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Report to Congressional Committees

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FDA REGULATION

Compliance by Dietary Supplement and Conventional Food Establishments

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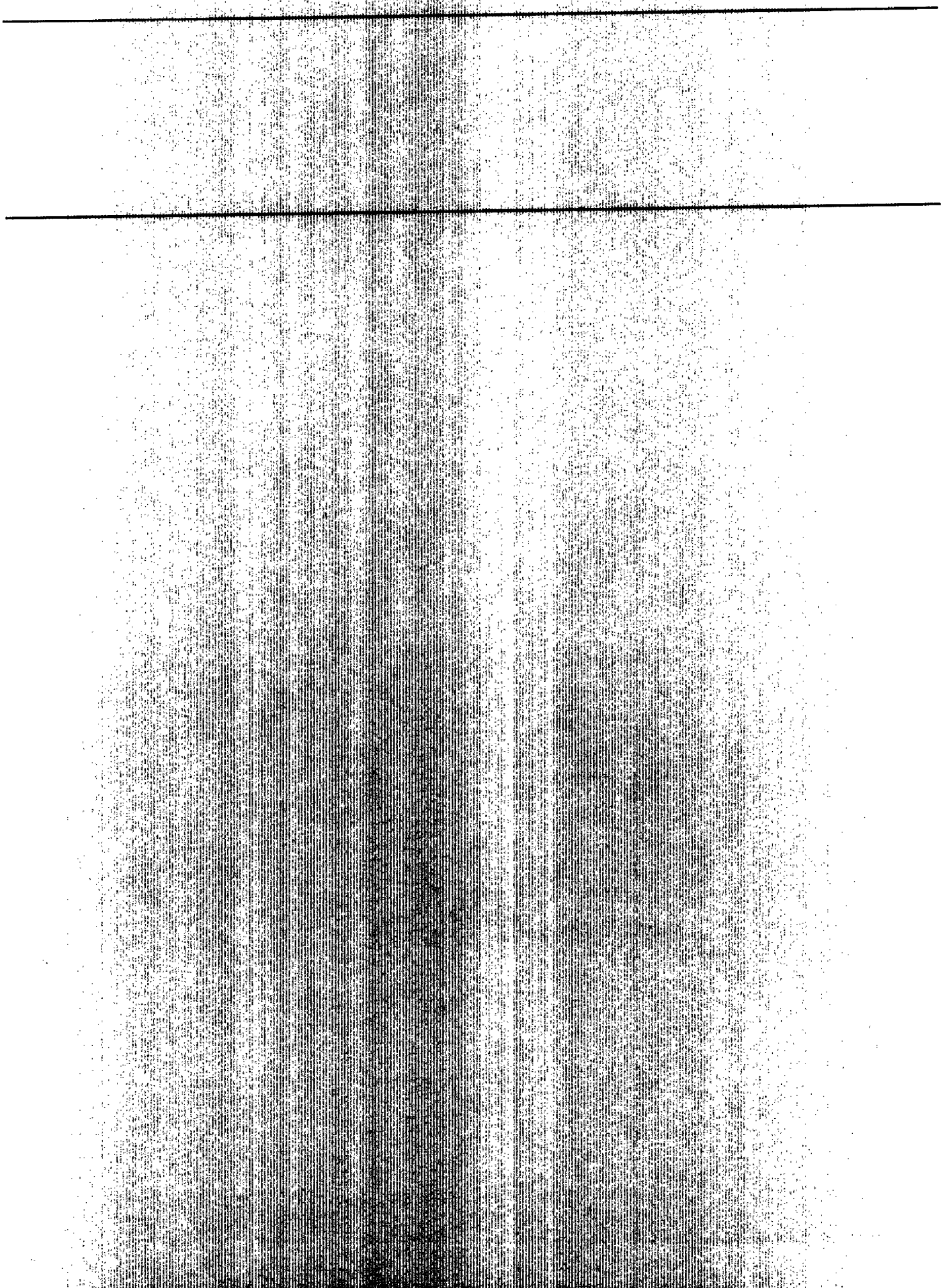

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Health, Education, and
Human Services Division

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June 13, 1994

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 industry has made claims of regulatory bias in the Food and Drug Administration's (FDA) treatment of dietary supplements and the public has expressed concern that FDA's actions could deprive consumers of many dietary supplements or require prescriptions for some of them. As a result, the Congress directed GAO through the Dietary Supplement Act of 1992 to study FDA's management activities related to dietary supplements. We submitted an interim report to the appropriate committees on July 2, 1993 (GAO/HRD-93-28R), which provided preliminary information on FDA's oversight of the dietary supplement industry.

