also using touch-screen computers for research information and consumer education, point-of-purchase displays, educational literature, pamphlets, and newsletters. Natural food stores also advertise their products, among other places, in magazines, on the Internet, and on radio and television.

Natural food stores have recently begun to broaden their customer base by establishing stores on military bases. GNC will open an undisclosed number of stores on military bases in order to tap an estimated $1 billion commissary market (Tascarella, 1997). In addition, Fitness and Nutrition Centers already has outlets on Department of Defense property.

5.2.5 Multilevel Marketing

Multilevel marketing, also known as direct selling, party plans, relationship selling, person-to-person selling, and network marketing, accounts for a large percentage of consumer sales in the

DS industry. In 1997, multilevel marketing firms accounted for 23 percent of overall DS sales (see Table 5-5). Multilevel marketing of DS products experienced no growth from 1996 to 1997. However, it accounted for the largest percentage of sales (38 percent) of herbal and botanical products in 1996 (see Table 5-6).

Direct selling has been a relatively successful distribution channel for the nutrition industry. The product is consumable, which is vital for the sustained growth and profitability of multilevel marketing firms, and sales benefit from consumer education and the word-of-mouth technique intrinsic in person-to-person selling. The personal relationship established between distributor and customer may be a competitive advantage for direct selling companies. Multilevel marketing also gives companies another sales advantage in that distributors are able to quickly and inexpensively dispense information on product research and new scientific studies. In addition, companies are able to keep their selling networks full with many new products as the nutrition industry expands.

Multilevel marketing is a growing industry that is increasingly attracting more companies for a variety of reasons. Multilevel marketing attracts small manufacturers in particular, as it is one of the few alternatives available to them without the high slotting fees and advertising expenditures of traditional retail sales. The improvement of information technology, which facilitates product distribution, and tracking of products, customers and distributor performance, has attracted more entrants into multilevel marketing. In addition to these cost-saving improvements, technology has enabled communication up and down the sales network to be more efficient and cost-effective, thereby enabling the companies to get the product to the consumer at a lower cost, which makes the business more attractive to potential entrants. The downsizing of corporate America and restructuring of the workforce has also contributed to the growth in multilevel firms by increasing the demand for entrepreneurial opportunities. Multilevel marketing provides an opportunity for "downsized" people to earn money to get back on their feet and bridge the gap between jobs or to start a new career.

5.2.6 Mail Order and Internet Sales and Marketing

Mail order channels make up only 6 percent of sales of dietary supplements (see Table 5-5). The market share of mail order remained fairly constant from 1996 to 1997 even as the nutrition industry's growth continued. Mail order accounted for a slightly larger percentage of herbal and botanical product sales (9 percent) in 1996 than overall supplement category sales (see Table 5-5 and 5-6). As of 1997, according to Nutrition Business Journal, there were about 300 mail order companies carrying dietary supplement products (Nutrition Business International, September 1998). Nutrition Headquarters and Amrion, which was acquired by Whole Foods, are two of the largest of these companies.

Marketing for mail order is carried out via 800 numbers on shopping channels on the television, on the Internet, and through media advertising. Advertisements on the Internet frequently refer to

scientific studies done on the product and generally include personal testimonials from "product users." Some companies carrying out mail order operations via the Internet have come under scrutiny by the Federal Trade Commission (FTC). The FTC contacted about 400 companies in November 1997 following a 2-day sting operation in which these companies were found to be making deceptive or potentially false advertising claims.

5.2.7 Health Care Practitioner Sales and Marketing

Health care practitioners made up a small segment of dietary supplement sales at 6 percent of the total DS product market in 1997 (see Table 5-5) and 4 percent of the herbal and botanical product market (see Table 5-6). However, sales grew by approximately 17 percent from 1996 to 1997 (see Table 5-5). Rather than being seen as a retail outlet, physicians and chiropractors are used generally by supplement manufacturers and companies as marketing avenues to get information about their products out to potential customers. The supplement companies educate health care practitioners on the science behind their products in hopes that the research-supported message of their products' benefits are passed on to the doctors' patients, who will then buy their supplements.

5.2.8 Specialty Shops

Specialty shops include small, family-run stores as well as ethnic food stores that carry dietary supplements in addition to other products. They account for only 2 percent of herbal and botanical product sales (see Table 5-6). Sales growth in 1996 was only 10 percent compared to a growth rate of 25 percent at all retail outlets for natural products (Nutrition Business International, September 1997a).

5.2.9 Distributor and Manufacturer Marketing Efforts

In addition to the marketing efforts of retail outlets, manufacturers and distributors engage in marketing efforts as well. To get their products on the shelves at supermarkets, drugstores, mass merchandise outlets, and health food stores, they use a variety of marketing techniques. For example, they place advertisements in medical journals and in the *Physicians' Desk Reference* as well as on network television and radio and in magazines to develop consumer and retailer brand loyalty to their products. Manufacturers also rely heavily on advertising in retail trade publications such as *Supermarket Business* and *Drug Store News* and support large retail outlets with advertising in the mass media and through public relations campaigns.

In addition, manufacturers supply retail outlets with the point-of-purchase displays to use in their stores, which gets their products into more heavily trafficked areas of the store. To generate sales of their own products and to make their products more attractive for retailers to carry, manufacturers provide coupons at the store level, give retailers money to advertise, and produce "bonus bottles" with, for example, 30 percent more of the product inside for free. They also offer retailers chain-specific promotions, targeted coupons, and cooperative advertising to client stores.

