

APPENDIX 2–A

REGULATION OF THE DIETARY SUPPLEMENT INDUSTRY

Background

- More than 130 million Americans take dietary supplements.
- Two thirds of US medical schools offer courses in alternative medicine.
- A coalition of professional health organizations, led by the March of Dimes, has launched a national campaign encouraging the consumption of multivitamins with folic acid.

DSHEA

DSHEA is the acronym for the Dietary Supplement Health and Education Act of 1994, which Congress passed by unanimous consent in October 1994. President Bill Clinton signed the legislation into law (PL 103-417) on October 25, 1994.

Dietary Supplements Defined

The DSHEA defines dietary supplements as products intended to supplement the diet. According to the DSHEA, dietary supplements may contain vitamins, minerals, herbs or other botanicals, amino acids, other dietary substances, or combinations or extracts of any of these dietary ingredients.

Publications Provided to Consumers

The DSHEA permits publications to be given to consumers in conjunction with the sale of dietary supplements, provided certain conditions are met, without those publications being considered labeling. This increases the ability to use materials such as scientific articles to help consumers make informed decisions about dietary supplements.

Source: Storlie J. DSHEA. *Pulse*. Winter 1999:5-9.

Good Manufacturing Practices for Dietary Supplements

As foods, dietary supplements are required to comply with good manufacturing practices (GMPs) for foods. GMPs require that:

- food-processing personnel follow sanitary procedures and have suitable training;
- processing facilities be clean;
- processing equipment be designed to permit thorough cleaning and be properly maintained;
- quality controls are in place to assure that raw materials are wholesome; and
- finished products are appropriately packaged, labeled, stored, and shipped.

The DSHEA confirmed that dietary supplements must comply with current GMPs and also authorized the FDA to establish separate GMPs for dietary supplements. The FDA published a notice regarding new dietary supplement GMPs in February 1997, based on a draft submitted jointly by the Council for Responsible Nutrition (CRN) and other industry groups. The new proposal would expand dietary supplement GMPs to require more extensive quality control, testing, and record keeping.

The FDA's DSHEA Actions:

- can initiate recalls for products whose safety has been questioned
- can remove products from store shelves
- can take criminal action if necessary

Office of Dietary Supplements

The DSHEA established an Office of Dietary Supplements (ODS) at the National Institutes of Health (NIH) to facilitate the scientific study of the benefits of dietary supplements for promoting health and preventing disease. Information about the ODS is available on the ODS home page at http://dietary-supplements.info.nih.gov/about/about_ods.aspx.

Supplements Facts Label

The labeling regulations, which were mandated by the DSHEA, were finalized on September 23, 1997. Using a format similar to the nutrition facts panel found on food products, the supplement facts panel clearly presents the nutrient contributions and other constituents of the dietary supplements. This new label will facilitate the process of evaluating dietary supplements and serve as a tool for educating the public.

To distinguish them from conventional foods, dietary supplements must be identified by the term *dietary supplement* as part of the product name. Alternatively, the term *supplement* may be used with the name of the supplement, e.g., "calcium supplement." The dietary supplement label must contain a list of all ingredients as part of the supplement facts panel or ingredients list.