Because FDA has not undertaken a program to assess risk and does not have data on manufacturers' costs, we agreed with your respective offices in our final report to provide an overview of FDA's regulation of dietary supplements and a comparison of FDA's compliance activities of dietary supplement establishments and conventional food establishments. Also, to the extent that manufacturers could provide us their costs to comply with regulatory requirements, this would be reported.

We conducted our study at two FDA district offices, Denver and Los Angeles, because these offices had a high concentration of dietary supplement establishments. These districts cover FDA work in southern

California, Colorado, Nevada, New Mexico, Utah, and Wyoming. Because FDA's information system could not readily or accurately identify all activities related to dietary supplements, we limited our review to these two districts and conducted a manual review and analysis of files and computer data for 3 fiscal years, 1990 through 1992. FDA provided information on the amount of resources expended on compliance activities. We visited several dietary supplement manufacturers to obtain cost data.

We conducted our study from September 1993 to March 1994 in accordance with generally accepted government auditing standards.

We obtained written comments from FDA. FDA found our report generally to be fair and accurate. Where appropriate, we have made suggested changes to further clarify the information presented.

Results in Brief

FDA regulates dietary supplements on a case-by-case basis, generally responding to complaints or other information regarding health risks, and takes action only when it has a concern about a product's safety or labeling. The frequency of inspections at dietary supplement establishments is somewhat less when compared with conventional food establishments. FDA takes official enforcement actions against dietary supplement establishments almost twice as often because FDA finds them to be in violation of the regulations more frequently. FDA does not maintain data on the costs that dietary supplement establishments incur to comply with FDA regulations. However, limited cost data provided to us from dietary supplement establishments show that such establishments incur a wide range of costs. Finally, we found that the resources FDA uses to regulate the dietary supplement industry represent a small percentage of its total work force.

Background

FDA considers dietary supplements to be tablets, capsules, powders, or liquids of vitamins and essential minerals; proteins; herbs, including botanicals such as ginseng and yohimbe; fish oils; oil of evening primrose; fibers such as psyllium; compounds not generally recognized as foods or nutrients such as bioflavonoids, enzymes, germanium, nucleic acids, para-amino-benzoic acid and rutin; and mixtures of these ingredients. An estimated 35 to 60 percent of the population uses dietary supplements daily or occasionally, and up to 60 million users take supplements daily.

Dietary supplements may be foods, food additives (a subcategory of foods), or drugs. Many of the substances used in dietary supplements fall within the food definition because they are used for taste, aroma, or nutritional value. Foods do not require FDA premarket approval.[1] However, food additives require such premarket approval unless they are generally recognized as safe. Dietary supplements that make drug claims are subject to drug regulations. Drug products require premarket approval and must be shown to be safe and effective before they can be marketed.

FDA considers dietary supplements that are added to food products to be subject to regulation as food additives and, thus, subject to premarket approval unless they are generally regarded as safe. The dietary supplement industry would like dietary supplements to be regulated as foods, not as food additives, because foods do not require premarket approval by FDA.