5.3 MARKET STRUCTURE OF THE DIETARY SUPPLEMENT INDUSTRY

Market structure is of interest because it determines the behavior of producers and consumers in the industry. If an industry is perfectly competitive, then individual producers are not able to influence the price of the output they sell or the inputs they purchase. This condition is most likely to hold if the industry has a large number of firms, the products sold and the inputs purchased are undifferentiated, and entry and exit of firms is unrestricted. Product differentiation can occur from both differences in product attributes and quality and from brand name recognition of products. Entry and exit of firms is unrestricted for most industries except, for example, in cases in which government regulates who is able to produce, one firm holds a patent on a product, one firm owns the entire stock of a critical input, or a single firm is able to supply the entire market.

In the next section, we consider the factors that affect the degree of competition (number of firms and concentration ratios, product differentiation, and barriers to entry) as well as the degree of vertical integration. We focus primarily on the input markets for raw materials and the output markets for wholesale DS products.

5.3.1 Market Concentration

Four-firm and eight-firm concentration ratios (CR4 and CR8) and Herfindahl-Hirschman indexes provide preliminary information that is useful in determining the structure of the market. Although the U.S. Department of Commerce computes these values, they do so only in census years and at the 4-digit SIC level. Because the most recent information available is from the 1992 census and DS products are scattered across SIC codes, measures of concentration from this source are of little use for the DS industry. However, we were able to construct a few measures of concentration using information available from the *Nutrition Business Journal*.

The September 1998 issue of the *Nutrition Business Journal* lists the top 40 manufacturing firms with their 1997 revenues and provides the summary information that is contained in Table 5-9. Using this information, we calculated that the CR4 is 23 percent, the CR8 is 39 percent, and the HHI is 250 (see Appendix A). Based on these values, the DS product manufacturing market is not highly concentrated. While there are not specific criteria for evaluating CR4s and CR8s, the 1992 Department of Justice's Horizontal Merger Guidelines states that industries with HHIs below 1,000 are unconcentrated.

The October 1996 issue of the *Nutrition Business Journal* provides the 1995 summary information on vitamin and herbal and botanical raw material suppliers that is contained in Table 5-9, but it does not list the revenues for individual suppliers that is necessary to construct all the measures of concentration. However, based on the information they provide, the CR8 for the vitamin raw material market is 73 percent and for the herbal and botanical raw material market, 36 percent.

Table 5-9. Summary of Number of Companies and Revenue, by Size Category in the DS Industry

Size Category	Number of Companies	Revenue ($ billion)	Percentage of Market
Supplement Manufacturers (1997)			
> $100 million	16	3.32	55%
$20 – $100 million	38	1.54	25%
< $20 million	996	1.19	20%
Total	1,050	6.05	100%
Vitamin Raw Material Suppliers (1995)			
> $50 million	8	0.68	73%
< $50 million	32	0.25	27%
Total	40	0.93	100%
Herb and Botanical Raw Material Suppliers (1995)			
> $20 million	8	0.176	36%
$5 – $20 million	15	0.135	28%
< $5 million	127	0.178	36%
Total	150	$0.489	100%

Source: Nutrition Business International. September 1997a. "$20 Billion and Counting: Nutrition Industry Momentum Builds." *Nutrition Business Journal* 2(9):1-5.
Nutrition Business International. October 1996b. "Botanicals International Has Bulk of Herb Market." *Nutrition Business Journal* 1(3):6-7.
Nutrition Business International. October 1996c. "Vitamin Suppliers Tackle Supply and Demand Issues." *Nutrition Business Journal* 1(3):13-16.
Nutrition Business International. September 1998. "$23 Billion and Counting: Nutrition Industry Braces for a Competitive Future." *Nutrition Business Journal* 3(9):1-5, 13, 18.

Thus, the vitamin raw material market is much more concentrated than either the DS manufacturing market or the herbal and botanical raw material market. In fact, the Justice Department is currently investigating alleged price fixing and collusion in the vitamin raw material market (Scott, 1998). Nearly all vitamin E, in particular, comes from one raw material supplier.

In the DS market as a whole, mergers and acquisitions have been occurring frequently and are expected to continue. Thus, we expect that market concentration will increase over time.

5.3.2 Product and Brand Differentiation

Dietary supplements are by nature heterogeneous products. Even within a particular DS product type, there are many different types of products and many different forms in which the products are made available. Thus, many niche markets exist in which companies may be the only or one of a few manufacturers of a product. However, some of the products are more commodity-like and there is little differentiation among different manufacturers of the products (e.g., single vitamin products).

Products may also be differentiated based on their brand names within a particular type of product. However, according to the *Nutrition Business Journal*, the nutrition industry in general has few dominant brands. Some of the reasons they cite are the large number of product niches, the variety of distribution channels, the dynamics of consumer trends (changing preferences over time), and the evolution of nutrition science (Nutrition Business International, December 1996b). In some markets, however, a few companies have established strong brand name recognition. These include, for example, Centrum, One-A-Day, and Flintstones in the multivitamin market and Ginsana and Ginkoba in the herbal and botanical market.

5.3.3 Barriers to Entry

In the past, barriers to entry in DS product manufacturing were not particularly high, and many small firms entered the industry. Many products, especially herbal and botanical products, can be produced in small-scale operations that are not highly capital-intensive. However, the barriers to entry are rising and will continue to do so primarily because of the effects of consolidation and the effects of regulation, both federal and self-imposed.

Because many distributors and retailers are consolidating, it is becoming harder for small companies to gain access to customers (Nutrition Business International, July 1997a). Mass merchandisers that carry DS products need to acquire adequate product from manufacturers to supply all their needs. Also, because other manufacturers are consolidating, they are purchasing inputs in volume and thus are able to negotiate lower raw material prices than smaller manufacturers.

