

# **Department of Health and Human Services**

## **OFFICE OF INSPECTOR GENERAL**

### **DIETARY SUPPLEMENTS: COMPANIES MAY BE DIFFICULT TO LOCATE IN AN EMERGENCY**



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Inspector General

October 2012  
OEI-01-11-00211

## **EXECUTIVE SUMMARY: DIETARY SUPPLEMENTS: COMPANIES MAY BE DIFFICULT TO LOCATE IN AN EMERGENCY**

**OEI-01-11-00211**

### **WHY WE DID THIS STUDY**

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 requires certain dietary supplement companies to register with the Food and Drug Administration (FDA). Registration in the Food Facility Registry (the registry) is intended to provide FDA with sufficient information to contact companies in an emergency. Previous Office of Inspector General work identified problems with FDA's registry. Recent recalls of dietary supplements tainted with prescription drugs, synthetic steroids, and other potentially dangerous ingredients highlight the importance of registration and adverse event contact information so that FDA can trace the source of the product. These problems raised questions about FDA's ability to identify and contact manufacturers in a food emergency to protect public health.

### **HOW WE DID THIS STUDY**

We analyzed a purposive sample of 127 weight loss and immune support dietary supplements. For 123 of these supplements, we determined whether the companies that produced them were registered with FDA and compared the information in the registry with information obtained during structured interviews with company representatives. We also analyzed the labels of all 127 dietary supplements to determine whether they contained required adverse event contact information.

### **WHAT WE FOUND**

Twenty-eight percent of contacted companies had facilities that failed to register with FDA as required. Of the companies with facilities that did register, 72 percent failed to provide the complete and accurate information required in the registry. Finally, 20 percent of dietary supplement labels in our sample did not provide the required telephone numbers or addresses.

### **WHAT WE RECOMMEND**

We recommend that FDA: (1) improve the accuracy of information in the registry, (2) seek authority to impose civil monetary penalties on companies that do not comply with registration requirements, and (3) educate the dietary supplement industry about registration and labeling requirements. FDA concurred with all of our recommendations.

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## OBJECTIVES

1. To determine the extent to which selected weight loss and immune support dietary supplement companies are registered with the Food and Drug Administration (FDA) in compliance with the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act).
2. To determine the extent to which information on selected weight loss and immune support dietary supplement companies in FDA's registry is complete and accurate.
3. To determine the extent to which selected weight loss and immune support dietary supplement labels include required adverse event contact information.

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## BACKGROUND

In the United States, dietary supplements are a \$20 billion-per-year industry and are used by 80 percent of adults for a wide range of purposes.<sup>1</sup> Products for weight loss or immune system support represent some of the fastest growing segments of the dietary supplement market.<sup>2, 3</sup> The Federal Food, Drug, and Cosmetic Act deems dietary supplements to be a category of food and defines them, in part, as products intended to supplement the diet. If a dietary supplement is contaminated or otherwise unsafe, FDA's ability to quickly locate a company that is able to stop the distribution of the supplement is essential. Recent recalls of dietary supplements tainted with prescription drugs, synthetic steroids, and other potentially dangerous ingredients highlight the importance of registration and adverse event contact information so that FDA can trace the source of the product.<sup>4, 5, 6</sup>

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<sup>1</sup> Natural Products Foundation, *What is the Current Economic Contribution of the Dietary Supplement Industry to the U.S. Economy?* Accessed at [www.naturalproductsfoundation.org](http://www.naturalproductsfoundation.org) on May 31, 2010.

<sup>2</sup> Government Accountability Office, *Dietary Supplements for Weight Loss: Limited Federal Oversight Has Focused More on Marketing Than on Safety*, GAO-02-985T, July 2002.

<sup>3</sup> Nutraceuticals World, *Getting Ahead of the Curve: Immunity*, October 1, 2010. Accessed at [www.nutraceuticalsworld.com](http://www.nutraceuticalsworld.com) on March 16, 2012.

