Docket #99N-1174

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THIS PRESENTATION IS BEING MADE PURSUANT TO THE FDA'S MAY 13, 1999 FEDERAL REGISTER NOTICE CONCERNING THE DEVELOPMENT OF AN OVERALL STRATEGY FOR ACHIEVING EFFECTIVE REGULATION OF DIETARY SUPPLEMENTS.

BACKGROUND

I am a lawyer who represents dietary supplement companies which are regulated by the FDA, the FTC, and comparable state agencies. Most of the clients who are provided services by the Denver office of our firm are located in the West and most of them have annual sales in the range of $5,000,000 - $75,000,000. Those clients are contract manufacturers, as well as distributors, retailers, formulators and related consultants.

In order to provide meaningful input to the FDA, our marketing director e-mailed a checklist of various regulatory alternatives to 30 of our clients; by June 8, we will have received responses from them and will tabulate the results and submit them to the FDA for its use.

COMMENTS

[1] The FDA should focus on working more closely with the dietary supplement industry on a regional basis in order to achieve effective regulation of dietary supplements and the individuals and businesses which produce, market and sell them.

(A) Regulation by Industry Cooperation-Outreach on a Regional Basis. The FDA will be unable to regulate, effectively, the dietary supplement industry without a mutual effort because:

> .....The prospect of amendments to DSHEA which would diminish benefits to the dietary supplement industry is remote.
>
> .....The prospect of the FDA issuing regulations which significantly diminish the benefits to the dietary supplement industry and which will be complied with is remote.

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.....The FDA's budget is unlikely to be substantially increased in the near future in order to permit the Agency to allocate enough human resources to monitor the daily activities of this industry and carry out a meaningful enforcement program.

(B) The FDA should, in addition to working with the major trade associations, meet periodically each year with small groups throughout the United States in order to gather their ideas about regulation and other valuable information about their problems and concerns. The FDA has done this successfully with medical device companies. For example, the FDA should organize regional meetings in Colorado, Utah, Arizona, San Diego, northern California, and Tacoma, Washington; one CFSAN representative could complement the local district office of the FDA.

[2] Guidance Documents, Not Regulations. In my judgment, use of guidance documents by the FDA should increase and be the preferred method of regulation rather than the issuance of formal or official rules or regulations.

[3] An Industry-Funded Check-Off Program. In my judgment, the FDA should encourage and support federal legislation which would establish an industry check-off system much like that used in the milk, propane, natural gas, beef and electric industries.

This check-off approach is consistent with the mutual regulation approach discussed in [1] above. In Glickman v. Wileman Brothers & Elliot, decided June 25, 1997, the United States Supreme Court stated that marketing orders, with respect to California nectarines, plums and peaches, issued by the Secretary of Agriculture pursuant to a specific federal statute, were constitutional; in this California case, each fruit grower, handler and processor was assessed a cost per unit by the Department of Agriculture, after a 2/3 vote of an industry committee or council. The money collected was used to promote the California fruit industry. For example, in the dietary supplement industry, a suggested assessment of 1¢ per supplement bottle sold would be assessed toward this industry group.

Funds raised by check-off programs can be used for industry purposes other than pure promotion of the industry. Research is another valid purpose of a check-off program. Another example of such a program is the Beef Promotion and Research Act which was held to be constitutional in Goetz v. Glickman, a July 10, 1998 decision by the Court of Appeals for the Tenth Circuit. That Act "requires cattle producers in the United States to pay a one dollar per head assessment on cattle sold in this country." An "Operating Committee develops and submits to the Secretary for approval promotion, advertising, research, consumer information and industry information plans and projects."

[4] Functional Foods, Cosmetic Drugs and Therapeutic Supplements. In the second column of page 25890 of the Federal Register of May 13, 1999, the FDA lists 8 items which should be included in an overall dietary supplement regulatory strategy. Those 8 items are:

(1) Boundaries between dietary supplements and conventional foods, between dietary supplements and drugs, and between dietary supplements and cosmetic products;

(2) claims;

(3) good manufacturing practices;

(4) adverse event reporting;

(5) laboratory capability;

(6) research needs;

(7) enforcement; and

(8) resource needs.

Item (1) is identified as "boundaries between dietary supplements" and (A) conventional foods, (B) drugs and (C) cosmetics. In my opinion, this is a very important item because there are numerous products in the market which create a perception of a blur in the distinction between these four articles [dietary supplements, conventional foods, drugs and cosmetics] from the standpoint of both consumers and those in the industry. For example, the unofficial category of "functional foods" needs to be dealt with by the Agency by regulation, statute or guidance document.

Item (3), the establishment of good manufacturing practices, is another crucial item because this area of quality control or safety is one which both consumers and manufacturers agree that regulation by official regulation or by industry standards is appropriate and important.