In addition, regulation is making it more difficult for small firms to enter the industry. It may be more difficult for these firms to acquire the needed resources to comply with labeling regulations as well as Good Manufacturing Practices (GMPs). Larger pharmaceutical firms that are branching out into DS product lines will have little trouble complying as their existing products lines in general must conform to much stricter regulations.

Some of the regulations are imposed by the industry itself. In particular, the industry, through organizations such as the National Nutritional Foods Association (NNFA), is working toward establishing standards for DS products. The NNFA has already established a True Label program in which it tests products to ensure that they are as represented on their labels. Although these self-imposed regulations are voluntary, consumers may come to expect products that conform and

may not purchase products that do not. As with federal regulations, smaller firms may not be able to garner the resources for compliance.

5.3.4 Vertical Integration

Vertical integration refers to the extent to which firms operate at more than one level of production and marketing. In general, we expect that firms that are more vertically integrated will be able to retain a higher level of profits than firms that concentrate on a single level of the industry.

In the DS industry, we see examples of both ends of the spectrum. While many firms concentrate on a single level, others, such as GNC, span nearly the entire spectrum from manufacturing to consumer sales. According to the *Nutrition Business Journal*, the chain of manufacturing from raw materials to finished products may span four or five companies (Nutrition Business International, August 1996). On the other hand, multilevel marketers and mail order companies, both of which have a large presence in the DS industry, span many of these levels.

SECTION 6
DIETARY SUPPLEMENT INDUSTRY DATA AND PROJECTIONS

Because the DS industry comprises a large number of diverse products, industry data must be compiled from a variety of sources. In this section, we present industry data as compiled from secondary data sources and discuss projections and predictions for the industry.

6.1 DS INDUSTRY DATA

Industry data are useful in characterizing baseline supply and demand conditions in particular DS product markets. Compiling this information is the necessary first step in conducting an economic impact analysis of a particular regulation.[9] Because the industry comprises such a large number of diverse products, providing detailed statistics on each product market is beyond the scope of this report. Instead, we provide aggregate industry data and describe our procedures for constructing these data.

6.1.1 Domestic Industry Data

The most complete and frequently reported industry data from the U.S. Bureau of the Census is reported at the 4-digit SIC level. After examining the descriptions of each SIC code to determine which contain DS products, RTI compiled the list of SIC codes in Table 6-1. In addition, the corresponding North American Industry Classification Scheme (NAICS) codes are provided as well.

Of the products listed in Table 6-1, some are solely DS products and others are used or manufactured by other industries as well. For example, the tea products in SIC 2099 include all teas in addition to those that are considered DS products. SIC codes 2833 and 2834 contain products that could be considered, depending on use and labeling, either DS products or pharmaceuticals (over the counter or prescription). SIC code 2075 contains all soybean products in addition to protein supplements. SIC codes 2819, 2869, and 2899 contain chemicals that are used in a wide variety of industries in addition to the DS industry.

Some value of shipments data are available for 5- and 7-digit SIC codes that are predominately DS products. These data are provided for SIC codes 2833 and 2834 for 1996 in Table 6-2. However, many DS products are most likely contained in the codes for products "not stated by kind."

[9]RTI provided detailed information on the types of data needed to conduct an economic impact analysis and the adequacy of secondary data sources for providing it (see Muth and Anderson, 1998).

Table 6-1. SIC Codes for Dietary Supplements, Included Dietary Supplement Products, and NAICS Codes for Dietary Supplements

SIC	SIC Description	Included Dietary Supplement Products	NAICS	NAICS Description
2075	Soybean Oil Mills	➤ lectithin, soybean ➤ soybean protein concentrates ➤ soybean protein isolates	311222	Soybean Processing
2099	Food Preparations, Not Elsewhere Classified	➤ tea	311920	Coffee and Tea Manufacturing
2819	Industrial Inorganic Chemicals, Not Elsewhere Classified	➤ aluminum ➤ calcium ➤ chromium ➤ copper ➤ iodine ➤ iron ➤ magnesium ➤ nickel ➤ phosphorus ➤ potassium ➤ sulfur ➤ zinc	325188	All other Basic Inorganic Chemical Manufacturing
2833	Medicinal Chemicals and Botanical Products	➤ adrenal derivatives ➤ agar-agar, ground ➤ alkaloids and salts ➤ botanical products, medicinal: ground, graded, and milled ➤ endocrine products ➤ fish liver oils, refined and concentrated for medicinal use	325411 325412	Medicinal and Botanical Manufacturing Pharmaceutical Preparation Manufacturing

(continued)

Table 6-1. SIC Codes for Dietary Supplements, Included Dietary Supplement Products, and NAICS Codes for Dietary Supplements (continued)

SIC	SIC Description	Included Dietary Supplement Products	NAICS	NAICS Description
2833	Medicinal Chemicals and Botanical Products (continued)	➤ gland derivatives: bulk, uncompounded ➤ glycosides ➤ herb grinding, grading, and milling ➤ hormones and derivatives ➤ kelp plants ➤ oils, vegetable and animal: medicinal grade, refined and concentrated ➤ ox bile salts and derivatives: bulk, uncompounded ➤ pituitary gland derivatives: bulk, uncompounded ➤ theobromine ➤ vegetable gelatin (agar-agar) ➤ vitamins, natural and synthetic: bulk, uncompounded ➤ ephedrine and derivatives		
2834	Pharmaceutical Preparations	➤ botanical extracts: powdered, pilular, solid, and fluid ➤ hormone preparations, except diagnostics ➤ vitamin preparations	325412	Pharmaceutical Preparation Manufacturing