<sup>4</sup> FDA, *Superior Metabolic Technologies Inc. Recalls Uprizing 2.0 Because the Product Contains Superdrol, Which is a Synthetic Steroid, Making it an Unapproved New Drug*, October 3, 2011. Accessed at [www.fda.gov](http://www.fda.gov) on February 17, 2012.

<sup>5</sup> FDA, *Globe All Wellness, LLC, Issues a Voluntary Recall of Dietary Supplement Found to Contain an Undeclared Drug Ingredient*, May 24, 2011. Accessed at [www.fda.gov](http://www.fda.gov) on February 17, 2012.

<sup>6</sup> FDA, *Ethos Environmental, Inc., Issues a Voluntary Recall of Specific Lots of the Dietary Supplement Regenerect*, April 28, 2011. Accessed at [www.fda.gov](http://www.fda.gov) on February 17, 2012.

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) requires that food facilities, including dietary supplement companies, register with FDA.<sup>7</sup> Registration is intended to provide FDA with sufficient information to contact companies in an emergency.<sup>8</sup> (The Bioterrorism Act requires facilities, rather than companies, to register, and a company may operate multiple facilities.) Previous Office of Inspector General (OIG) work identified problems with FDA's Food Facility Registry (the registry). That work found that company contact information in the registry was frequently out of date or incorrect. These problems raised questions about FDA's ability to identify and contact manufacturers in a food emergency to protect public health.<sup>9</sup>

### **Dietary Supplements**

The Dietary Supplement Health and Education Act of 1994, an amendment to the Federal Food, Drug, and Cosmetic Act, defines a dietary supplement, in part, as a product that is ingested by mouth to supplement the diet and contains one or more of the following ingredients:

- a vitamin;
- a mineral;
- an herb or other botanical;
- an amino acid;
- a dietary substance for use by man to supplement the diet by increasing the total dietary intake; or
- a concentrate, a metabolite, a constituent, or an extract.<sup>10</sup>

Consumers may purchase dietary supplements over the counter without a prescription. In the absence of a premarket approval requirement for dietary supplements, FDA gathers information about these products from a variety of sources and takes action against adulterated or misbranded supplements after they reach the market. FDA does this by monitoring adverse event reports and consumer complaints, searching the Internet for supplements that do not comply with regulations, conducting onsite

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<sup>7</sup> Companies that manufacture, process, pack, or hold food, including dietary supplements, for consumption in the United States must register with FDA before producing or selling their products. P.L. 107-188 § 305(a) (codified at 21 U.S.C. § 350d).

<sup>8</sup> 68 Fed. Reg. 58893, 58895 (Oct. 10, 2003): *Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*.

<sup>9</sup> OIG, *FDA's Food Facility Registry*, OEI-02-08-00060, December 2009.

<sup>10</sup> P.L. 103-417 § 3 (codified at 21 U.S.C. § 321(ff)). Other statutory requirements for a dietary supplement include that it may not be represented for use as a conventional food or as a sole item of a meal and that it must be labeled as a dietary supplement.

inspections of manufacturers or imported shipments of supplements, and reviewing new dietary ingredient notifications.<sup>11</sup>

### **Registration of Manufacturers and Distributors**

Under the Bioterrorism Act, all companies that manufacture, process, pack, or hold food, including dietary supplements, for consumption in the United States must register with FDA before engaging in any of these activities.<sup>12</sup> (Companies that are solely retailers of dietary supplements and do not otherwise manufacture, process, hold, or pack the products are not required to register with FDA.<sup>13</sup>) Registration is intended to provide reliable information about these companies. The registry also enables FDA to quickly locate companies during an outbreak of illness caused by contaminated food or supplements and to locate the facilities for inspection. Food and dietary supplement companies must register their contact information with FDA, including the company names, addresses, and emergency contact telephone numbers.<sup>14</sup> Companies must update their registrations within 60 calendar days of any change in the information submitted previously.<sup>15</sup> Currently, some categories of dietary supplements are not required to be identified in the registry; therefore, we could not determine the number of dietary supplement companies in the registry.<sup>16</sup>

