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GAO

United States
General Accounting Office
Washington, D.C. 20548

Human Resources Division

B-252966

July 2, 1993

The Honorable Edward M. Kennedy
Chairman, Committee on Labor and
Human Resources
United States Senate

The Honorable Nancy L. Kassebaum
Ranking Minority Member, Committee on
Labor and Human Resources
United States Senate

The Honorable John D. Dingell
Chairman, Committee on Energy and Commerce
House of Representatives

The Honorable Carlos J. Moorhead
Ranking Minority Member, Committee on
Energy and Commerce
House of Representatives

The Dietary Supplement Act of 1992 requires the General Accounting Office to review the Food and Drug Administration's (FDA) management activities related to the regulation of dietary supplements. In introducing this legislation, the Chairman and the Ranking Minority Member of the Senate Committee on Labor and Human Resources stated that as a general policy the American public must be assured that the dietary supplements they choose to consume are safe, made to quality standards, bear informative labeling, and that health or disease-related claims are properly supported.

Specifically, with regard to dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances, the act requires us to examine how FDA determines:

-- that a substance poses a risk to public health and safety, justifying the expenditure of agency resources;

-- if a substance is adulterated, misbranded, or improperly manufactured;

-- the adequacy of proof necessary to establish the relative safety or risk of a substance; and

-- to adjust its efforts in response to specific issues so that they are commensurate with the severity of the problems it addresses.

In addition, the act requires us to examine:

-- the proportion of resources devoted to regulation and enforcement activities that are related to dietary supplements, food additives that are not such dietary supplements, drugs, devices, and cosmetics;

-- the relationship of FDA's costs, hours spent, its expertise in regulating dietary supplements, and the cost of compliance to manufacturers with the level of risk suspected and determined to be posed by supplements; and

-- the proportion of FDA resources used to evaluate whether dietary supplements, foods, and food additives are misbranded, improperly manufactured, unsafe, or adulterated.

As required by the Dietary Supplement Act, this letter is an interim report that provides the results of our work to date on FDA's approach and allocation of resources to dietary supplement activities. Much of this information was obtained from FDA and we have not yet audited the information to verify its accuracy. More complete information on these and the other issues called for in the act will be provided in our final report.

BACKGROUND

FDA considers moderately potent vitamin and mineral dosages to be generally safe. FDA is concerned that other substances that may be dietary supplements, such as amino acids, herbals, and botanical oils, and some megadosages of vitamins and minerals could pose a health risk. One example of this is L-tryptophan, an amino acid, which was removed from the market in 1990 after it was responsible

for about 1,500 illnesses and at least 37 deaths.[1] L-tryptophan was sold, for the most part, without any drug claims on its label, but was often used to treat insomnia or depression.

An estimated 35 to 60 percent of the population use dietary supplements daily or occasionally, and up to 60 million users take supplements daily. Dietary supplements represent a broad category of products sold in pill, capsule, or liquid form that include vitamins, minerals, amino acids, oils, herbs, and other substances that purport to have nutritional value. These products may be foods, drugs, or both, depending on the manufacturer's intent as discerned from the claims that are made for them on their labels or in labeling. Dietary supplements that make a health or nutritional claim are subject to food regulations; those that make drug claims are subject to drug regulations, and those that make nutritional or health and drug claims may be subject to both regulations.[2]

The dietary supplement industry and FDA differ in their views of the legal basis for regulating these supplements. The industry believes such supplements should be regulated as foods that are not subject to premarket approval by FDA. FDA considers vitamins, minerals, amino acids, herbs, and other ingredients in dietary supplements to be subject to regulation as food additives and, thus, subject to premarket approval. However, dietary supplements that are "generally recognized as safe" are not considered food additives and not subject to premarket approval.[3] An FDA

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[1]A Centers for Disease Control and Prevention (CDC) official told us that CDC confirmed reports of more than 1,500 serious illnesses and 37 deaths related to L-tryptophan. An FDA official, however, advised us that most illnesses attributed to L-tryptophan were not reported to CDC. She said that between 5,000 and 10,000 people likely became seriously ill from the product.

[2]Drug claims purport to prevent, treat, cure, or mitigate disease or purport to affect the structure or function of the body in a different way than food.

[3]Substances that are generally recognized as safe include those that experts qualified by scientific training and experience have generally recognized as safe when used as intended in food. This recognition may be based on scientific procedures, a safe history of common use in food

official told us that, except for vitamins and minerals, most ingredients of dietary supplements are not included in the list of substances that are generally recognized as safe. Dietary supplements that make drug claims must, like all drug products, be shown to be safe and effective before they can be marketed.