(continued)

Table 6-1. SIC Codes for Dietary Supplements, Included Dietary Supplement Products, and NAICS Codes for Dietary Supplements (continued)

SIC	SIC Description	Included Dietary Supplement Products	NAICS	NAICS Description
2869	Industrial Organic Chemicals, Not Elsewhere Classified	➤ enzymes ➤ fatty acids ➤ potassium ➤ solvents (used in extraction) ➤ stearic acid ➤ tannic acid ➤ tartaric acid	325199	All other Basic Organic Chemical Manufacturing
2899	Chemicals and Chemical Preparations, Not Elsewhere Classified	➤ essential oils ➤ fatty acids: margaric, oleic, and stearic ➤ gelatin capsules	325188 325199	All other Inorganic Chemical Manufacturing All other Basic Organic Chemical Manufacturing

Sources: U.S. Department of Labor, Occupational Safety and Health Administration. "Standard Industrial Classification Search." <http://spider.osha.gov/oshstats/sicser.html>. As obtained on March 24, 1998.

U.S. Department of Commerce, Bureau of the Census. "1997 NAICS and 1987 SIC Correspondence Tables." <http://www.census.gov/epcd/www/naicstab.htm>. As obtained on March 24, 1998.

Table 6-2. Detailed SIC Breakdown for SIC Codes 2833 and 2834, 1996

SIC Codes: 5 and 7 Digit	Description	1996 Value of Shipments ($ million)[a]
2833 Medicinals and Botanicals		
28333	Other medicinal chemicals and botanical products, in bulk, not elsewhere contained	1,586.4
2833315	Alkaloids, including opium and nicotine	NA
2833318	Other botanical drugs, including glycosides and ginseng extract	NA
2833323	Vitamin C	NA
2833325	Vitamin E	NA
2833326	Other naturally occurring vitamins	NA
2833344	Drugs of animal origin, including hormones, dried glands, organs, and tissues and extractions thereof	NA
2833300	Other medicinal chemicals and botanical products, in bulk, not elsewhere contained, not stated by kind	NA
28330	Medicinals and botanicals, not stated by kind	226.6
2834 Pharmaceutical Preparations		
28347	Vitamin, nutrient, and hematinic preparations, for human use	4,811.6
2834711	Multivitamins, plain and with minerals (except B complex vitamins and fish livers oils)	1,154.4
2834713	Pediatric vitamin preparations (drops, suspensions, and chewable tablets)	91.8
2834714	Prenatal vitamin preparations	30.0
2834715	B complex preparations	104.4
2834717	Fluoride preparations	1.7
2834719	All other vitamin preparations	616.7
2834721	Fish liver oils	11.8
2834731	Nutrients, excluding therapeutic dietary foods and infant formulas	261.2
2834741	Tonics and alternatives	19.9
2834751	Hematinics, with B_{12}, oral	15.4
2834755	Other hematinics, oral	24.6
2834761	Hospital solutions	1,470.3
2834798	Other vitamin, nutrient, and hematinic preparations, for human use	477.6
28340	Pharmaceutical preparations, not stated by kind	652.9

[a]Value of shipments data for all of SIC 2833 and for SIC 28340 at the 7-digit level are available only in census years. Thus, the most recently available data were collected for 1992 and are not reported here.

NA = not available

Sources: U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census. February 1998. "1996 Annual Survey of Manufactures: Statistics for Industry Groups and Industries." M96(AS)-1.

U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census. May 1995. "1992 Census of Manufactures: Industry Series, Drugs." MC92-I-28C.

U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census. January 1998. "Current Industrial Reports: Pharmaceutical Preparations, Except Biologicals." MA28G(96)-1.

6.1.2 International Trade Data

Using 6-digit international codes, RTI compiled information on trade volumes for codes that contain DS products.[10] The list of international codes used is provided in Table 6-3 along with the DS type to which we assigned each, their descriptions, and their corresponding SIC codes. Herbal and botanical extracts are combined with all herbals and botanicals because it is not possible to determine the form of the product based on the international codes. Concentrates, constituents, and metabolites are not specifically identified because they are forms of the products included elsewhere.

The products that are classified in the international codes in Table 6-3 include, in addition to dietary supplements, foods, drugs, and products with industrial uses. Thus, estimates of trade volumes and values based on these 6-digit codes may overstate the true volumes and values for DS products alone. In particular, vitamins include not only vitamins sold as DS products but vitamins used to fortify foods. Minerals include products that may be for industrial uses as well. Sulfur, for example, is sold as a dietary supplement, but most of its sales is likely for industrial uses. Products classified in herbals and botanicals include some products that may be sold as OTC or prescription drugs (e.g., ephedrine). Amino acids, proteins, and teas may be food products in addition to DS products.

Using the classifications in Table 6-3, we tabulated trade statistics as reported by the International Trade Commission. However, these trade values include all products for each code rather than DS products only. In Table 6-4, import values for 1997 are listed by DS product type. Within each DS product type, the top 10 countries from which the United States imports (by import values) are listed individually. In Table 6-5, export values for 1997 are listed as well. Again, within each DS product type, the top 10 countries to which the United States exports (by export values) are listed individually.

6.2 DS INDUSTRY PROJECTIONS

Although some trade publications cite the opinion that the DS industry is beginning to mature, high growth rates are still predicted for the foreseeable future. In the recent past, some have estimated that industry sales have been growing at a rate of 20 to 30 percent a year. The *Nutrition Business Journal* is predicting an average growth rate of 10 to 14 percent per year to the year 2000 across all DS product types (Nutrition Business International, September 1998). Within individual product categories, it is predicting 16 to 18 percent growth rates for herbals and

[10] Initially, RTI identified 10-digit international codes for dietary supplements (see Muth, 1998). However, because 10-digit codes can differ depending on whether the product is imported or exported, using 6-digit codes appears to be a more reliable approach.