FDA considers moderately potent vitamin and mineral dosages to be generally safe. FDA is concerned that other substances, such as amino acids, herbals, botanical oils, and some megadosages of vitamins and minerals could pose a health risk.[2]

The Dietary Supplement Act placed about a 1-year moratorium on implementing the provisions of the Nutrition Labeling and Education Act of 1990 with respect to dietary supplements that were not in the form of conventional foods such as breakfast cereals.[3] The moratorium was enacted so that consideration could be given by FDA and other principals to the best way to regulate dietary supplements. The moratorium expired in December 1993 and FDA issued final regulations in January 1994. The regulations will be fully implemented by July 1995. Under the regulations, supplement labels will have to provide the same kinds of information as that required for conventional foods. The regulations will permit health claims on supplement labels if FDA finds significant agreement among

[1]Foods are regulated under the Federal Food, Drug and Cosmetic Act to protect the public from products that may be deleterious, unclean or decomposed, exposed to unsanitary conditions, or contaminated with filth. FDA performs inspections of food establishments to assure that good manufacturing and storage practices are followed to prevent these conditions.

[2]A serious case of this was L-tryptophan, an amino acid, that was removed from the market in 1989 after it was responsible for about 1,500 illnesses and at least 38 deaths. An FDA official advised us that most illnesses attributed to L-tryptophan were not reported to the Centers for Disease Control and Prevention. She said that between 5,000 and 10,000 people likely became seriously ill from products containing L-tryptophan. L-tryptophan was sold, for the most part, without any drug claims on its label, but was often used to treat insomnia or depression.

[3]Without the moratorium, the act would have required FDA to issue nutrition and health claim labeling regulations by November 1992.

qualified experts that these claims are scientifically valid. The health claims regulation goes into effect on July 5, 1994.

FDA Regulates Dietary Supplements on a Case-by-Case Basis

FDA's objective for regulating dietary supplements is to ensure that they are safe and that their labeling claims are truthful and not misleading. FDA regulates dietary supplements on a case-by-case basis as food, drugs, or both, depending on their intended use and claims.

FDA's Commissioner stated in a 1992 internal memorandum that FDA will not take action against a dietary supplement manufacturer that does not comply with the legal requirements for a food additive unless it has a concern about safety or mislabeling. FDA officials said that the agency has not systematically regulated these products (for example, as it does for drugs, medical devices, and foods, where FDA routinely schedules inspections) since the 1976 enactment of the Proxmire amendment.[4]

The Proxmire amendment restricts FDA from establishing limits on the potency of vitamins and minerals unless safety is a concern. 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 dissuaded the agency from routinely regulating these products.[5] 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 officials told us that FDA evaluates the health risks of dietary supplements on a case-by-case basis, responding to complaints or other information brought to FDA concerning a product's safety or labeling. Manufacturers do not submit data to FDA to evaluate the safety of such products before marketing; rather the manufacturers make a determination that their products are generally recognized as safe. FDA

[4]Section 501 of the Health Research and Health Services Amendments of 1976 (P.L. 94-278).

[5]For example, FDA sought to condemn 29 cartons of encapsulated black currant oil (BCO) contending that it was an unapproved food additive of questionable safety, U.S. v. 29 Cartons of *** An Article of Food, 987 F.2d 33 (1st Cir. 1993). FDA argued that the BCO, contained in capsules made from gelatin and glycerin (inert substances), could be regulated as a food additive. A federal district court disagreed, holding that the BCO had no effect on the capsules themselves and could not be considered a food additive. The court held that BCO was a food, in which case it is presumed to be safe unless FDA could show otherwise. The appellate court upheld the lower court's decision to dismiss FDA's complaint and its order to release the BCO.

does not schedule, as part of its overall work program, inspections for dietary supplement establishments. Compliance inspections are performed when FDA receives complaints or other information concerning a specific product's safety or labeling. However, FDA district offices can schedule inspections of dietary supplement establishments as part of their internal work plans.

Concerned over several incidents of adverse reactions attributable to dietary supplements, FDA took actions to improve its monitoring of these products. In 1992 FDA created the Office of Special Nutritionals within the Center for Food Safety and Applied Nutrition to collect and evaluate reported adverse effects from dietary supplements. Also, in June 1993 FDA specifically included dietary supplements in its instructions to health professionals for reporting adverse effects through its voluntary MedWatch program.