FDA does not have a complete inventory of products and establishments that process dietary supplements. A 1986 National Center for Health Statistics survey estimated that 3,400 nonprescription vitamin and mineral supplements were marketed. The number of establishments involved with the processing of these vitamins and minerals is about 1,600. Information FDA provided to us indicates that other varieties of dietary supplements, such as amino acids, and fish oils are also marketed. Retail sales of dietary supplements total about $3.3 billion annually. Sales of nonprescription vitamins and minerals, which comprise 88 percent of the market, total $2.9 billion. Sale of other varieties of dietary supplements, excluding protein powders and herbals, make up the remaining $400 million.

Because FDA does not have complete data on the dietary supplement industry, we could not compare its size with the size of other industries, such as drugs, medical devices, and conventional foods, that are regulated by FDA. FDA estimates there are 47,000 conventional food companies and more than 196,000 conventional food products, 15,000 drug establishments and 84,000 drug products, as well as 22,000 medical device establishments and 65,000 medical devices.

FDA published proposed regulations for dietary supplements in the June 18, 1993, Federal Register. Final regulations are to be issued by December 31, 1993.

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before 1958, or scientific evidence only for substances introduced after 1958 (21 U.S.C. 321(s) (1988); 21 C.F.R. 170.30 (1992)). The list of substances that are generally recognized as safe is not all inclusive. A manufacturer may independently claim its substance is generally recognized as safe without FDA's premarket approval. However, FDA could challenge that claim.

FDA's REGULATION OF DIETARY SUPPLEMENTS

FDA's stated objective for dietary supplements is to ensure that they are safe and their labeling claims are truthful and not misleading. FDA generally does not regulate dietary supplements as it does food additives and other products.

Although FDA believes that the ingredients of dietary supplements are subject to regulation as food additives, FDA's Commissioner stated in a 1992 internal memorandum that FDA will not take action against a dietary supplement that does not comply with the legal requirements for a food additive unless it has a concern about safety or misbranding.

FDA officials responsible for administering FDA's inspection and other compliance activities told us that they do not schedule routine periodic inspections of dietary supplement companies. Rather FDA regulates the companies on a case-by-case basis as it receives complaints or other information concerning a product's safety or labeling. These officials said that FDA has not systematically regulated these products since the 1976 enactment of the Proxmire amendment, which restricts establishing limits on the potency of vitamins and minerals unless safety is a concern.[4] The amendment also prohibits classifying vitamins and minerals as drugs because they are more potent than FDA considers to be nutritionally rational or useful. FDA officials said that this amendment and actions taken by the courts relative to cases on other dietary supplements presented by FDA dissuaded the agency from routinely regulating these products. As a result, according to FDA officials, FDA's current approach to regulating dietary supplements in general is contrary to its basic principles of trying to prevent harm rather than reacting to a condition after some harm, physical or economic, has occurred.

FDA Actions Taken Against Dietary Supplements

Preliminary information we obtained from FDA indicates that from fiscal year 1989 to 1992 FDA had taken action against about 290 companies that manufactured or marketed dietary

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[4]Section 411 of the Federal Food, Drug, and Cosmetic Act.

supplements. FDA took action against about 250 of the companies because it determined that their products' labeling contained unsubstantiated drug claims and, thus, the products were new drugs that were misbranded. FDA took action against the remaining companies because it considered the substances in their products to be unsafe food additives because they were not generally regarded as safe and had not been approved by FDA for use in foods or their products' labeling did not contain a complete list of ingredients.

As a result, FDA seized products of 10 companies and considered seizure actions of products of 88 other companies as of October 1992. FDA issued warning letters to about 225 companies requiring them to correct the products' labeling or establish the products' the safety. Additionally, FDA obtained court injunctions against two companies whose products were found to be misbranded. We have not yet determined the final disposition of all the actions taken against the companies and their products.

FDA RESOURCES EXPENDED FOR DIETARY SUPPLEMENT ACTIVITIES

The amount of resources FDA expends on activities related to dietary supplements is determined primarily by the information the agency receives about problem products and its assessment of the risks that such products could pose to the public health. FDA estimated that between fiscal years 1988 and 1992, the amount of resources expended to address reported problems or complaints involving dietary supplements ranged from 13 to 57 full-time-equivalent employees. In most years, FDA used 20 or fewer full-time equivalent employees to deal with reported problems. However, in 1990 the equivalent of 48 full-time employees were used to remove L-tryptophan from the dietary supplement market place. As indicated earlier, L-tryptophan caused thousands of people to become ill and a number to die. Except for 1990, FDA's estimated staff usage of about 20 full-time equivalent employees between fiscal years 1988 and 1992 to regulate dietary supplements represented less than 1 percent of the total 3,400 full-time-equivalent employees that were involved in regulating all products under FDA's jurisdiction.

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If you or your staff would like to discuss any of the issues in this letter, please contact me at (202)-512-7119.

Sincerely yours,

Mark V. Nadel
Associate Director, National and
Public Health Issues

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