Table 6-3. International Codes by Dietary Supplement Type

Dietary Supplement Type	International Code	Description	SIC[a] Code
Amino acids	292241	Lysine and its esters; salts thereof	2833
Amino acids	292249	Amino acids and their esters, not containing more than one oxygen function, and salts, nesoi	2869
Amino acids	350790	Enzymes and prepared enzymes, nesoi	2869
Animal extracts	051000	Ambergris castoreum civet and musk; cantharides; bile; glands and other animal products for use in pharmaceutical products—fresh, frozen, etc.	2011
Animal extracts	150410	Fish-liver oils and their fractions—whether or not refined but not chemically modified	NA
Animal extracts	150420	Fish fats and oils and their fractions	2077
Animal extracts	150430	Fats and oils and their fraction of marine mammals, whether or not refined but not chemically modified	2077
Animal extracts	300110	Glands and other organs—dried, whether or not powdered	NA
Animal extracts	300120	Extracts of glands or other organs or of their secretions	2833
Animal extracts	300190	Heparin and its salts; other human or animal substances prepared for therapeutic or prophylactic uses, not elsewhere specified or included	2833
Herbals and botanicals	070320	Garlic—fresh or chilled	161
Herbals and botanicals	091010	Ginger	2099
Herbals and botanicals	091020	Saffron	2099
Herbals and botanicals	091030	Tumeric (curcuma)	2099
Herbals and botanicals	121120	Ginseng roots—fresh or dried, whether or not cut, crushed, or powdered	831
Herbals and botanicals	121190	Plants and parts of plants (including seeds and fruits) used primarily in perfumery, pharmacy, or for insecticides, etc.—fresh or dried, etc., nesoi	NA
Herbals and botanicals	121220	Seaweeds and other algae—fresh or dried, whether or not ground	919
Herbals and botanicals	130231	Agar-agar	2833
Herbals and botanicals	293940	Ephedrines and their salts	2833
Herbals and botanicals	293942	Pseudoephedrine and their salts	2833
Herbals and botanicals	293949	Ephedrines and their salts, nesoi	2833
Herbals and botanicals	330124	Essential oils of peppermint (mentha piperita)	2899

(continued)

Table 6-3. International Codes by Dietary Supplement Type (continued)

Dietary Supplement Type	International Code	Description	SIC[a] Code
Minerals	280120	Iodine	2819
Minerals	280130	Fluorine; bromine	2819
Minerals	280200	Sulfur—sublimed or precipitated; collodial sulfur	2819
Minerals	280450	Boron; tellurium	2819
Minerals	280470	Phosphorus	2819
Minerals	280490	Selenium	3339
Minerals	280521	Calcium	2819
Minerals	281000	Oxides of boron; boric acids	2819
Minerals	281122	Silicon dioxide	2819
Minerals	281610	Magnesium hydroxide and magnesium peroxide	2819
Minerals	282530	Vanadium oxides and hydroxides	2819
Minerals	282560	Germanium oxides and zirconium dioxide	2819
Minerals	282611	Fluorides of ammonium or of sodium	2819
Minerals	282720	Calcium chloride	2819
Minerals	282760	Iodides and iodide oxides	2819
Minerals	283325	Copper sulfate	2819
Minerals	283326	Zinc sulfate	2819
Minerals	283522	Mono- or disodium phosphates	2819
Minerals	283524	Potassium phosphate	2819
Minerals	283640	potassium carbonates	2819
Minerals	283650	Calcium carbonate	2819
Minerals	284170	Molybdates (Molybdenum content)	2819
Other	293710	Pituitary (anterior) or similar hormones	2833
Other	293721	Adrenal cortical hormones and their derivatives	NA
Other	293729	Other adrenal cortical hormones and their derivatives, nesoi	2833
Other	293890	Glycosides—natural or reproduced by synthesis and their salts, ethers, esters and other derivatives, nesoi	2833
Other	300339	Medicaments containing hormones or other steroids used primarily as hormones, but not containing antibiotics	2834

(continued)

Table 6-3. International Codes by Dietary Supplement Type (continued)

Dietary Supplement Type	International Code	Description	SIC[a] Code
Proteins	040410	Whey and modified whey, whether or not concentrated or containing added sweeteners	2023
Proteins	210610	Protein concentrates and textured protein substances	2075
Proteins	350210	Egg albumin	2015
Proteins	350211	Egg albumin, dried	NA
Proteins	350219	Egg albumin, other	NA
Proteins	350220	Milk albumin, including concentrates of two or more whey proteins	NA
Proteins	350290	Albumins, albuminates, and other albumin derivatives, nesoi	2869
Proteins	350400	Peptones and derivatives; other proteins and derivatives, nesoi; hide powder—chromed or not	2075
Teas	090210	Green tea (not fermented), nesoi, in immediate packings of a content not exceeding 3kg	2099
Teas	090220	Green tea (not fermented),nesoi	2099
Teas	090230	Black tea (fermented) and partly fermented tea, in immediate packings of a content not exceeding 3 kg (6.61 lb.)	2099
Teas	090240	Black tea (fermented) and other partly fermented tea, nesoi	2099
Teas	090300	Mate	2099
Teas	210120	Tea or mate extracts, essences, and concentrates and preparations with a basis of these products or with a basis of tea or mate	2099
Teas	210690	Food preparations, nesoi	2099
Vitamins	292310	Choline and its salts	2869
Vitamins	292320	Lecithins and other phosphoaminolipids	2869
Vitamins	293610	Provitamins, unmixed	2833
Vitamins	293621	Vitamins A and their derivatives, unmixed	2833
Vitamins	293622	Vitamin B_1 (thiamine) and its derivatives	2833
Vitamins	293623	Vitamin B_2 (riboflavin) and its derivatives	2833
Vitamins	293624	D- or DL-pantothenic acid (vitamin B_3 or vitamin B_5) and its derivatives	2833
Vitamins	293625	Vitamin B_6 (pyridoxine and related compounds with vitamin B_6 activity) and its derivatives, unmixed	2833