Dietary Supplement Establishment Inspections Not Emphasized

The percentage of firms inspected by FDA and the extent of repeat inspections did not vary greatly between dietary supplement establishments and conventional food establishments. The number of dietary supplement and conventional food establishments inspected by FDA's Denver and Los Angeles district offices during fiscal years 1990, 1991, and 1992 averaged 12.8 percent and 15.9 percent, respectively, as a percentage of the establishments listed on the Official Establishment Inventory (OEI).[6] FDA's Denver district office performed a greater percentage of inspections of dietary supplement establishments than conventional food establishments. Conversely, the Los Angeles district office performed a greater percentage of inspections of conventional food establishments than dietary supplement establishments. (Table I.1 in appendix I shows the number of inspections in the Denver and Los Angeles districts for fiscal years 1990-92.)

We found that frequencies of repeat inspections during fiscal years 1990-92 were relatively close. At FDA's Denver district, of the 34 dietary supplement establishments that were inspected during the 3-year period, 9, or about 26 percent, were inspected more than once. Of the 389 conventional food establishments inspected during the same period, 87, or 22 percent, were inspected more than once. From 1990 through 1992, FDA's Los Angeles

[6]The Official Establishment Inventory (OEI) is a computerized database of firms maintained by the FDA Office of Regulatory Affairs. This inventory includes among other things for each firm (1) the name and address of the firm, (2) appropriate establishment information and industry codes, (3) information on whether the firm has gone out of business, (4) the last inspection date, (5) the last violative inspection date, and (6) the size of the firm.

district office inspected 106 dietary supplement establishments, and 18, or 17 percent, were inspected more than once. Of the 943 conventional food establishments inspected by FDA's Los Angeles staff, 214, or 23 percent, were inspected more than once. (Table I.2 in appendix I compares the number of multiple inspections performed in the Denver and Los Angeles districts for fiscal years 1990-92.)

About 73 percent of the inspections at dietary supplement establishments took place at manufacturers, packers, repackers, and distributors. Retailers accounted for about 9 percent of the inspections; warehouses represented 12 percent; and the remainder, about 6 percent, included corporate headquarters and laboratories.

FDA did not perform an analysis to determine the reasons that inspections were conducted at dietary supplement establishments. At the Denver and Los Angeles offices, we reviewed files for cases where regulatory actions were recommended by these districts. We found that 54 percent of the inspections were initiated by complaints. The remaining 46 percent were initial or reinspections scheduled by the districts as part of their routine compliance work. Complaints from consumers were 52 percent of all complaints. Complaints from competitors were another 21 percent, and the remaining 27 percent of complaints came from other government entities such as the Federal Trade Commission and a state food and drug department.

Enforcement Actions Taken More Frequently Against Dietary Supplement Establishments

Compliance inspections performed by FDA district offices at conventional food and dietary supplement establishments have resulted in reports concluding that (1) no violations were found and no actions were needed, (2) violations were found of varying degrees and the establishments could take voluntary action to correct the objectionable conditions, or (3) violations were found that should result in an official regulatory action. An official action can constitute a warning letter, recall, seizure/detention, or other sanctions. Generally, recommendations that involve official actions for dietary supplements and labeling issues are forwarded by the districts to FDA headquarters for a decision.

Our data show that a higher percentage of official actions were recommended for dietary supplement establishments than conventional food establishments. Over fiscal years 1990-92, investigators recommended official actions for 0.4 percent and 3.5 percent of the conventional food establishments inspected in the Denver and Los Angeles

districts, respectively. By contrast, during the same period investigators believed that official actions were needed for 29.6 percent and 26.8 percent of the dietary supplement establishments inspected in the Denver and Los Angeles districts, respectively. Investigators were twice as likely to report voluntary actions for conventional food establishments compared with dietary supplement establishments. (Table I.3 in appendix I shows the results of inspections in the Denver and Los Angeles districts for fiscal years 1990-92.)

FDA officials told us that no analysis has been made to explain why there is higher incidence of reporting or recommending official actions for dietary supplement establishments than conventional food establishments. An FDA headquarters official suggested that inspections at conventional food establishments, which are normally routine and scheduled as part of FDA's work plans, are related primarily to sanitation. Problems are more clearly identified and communicated at the time of the inspection. For example, conventional food establishments are either clean and rodent free or they are not, and operators of conventional food establishments can readily see what actions are necessary to come into compliance, thus avoiding the need for official actions. Conventional food establishments, according to the official, are more familiar with FDA's inspection procedures and the actions needed to correct the condition.