The FDA Food Safety and Modernization Act, enacted in 2011 (FSMA) strengthened registration requirements.<sup>17</sup> Beginning in 2012, companies must renew their registrations every 2 years.<sup>18</sup> In addition, FSMA authorizes FDA to suspend registration of a company if it has reason to believe that a product poses a serious threat to public health.<sup>19</sup>

FDA does not regularly review or test the data in the registry for accuracy, but has periodically reminded companies through postcards and telephone alerts to maintain accurate information in the registry. FDA uncovers registration violations primarily by inspecting a company's manufacturing

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<sup>11</sup> A new dietary ingredient is an ingredient that was first marketed in the United States after October 15, 1994. 21 U.S.C. § 350b.

<sup>12</sup> 21 U.S.C. § 350d(a); FDA's implementing regulations on the registration of food facilities are located at 21 CFR §§ 1.225–1.243.

<sup>13</sup> 21 U.S.C. § 350d(c)(1), 21 CFR §§ 1.226(c), 1.227(b)(11).

<sup>14</sup> 21 CFR § 1.232.

<sup>15</sup> 21 CFR § 1.234.

<sup>16</sup> 21 CFR § 170.3.

<sup>17</sup> P.L. 111-353, § 102, January 4, 2011.

<sup>18</sup> 21 U.S.C. § 350d(a)(3).

<sup>19</sup> 21 U.S.C. § 350d(b)

facilities.<sup>20</sup> FDA's field offices also monitor their regions for unregistered facilities. FDA may notify unregistered facilities of registration requirements during a routine inspection or by letter. If a company continually fails to register as required, FDA may take regulatory action against it by issuing a warning letter, prohibiting the sale of the supplement through an injunction, or referring the matter for criminal prosecution.<sup>21</sup> In the absence of complete information in the registry, FDA may use other sources of contact information to locate a company.<sup>22</sup>

### **Adverse Event Reporting and Required Contact Information on Dietary Supplement Labels**

One way that FDA learns about unsafe dietary supplements is by monitoring adverse event reports. If consumers encounter a problem with a particular supplement, they must be able to quickly report adverse events to a responsible company so that FDA can respond if necessary.<sup>23</sup> To facilitate consumer adverse event reporting, the Dietary Supplement and Nonprescription Drug Consumer Protection Act, enacted in 2006, amended the Federal Food, Drug, and Cosmetic Act to require that dietary supplement labels include the domestic telephone number or address of the dietary supplement firm responsible for receiving adverse event reports for the product and reporting them to FDA.<sup>24</sup> FDA guidance specifies that a complete telephone number must include the area code and a complete address must include the full street address or post office box of the responsible party.<sup>25</sup> The telephone number and address provided on the dietary supplement label are not intended to match those provided in FDA's registry. Although contact information on the label is intended to provide consumers, health care providers, and others with the means to report an adverse event to a dietary supplement company, it may also be

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<sup>20</sup> FDA, *Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002*, Compliance Policy Guide § 110.300, 2003, revised 2006.

<sup>21</sup> 21 U.S.C. § 331(dd); 21 U.S.C. § 332; 21 U.S.C. § 333; 21 CFR § 1.241. See also *FDA Regulatory Procedures Manual*. Accessed at [www.fda.gov](http://www.fda.gov) on May 17, 2012.

<sup>22</sup> One such source is the Official Establishment Inventory, a database maintained by FDA to collect information on food, drug, and other types of FDA-regulated facilities for inspection purposes. FDA, *Field Management Directives, Official Establishment Inventory Development and Maintenance Procedures*, July 17, 2006. Accessed at [www.fda.gov](http://www.fda.gov) on June 21, 2012.

<sup>23</sup> Federal regulations require dietary supplement companies to report serious adverse events to FDA, including death and life-threatening injury. Companies are not required to report minor adverse events. 21 U.S.C. § 379aa-1(b).

<sup>24</sup> P.L. 109-462, § 3(c), codified at 21 U.S.C. § 343(y).