(continued)

Table 6-3. International Codes by Dietary Supplement Type (continued)

Dietary Supplement Type	International Code	Description	SIC[a] Code
Vitamins	293626	Vitamin B_{12} (cyanocobalamin and related compounds with vitamin B_{12} activity) and its derivatives	2833
Vitamins	293627	Vitamin C (ascorbic acid) and its derivatives	2833
Vitamins	293628	Vitamin E (tocopherols and related compounds with vitamin E activity) and its derivatives, unmixed	2833
Vitamins	293629	Vitamins and their derivatives, unmixed, nesoi	2833
Vitamins	293690	Provitamins and vitamins (including natural concentrates) derivatives thereof used primarily as vitamins and intermixtures of the foregoing, nesoi	2833
Vitamins	300450	Medicaments in measured doses, etc., containing natural or synthetic vitamins and their derivatives	2834

NA = not available (SIC code was not contained in the Concordance file supplied by FDA).

nesoi = not elsewhere specified or included

[a] The SIC code descriptions are:

0161 Vegetables and Melons
0831 Forest Nurseries and Gathering of Forest Products
0919 Miscellaneous Marine Products
2011 Meat Packing Plants
2023 Dry, Condensed, and Evaporated Dairy Products
2075 Soybean Oil Mills
2077 Animal and Marine Fats and Oils
2099 Food Preparations, Not Elsewhere Classified
2819 Industrial Inorganic Chemicals, Not Elsewhere Classified
2833 Medicinal Chemicals and Botanical Products
2834 Pharmaceutical Preparations
2869 Industrial Organic Chemicals, Not Elsewhere Classified
2899 Chemicals and Chemical Preparations, Not

Sources: U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census. "Schedule B Keyword Search." <http.//www.census.gov/foreign-trade/schedules/b/index.html>. As obtained on September 21, 1998.

U.S. Department of the Treasury, U.S. Customs Service. "Harmonized Tariff Schedule of the U.S." <http:/www.customs.ustreas.gov/imp-exp/harmoniz/index.htm>. As obtained on September 21, 1998.

Table 6-4. Import Quantities and Dollar Values for Trade Codes that Contain Dietary Supplement Products, 1997

Dietary Supplement Type	Import Country	Import Value ($ million)[a]
Vitamins	France	109.09
	Japan	108.74
	Germany	91.18
	Switzerland	81.73
	China	81.15
	Canada	40.89
	Denmark	37.07
	United Kingdom	30.40
	Netherlands	7.57
	Australia	7.51
Total (top 10 countries)		595.33
Total (other countries)		54.04
Total (all countries)		649.37
Minerals	Japan	77.76
	Chile	66.53
	Germany	48.02
	Canada	39.88
	United Kingdom	35.87
	Mexico	23.15
	China	19.51
	South Africa	13.24
	Israel	11.61
	France	11.29
Total (top 10 countries)		346.86
Total (other countries)		50.16
Total (all countries)		397.02
Herbals and Botanicals	India	62.63
	China	55.32
	Germany	38.07
	Mexico	19.93
	Chile	16.64
	Japan	14.48
	Spain	14.38
	Korea	9.21
	Hong Kong	8.63
	Brazil	6.41
Total (top 10 countries)		245.70
Total (other countries)		72.48
Total (all countries)		318.18

(continued)

Table 6-4. Import Quantities and Dollar Values for Trade Codes that Contain Dietary Supplement Products, 1997 (continued)

Dietary Supplement Type	Import Country	Import Value ($ million)[a]
Animal Extracts	Canada	49.50
	China	42.47
	Germany	22.34
	France	22.30
	Spain	11.63
	Norway	11.62
	Netherlands	4.62
	Sweden	3.67
	Argentina	3.02
	Denmark	2.69
Total (top 10 countries)		173.86
Total (other countries)		11.40
Total (all countries)		185.25
Amino Acids	Japan	76.12
	Denmark	55.03
	France	45.09
	Germany	43.59
	Korea	31.12
	United Kingdom	24.12
	Indonesia	19.79
	Ireland	16.16
	Netherlands	14.63
	Switzerland	14.27
Total (top 10 countries)		339.91
Total (other countries)		86.32
Total (all countries)		426.23
Proteins	New Zealand	23.99
	Canada	16.64
	Germany	8.03
	Australia	6.36
	United Kingdom	4.17
	France	3.67
	Denmark	3.63
	Mexico	3.39
	Japan	2.24
	Switzerland	1.64
Total (top 10 countries)		73.76
Total (other countries)		5.29
Total (all countries)		79.05

(continued)

Table 6-4. Import Quantities and Dollar Values for Trade Codes that Contain Dietary Supplement Products, 1997 (continued)

Dietary Supplement Type	Import Country	Import Value ($ million)[a]
Other	Switzerland	178.29
	Korea	44.14
	Japan	26.49
	Netherlands	20.75
	France	19.78
	Sweden	8.35
	Germany	6.84
	China	6.55
	United Kingdom	2.90
	Argentina	2.80
Total (top 10 countries)		316.89
Total (other countries)		3.85
Total (all countries)		320.73
Teas	Canada	113.98
	Germany	50.88
	China	39.84
	Argentina	28.42
	India	23.32
	France	22.90
	Taiwan	19.45
	Thailand	17.91
	Japan	14.89
	United Kingdom	14.55
Total (top 10 countries)		346.13
Total (other countries)		120.90
Total (all countries)		467.03

[a]General import C.I.F. (cash insurance freight) values.