On the other hand, inspections at dietary supplement establishments often focus on product literature and labels that make health-related claims. An FDA headquarters official stated that when dietary supplement establishments disagree with FDA about health-related claims, which are more subjective than sanitary conditions, and do not take corrective action, FDA frequently recommends an official action. Moreover, inspections at dietary supplement establishments often stem from complaints, headquarters health fraud bulletins or other concerns, or previous FDA work, indicating that a problem and a potential violation already exist.

Costs of Compliance Vary With Industry

FDA does not have data showing the costs that dietary supplement establishments incurred to comply with FDA regulations. However, limited cost data provided to us from manufacturers show that dietary supplement establishments incurred a wide range of costs. These costs most frequently represented expenditures for legal and consulting fees and product relabeling, but also included quality control measures, laboratory analyses, and, in some instances, the value of seized products. In

commenting on this report, FDA stated that the types of compliance costs cited by dietary supplement establishments are common to regulated industry.

We visited nine dietary supplement establishments, primarily manufacturers, and requested financial data to show the costs that they incurred. Of these nine establishments, eight provided us with financial information. The median average amount expended to meet regulatory requirements for these establishments was $47,050. These costs ranged from $1,400 for one small establishment to $850,000 for a large establishment. Although we did not verify this cost data, almost all these establishments had been the subject of some type of enforcement action. Therefore, portions of their reported costs were to correct FDA-cited problems. In addition, establishments legitimately incur costs as part of their normal business practices to maintain quality standards, just as any food or drug manufacturer is required to do by FDA.

To illustrate the kinds of costs incurred, one small manufacturer spent $1,400 to delete health claims from its labels and to install storage shelves to meet sanitation requirements. Of the eight firms, seven indicated that they had incurred legal fees. The average legal fee was $17,700. The range of legal fees was from $4,100 to $185,000, and often represented the costs for outside counsel and advice on labeling or product literature to prevent or correct problems. In two instances, establishments cited the costs of products seized by FDA, amounting to $15,000 at one establishment and $457,000 at the other.

Officials at several of the establishments we visited said that they make expenditures to avoid FDA enforcement actions by making certain that their products are marketed in accordance with FDA requirements. For example, one establishment showed that it spent almost $500,000 for quality control measures and equipment to ensure that it met good manufacturing practices.

Limited Amount of Resources Expended on Dietary Supplements

As measured by its total workforce used to regulate all products, FDA does not expend a significant amount of its resources on its dietary supplement compliance activities. Our interim report stated that FDA estimated that about 20 full-time-equivalent employees per year between fiscal years 1988 and 1992 were used to regulate dietary supplements. This was less than 1 percent of the total 3,400 full-time-equivalent employees that were involved in regulating all products under FDA's jurisdiction. Since our

interim report and at our request, FDA reassessed the amount of resources that were used in its compliance activities for dietary supplements. Due to limitations in its information system, FDA had to do a manual and time-consuming review of the data, and provided information for only fiscal year 1992. FDA now estimates that 79 full-time-equivalent employees were used to regulate dietary supplements. This represents about 2.3 percent of its 3,400 full-time-equivalent employees used to regulate all products.

FDA understated its resources used in regulating dietary supplements at about 20 full-time-equivalent employees because not all dietary supplement products were identified under the same industry code. FDA found, for example, that investigators used other industry codes, such as the code for human drugs, if products made health-related claims. Beginning in fiscal year 1994, FDA consolidated all dietary supplement actions under one code. This consolidation should allow FDA to identify the resources used to regulate dietary supplement establishments.