<sup>25</sup> FDA, *Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act*, December 2007, revised September 2009.

helpful for FDA when tracing the source of a supplement or responding to adverse event reports.

This report is being issued in conjunction with another OIG evaluation report, entitled *Dietary Supplements: Structure/Function Claims Fail To Meet Federal Requirements* (OEI-01-11-00210). Both reports are based on the same sample of dietary supplements.

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## METHODOLOGY

### Scope

This study assessed the extent to which selected dietary supplement companies registered with FDA and provided complete and accurate information. This study also assessed the extent to which a sample of dietary supplement labels provided required contact information for the purpose of reporting adverse events. This study did not assess FDA's adverse event reporting system for dietary supplements. This study is limited to the sample of supplements that we purchased.

We focused our review of the registry on key information that FDA would likely need to contact a dietary supplement company in an emergency. We included only domestic companies in our analysis and did not attempt to contact companies with foreign telephone numbers and addresses to confirm registration information. The findings are limited to selected companies and are not projectable to all dietary supplement companies subject to FDA's registration requirements.

### Data Collection and Analysis

We analyzed a purposive sample of 127 dietary supplements that we purchased from retail stores in selected U.S. cities and from various Internet sites. We focused on two types of supplements—immune support supplements and weight loss supplements—after consulting with FDA. Our sample includes 67 immune support supplements and 60 weight loss supplements. We purchased 67 of the supplements from retail stores and 60 from Internet sites. (For additional descriptive statistics, see Appendix A.)

*Supplements Purchased From Retail Stores.* We selected five major U.S. cities to achieve a wide regional distribution: New York, Chicago, Dallas, Los Angeles, and Seattle. Within each city, we purchased a minimum of 12 unique supplements from a mix of small and large pharmacies, supermarkets, and supplement retailers. We did not seek supplements that appeared to violate FDA regulations, but rather we sought to purchase a variety of weight loss and immune support supplements with a variety of structure/function claims on their labels.



Supplements Purchased From the Internet. We created a set of search terms related to weight loss or immune support. Using three major search engines, we searched the Internet with these terms. We selected sites and products with the goal of purchasing as many different brands of supplements as possible.

Determining Registration Status of Sampled Dietary Supplement Companies. We used the company listed on the product's label as the first point of contact. We first searched the registry to determine whether the company was registered with FDA. We considered a company to be required to register with FDA if its representative reported that it had at least one facility that manufactured, processed, packed, distributed, or stored dietary supplements.

We dropped four dietary supplements from the analysis of FDA's registry because the companies listed on the labels were located outside the United States. The 123 supplements included in the registry analysis were associated with 106 companies; 13 companies were associated with multiple supplements in the sample.

We then attempted to contact each of the 106 companies by telephone to confirm registry information and to administer a structured interview. We used either the telephone number listed on the supplement label or, if no telephone number was listed, the emergency contact number listed in the registry. To contact companies that did not have a telephone number listed on their products' labels or in the registry, we searched the Internet for valid telephone numbers.

Structured Interviews With Representatives of Dietary Supplement Companies. We conducted structured interviews with either the company's emergency contact or the manager in charge of registration with FDA. We made three attempts to contact each company and reached 91 company representatives. Five declined to complete the interview. In total, we interviewed representatives of 86 of the 106 companies, resulting in an 81-percent response rate.

We asked each representative to verify the company's registration information, including the company's name, full address, emergency contact name, and emergency contact telephone number. We asked the representative to provide contact information for any facilities that manufactured the supplement in our sample. If the company or one of its manufacturing facilities was listed in the registry, we considered the company to be registered.

If the contact information provided by the company representative did not match the information in the registry, we questioned the representative

about the discrepancy and asked when the information had changed. If we could not initially find a company in the registry, we asked the company representative about alternate company names and addresses. We then searched the registry again to determine whether the company was registered under an alternate name. We also asked company representatives about their familiarity with the registry.