Sources: U.S. International Trade Commission Trade Database. <http://205.197.120.17/scripts/user_set.asp>. As obtained June 1998.

U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census. "Schedule B Keyword Search." <http.//www.census.gov/foreign-trade/schedules/b/index.html>. As obtained June 1998.

U.S. Department of the Treasury, U.S. Customs Service. "Harmonized Tariff Schedule of the U.S." <http:/www.customs.ustreas.gov/imp-exp/harmoniz/index.htm>. As obtained June 1998.

Table 6-5. Export Quantities and Dollar Values for Trade Codes that Contain Dietary Supplement Products, 1997

Dietary Supplement Type	Export Country	Value of Exports ($ million)[a]
Vitamins	Canada	116.80
	Japan	37.30
	Germany	30.47
	Netherlands	29.66
	Mexico	22.22
	United Kingdom	21.04
	France	19.90
	Poland	17.60
	Brazil	16.58
	Australia	14.73
Total (top 10 countries)		326.30
Total (other countries)		160.13
Total (all countries)		486.44
Minerals	Canada	66.41
	Mexico	46.68
	Japan	38.47
	Netherlands	22.94
	Germany	19.94
	Belgium	12.14
	France	11.99
	United Kingdom	11.25
	Korea	11.08
	Taiwan	9.35
Total (top 10 countries)		250.26
Total (other countries)		83.10
Total (all countries)		333.36
Herbals and Botanicals	Hong Kong	58.72
	Canada	22.54
	Mexico	17.55
	United Kingdom	14.92
	Japan	12.18
	Germany	11.51
	Taiwan	9.76
	Malaysia	7.92
	France	6.12
	Australia	6.10
Total (top 10 countries)		167.32
Total (other countries)		54.32
Total (all countries)		221.64

(continued)

Table 6-5. Export Quantities and Dollar Values for Trade Codes that Contain Dietary Supplement Products, 1997 (continued)

Dietary Supplement Type	Export Country	Value of Exports ($ million)[a]
Amino Acids	Netherlands	117.82
	Canada	83.20
	Denmark	75.40
	Italy	58.26
	United Kingdom	58.19
	Mexico	41.29
	Hong Kong	29.58
	Spain	24.80
	Japan	23.37
	Brazil	21.90
Total (top 10 countries)		533.80
Total (other countries)		180.41
Total (all countries)		714.20
Animal Extracts	Germany	107.09
	United Kingdom	65.59
	Japan	40.46
	Netherlands	37.14
	Canada	16.36
	France	9.80
	Sweden	9.42
	Mexico	6.49
	Brazil	4.48
	Australia	4.24
Total (top 10 countries)		301.08
Total (other countries)		23.81
Total (all countries)		324.89
Proteins	Switzerland	310.56
	Japan	60.55
	Mexico	57.83
	Canada	47.16
	Belgium	42.99
	Netherlands	35.95
	Hong Kong	23.48
	Korea	22.88
	Taiwan	21.72
	Australia	17.71
Total (top 10 countries)		640.83
Total (other countries)		170.00
Total (all countries)		810.84

(continued)

Table 6-5. Export Quantities and Dollar Values for Trade Codes that Contain Dietary Supplement Products, 1997 (continued)

Dietary Supplement Type	Export Country	Value of Exports ($ million)[a]
Other	France	54.57
	Belgium	44.07
	Canada	18.55
	Hong Kong	8.39
	Sweden	7.31
	United Kingdom	6.73
	Germany	6.40
	Japan	5.92
	Colombia	5.68
	Brazil	4.65
Total (top 10 countries)		162.26
Total (other countries)[d]		40.96
Total (all countries)		203.23
Teas	Canada	300.39
	Japan	192.76
	Hong Kong	131.61
	Mexico	65.74
	Malaysia	49.93
	Korea	48.45
	Taiwan	42.92
	Australia	38.06
	Saudi Arabia	34.10
	Bahamas	28.48
Total (top 10 countries)		932.45
Total (other countries)		567.15
Total (all countries)		1,499.60

[a]F.A.S. (free alongside) values.

Sources: U.S. International Trade Commission Trade Database. <http://205.197.120.17/scripts/user_set.asp>. As obtained June 1998.

U.S. Department of Commerce, Economics and Statistics Administration, Bureau of the Census. "Schedule B Keyword Search." <http.//www.census.gov/foreign-trade/schedules/b/index.html>. As obtained June 1998.

U.S. Department of the Treasury, U.S. Customs Service. "Harmonized Tariff Schedule of the U.S." <http:/www.customs.ustreas.gov/imp-exp/harmoniz/index.htm>. As obtained June 1998.

botanicals, 6 to 7 percent growth rates for vitamins, 7 to 8 percent growth rates for minerals, 14 to 16 percent for specialty supplements, and 6 to 8 percent for sports supplements (Nutrition Business International, September 1998).

As new products are introduced, the range of DS products will continue to grow. In some cases, sales of individual products will grow as new research indicates the potential use or value of the product. In other cases, whole new types of products will be introduced in the market. In particular, the industry expects increased sales of herbal products used in Ayurvedic healing, which is a traditional medicine system originating in India (Nutrition Business International, September 1997a).