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

Sincerely yours,

Mark V. Nadel

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

Contents

Abbreviations

BCO	black currant oil
FDA	Food and Drug Administration
OEI	Official Establishment Inventory

FDA Inspections in Denver and Los Angeles Districts

Table I.1: Number of Dietary Supplement and Conventional Food Establishments Inspected in the Denver and Los Angeles Districts (Fiscal Years 1990-92)

Type of establishment	District	Fiscal year	Number inspected	Percent of OEI[a]
Dietary supplement	Denver	1990	9	13.6
		1991	14	21.2
		1992	18	27.3
	Los Angeles	1990	42	12.1
		1991	40	11.5
		1992	36	10.4
	Both districts	**1990-92**	•	**12.8**
Conventional food	Denver	1990	152	16.5
		1991	145	15.7
		1992	164	17.7
	Los Angeles	1990	467	19.6
		1991	464	19.5
		1992	183	7.7
	Both districts	**1990-92**	•	**15.9**

[a]For computation purposes, we used the November 9, 1992, Official Establishment Inventory (OEI) of 66 dietary supplement and 924 conventional food establishments in the Denver district, and 347 dietary supplement and 2,384 conventional food establishments in the Los Angeles district. The computed inspection percentages may be slightly overstated or understated due to inventory decreases or increases between fiscal years 1990 and 1992.

Table I.2: Comparison of Dietary Supplement and Conventional Food Establishments With Multiple Inspections (Fiscal Years 1990-92)

		Denver		Los Angeles	
Type of establishment	Number of inspections	Number of establishments	Percent of OEI	Number of establishments	Percent of OEI
Dietary supplement	0	32	48.5	241	69.4
	1	25	37.9	88	25.4
	2	8	12.1	15	4.3
	3	1	1.5	3	0.9
	4	0	0	0	0
	5	0	0	0	0
	6	0	0	0	0
Conventional food	0	535	57.9	1,441	60.4
	1	302	32.7	729	30.6
	2	74	8.0	163	6.8
	3	9	1.0	32	1.3
	4	3	0.3	12	0.5
	5	0	0	2	0.1
	6	1	0.1	5	0.2

Table I.3: Results of Inspections in the Denver and Los Angeles Districts (Fiscal Years 1990-92)

Type of establishment	District	Fiscal year	Number of inspections
Dietary supplement	Denver	1990	9
		1991	15
		1992	20
	Total	**1990-92**	**44**
	Los Angeles	1990	44
		1991	45
		1992	38
	Total	**1990-92**	**127**
Conventional foods	Denver	1990	168
		1991	157
		1992	170
	Total	**1990-92**	**495**
	Los Angeles	1990	543
		1991	509
		1992	193
	Total	**1990-92**	**1,245**

Official action indicated[a]	Percent	Voluntary action indicated[b]	Percent	No action indicated[c]	Percent	Other[d]	Percent
1	11.1	2	22.2	5	55.6	1	11.1
6	40.0	5	33.3	4	26.7	0	0
6	30.0	4	20.0	8	40.0	2	10.0
13	**29.6**	**11**	**25.0**	**17**	**38.6**	**3**	**6.8**
5	11.4	15	34.1	22	50.0	2	4.5
14	31.1	10	22.2	19	42.2	2	4.4
15	39.5	11	28.9	12	31.6	0	0
34	**26.8**	**36**	**28.3**	**53**	**41.7**	**4**	**3.1**
2	1.2	79	47.0	86	51.2	1	0.6
0	0	63	40.1	93	59.2	1	0.6
0	0	87	51.2	83	48.8	0	0
2	**0.4**	**229**	**46.3**	**262**	**52.9**	**2**	**0.4**
17	3.1	332	61.1	183	33.7	11	2.0
20	3.9	296	58.2	185	36.3	8	1.6
7	3.6	115	59.6	66	34.2	5	2.6
44	**3.5**	**743**	**59.7**	**434**	**34.9**	**24**	**1.9**

[a]Official Action Indicated represents recommendations to initiate actions such as recalls, regulatory letters, seizures, or other sanctions.

[b]Voluntary Action Indicated represents recommendations to the establishment that objectionable conditions be corrected, but do not justify official action at this time.

[c]No Action Indicated represents no objectionable conditions were found which warrant action by FDA or the establishment.

[d]Other includes no recommendations, pending recommendations, or referrals to states for action.

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