Finally, we asked about the functions performed by the company with respect to the sampled dietary supplement (i.e., manufacturing, distributing, warehousing). We did not independently verify each company's self-reported function.

*Analysis of Adverse Events Contact Information on Dietary Supplement Labels.* We analyzed the labels of 127 dietary supplements to determine whether they were in compliance with Federal regulations regarding required adverse events contact information. We determined that a label provided complete contact information if it included either a complete telephone number or a complete address for a responsible party.

### **Limitations**

Because no comprehensive list of dietary supplements or dietary supplement companies exists, the universe of supplements and companies is unknown. Therefore we were unable to draw a random sample of dietary supplements and companies and do not generalize our findings to all dietary supplement companies. Using self-reported information about the companies' functions, we determined whether companies were required to be registered with FDA. Only FDA can make a final determination about whether each company was required to register.

### **Standards**

This study was conducted in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

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## **FINDINGS**

### **Twenty-eight percent of contacted companies failed to register with FDA as required**

Dietary supplement companies must register with FDA if they manufacture, process, pack, or hold dietary supplements for consumption in the United States, pursuant to the Bioterrorism Act of 2002. Of the 86 companies we interviewed, 79 had 1 or more facilities that were

required to register with FDA.<sup>26</sup> Of those 79 companies, 22 (28 percent) did not have any facilities registered with FDA. Thirteen of these companies were associated with products we purchased on the Internet and nine with products we purchased in retail stores (see Appendix A). FDA officials and other stakeholders told us that oversight of Internet companies is particularly challenging because of the vast number of Web sites and difficulty identifying those responsible for them.

Of the 86 companies we contacted, company representatives of 32 were unaware of FDA's registration requirements. Even among the 57 companies that did have registered facilities, 13 company representatives we spoke with were unfamiliar with the registry. This raises questions about whether registered companies are keeping their contact information up to date. On the other hand, eight representatives of companies that failed to register with FDA reported that they were familiar with the registry.

### **Among companies in our sample that registered with FDA, 72 percent failed to provide complete and accurate information required in the registry**

Of the 57 companies with registered facilities, 41 (72 percent) had incomplete or inaccurate required contact information in the registry.<sup>27</sup> FDA regulations require companies to maintain complete and accurate information in the registry so that it can locate them quickly in an emergency. If a company relocates to a new address or has other changes, it must update the registry with the accurate information within 60 days.<sup>28</sup> Sixteen companies had inaccurate addresses in the registry, but none reported relocating within the 60-day window (see Chart 1).

Additionally, 34 companies with registered facilities did not provide accurate emergency contact telephone numbers in the registry as required. The emergency contact name, which is not required, was often inaccurate as well. Thirty companies with registered facilities did not provide accurate emergency contact names. At a large company with multiple divisions, FDA may have trouble identifying and contacting a person who is able to respond to an emergency if no emergency contact name is

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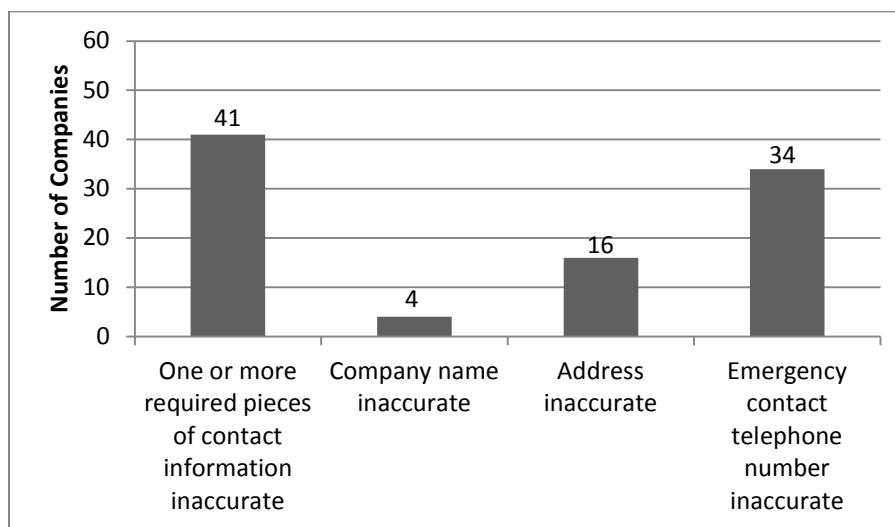
<sup>26</sup> These 79 companies were supplement manufacturers, distributors, warehouse, packagers, or some combination thereof. We determined that seven companies were not required to register because six were retailers and one was a wholesaler.