Over time, the industry is expected to continue consolidating into a smaller number of manufacturing firms (Nutrition Business International, July 1997a). The number of small businesses, in particular, is expected to decline due to economies of scale in production and the cost efficiencies that larger manufacturers obtain from volume purchase of inputs. In addition, small manufacturers may be unable to serve the larger retailers that are increasingly selling DS products.

Sales of DS products by mass merchandisers such as Costco and Kmart are increasing and are expected to continue to grow in the future (Nutrition Business International, October/November 1997a). In the past, mass merchandisers carried primarily the traditional vitamin and mineral products. However, they are starting to carry a broader range of DS products, including herbal products and products such as shark cartilage and melatonin. In addition, strong sales growth is expected through multilevel marketing firms (Nutrition Business International, November 1996).

Combined with the consolidation of manufacturing firms and the growth of sales by mass merchandisers is the importance of identifiable brand names (Nutrition Business International, December 1996a). Consumers seeking consistent quality of products migrate toward particular brand names. The larger manufacturing firms are more likely to have the resources needed to maintain consistent quality, the advertising budgets to establish brand name recognition, and the resources to serve a large enough portion of the market to maintain brand name recognition.

Because the industry has grown rapidly and is beginning to be considered a legitimate industry, it has attracted the attention of investors on Wall Street (Nutrition Business International, July 1997b). The *Nutrition Business Journal* and *Natural Business* both maintain stock market information on publicly traded DS product companies. The influx of outside investment dollars will allow the industry to continue to grow, both by adding new products and by serving additional markets.

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APPENDIX A
CALCULATION OF MARKET CONCENTRATION MEASURES

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Using information contained in the September 1998 issue of *Nutrition Business Journal*, RTI calculated 4-firm and 8-firm concentration ratios (CR4s and CR8s) and Herfindahl-Hirschman indexes (HHIs) for the dietary supplement industry (Nutrition Business International, 1998). In Table A-1, we list the manufacturers and 1997 revenues as reported in the *Nutrition Business Journal*. First, we calculated each firm's share of total sales. We added the shares of the top 4 firms to obtain a 4-firm concentration ratio of 22.8 percent and the shares of the top 8 firms to obtain an 8-firm concentration ratio of 38.9 percent. To calculate the Herfindahl-Hirschman index, we first squared the shares of each manufacturer and then added them together for all 40 firms listed to arrive at an HHI of 250.2. Although the HHI theoretically includes the shares of all firms in the industry, adding the squared shares of firms below the 40th would have little effect on the HHI.

Table A-1. Revenues and Market Shares of the Top Dietary Supplement Manufacturers, 1997

Manufacturer	Revenue (millions)	Market Share	Squared Share
Leiner Health Products (Your Life)	425	7.02%	49.35
Pharmavite (Nature Made)	340	5.62%	31.58
American Home Products/Lederle (Centrum)	325	5.37%	28.86
Rexall Sundown	291	4.81%	23.14
NBTY (Natures Bounty)	281	4.64%	21.57
General Nutrition Companies (GNC)	260	4.30%	18.47
Weider Nutrition Group (Schiff)	219	3.62%	13.10
Twin Laboratories (Nature's Herbs)	213	3.52%	12.40
Abbott Labs (Ross Products)	170	2.81%	7.90
Perrigo	152	2.51%	6.31
Solgar Vitamin and Herb Company	120	1.98%	3.93
Bayer Corporation (One-a-Day)	110	1.82%	3.31
IVC Industries (International Vitamin Corp.)	109	1.80%	3.25
Experimental and Applied Sciences (EAS)	108	1.79%	3.19
Nature's Way Products (MMS)	100	1.65%	2.73
Nutraceutical International (KAL, Solaray)	98	1.62%	2.62
Pharmaton Natural Health Products (Ginsana)	90	1.49%	2.21
PowerFoods Inc.	90	1.49%	2.21
MET-Rx USA	88	1.45%	2.12
Country Life Vitamins	70	1.16%	1.34
Mead Johnson	70	1.16%	1.34
Amrion (Whole Foods Market)	65	1.07%	1.15
Now Foods	55	0.91%	0.83
Enzymatic Therapy	50	0.83%	0.68
Anabolic Labs (Vitamer)	50	0.83%	0.68
Vitatech International	50	0.83%	0.68
Natural Alternatives	49	0.81%	0.66
Optimum Nutrition	45	0.74%	0.55
Natrol	43	0.71%	0.51
Balance/Bio Foods, Inc.	40	0.66%	0.44
Chattem (Sun Source)	40	0.66%	0.44

(continued)

Table A-1. Revenues and Market Shares of the Top Dietary Supplement Manufacturers, 1997 (continued)

Manufacturer	Revenue (millions)	Market Share	Squared Share
Nature's Plus	35	0.58%	0.33
Planetary Formulas	35	0.58%	0.33
Chai-Na-Ta Corp	34	0.56%	0.32
HVL Inc.	34	0.56%	0.32
Weinstein Nutritional Products (Ashland)	33	0.55%	0.30
Metagenics	32	0.53%	0.28
Pharmanex	32	0.53%	0.28
Standard Process, Inc.	30	0.50%	0.25
Tishcon Corp.	30	0.50%	0.25
All Other Manufacturers	1,539	25.44%	
Total	6,050	100.00%	

Source: Nutrition Business International. September 1998. "$23 Billion and Counting: Nutrition Industry Braces for a Competitive Future." *Nutrition Business Journal* 3(9):1-5, 13, 18.