<sup>27</sup> As part of registration, a company is required to provide a complete and accurate name, address, and telephone number for the facility; the facility's owner, operator, agent in charge, and U.S. agent (for a foreign facility); and, if the facility is a subsidiary, the facility's parent company. In addition, an emergency telephone number must be provided for the facility or, in the case of a foreign facility, the facility's U.S. agent. 21 CFR § 1.232.

<sup>28</sup> 21 CFR § 1.234.

provided. If a dietary supplement poses a public health threat, FDA should be able to rely on the registry for contact information. In an emergency involving a dietary supplement, it is critical that FDA be able to quickly trace the source of the product. Incomplete emergency contact information in the registry may cause a delay when FDA is tracing the source of an unsafe supplement.

**Chart 1: Dietary Supplement Companies With Inaccurate Required Contact Information in the Registry (n=58)**



Source: OIG analysis of data from FDA's Food Facility Registry and interviews with dietary supplement companies, September 2011.

Note: Categories are not mutually exclusive. FDA requires that companies provide a company name, a physical address, and an emergency contact telephone number in the registry.

## **Twenty percent of dietary supplement labels in our sample did not provide the required telephone numbers or addresses**

Federal law requires that dietary supplement labels include the telephone numbers or complete addresses of the dietary supplement firms responsible for receiving adverse event reports.<sup>29</sup> Consumers and medical providers use this information to report adverse events. Of the 127 dietary supplement labels in our sample, 26 did not include either the telephone numbers or complete addresses of responsible parties. Of these 26 supplements, 17 also did not have responsible companies listed in FDA's registry. This raises questions about the ease of obtaining contact information for these 17 companies.

Complete contact information on dietary supplement labels is essential to enable consumers and their medical providers to report adverse events. If

<sup>29</sup> 21 U.S.C. § 343(y).

a dietary supplement does not provide contact information on the label, FDA may not learn of unsafe supplements in a timely manner. Additionally, if information in FDA's registry is inaccurate or incomplete, FDA must rely on other sources of information to contact a responsible company. Incomplete contact information on dietary supplement labels may put FDA at a disadvantage in learning about and tracing the source of unsafe supplements.

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## CONCLUSION AND RECOMMENDATIONS

In a public health emergency involving a dietary supplement, FDA's ability to quickly locate a company responsible for the supplement's safety is essential. FDA's Food Facility Registry is intended to provide sufficient contact information for dietary supplement companies in these circumstances. In addition, a dietary supplement label must include a telephone number or an address for a responsible company so that consumers and others can report adverse events.

This review raises questions about the accuracy and utility of the registry in emergencies and the availability of contact information on supplement labels that could be used to report adverse events to the responsible company. Twenty-eight percent of contacted companies failed to register as required. Of those that did register, 72 percent failed to provide complete and accurate information. Finally, 20 percent of dietary supplement labels in our sample did not provide required adverse event contact information.

To address the findings in this report, we recommend that FDA:

### **Improve the Accuracy of the Information in the Registry**

Beginning in 2012, all dietary supplement companies must renew their facilities' registrations during defined periods every 2 years.<sup>30</sup> To improve the accuracy of information in the registry, FDA could publicize this new requirement and remind registered companies of the requirement to update their information within 60 days of any change. FDA could accomplish this by:

- emailing reminders to companies' registered email addresses,
- presenting information on registration requirements at industry meetings,
- publishing reminders in trade and industry publications, and
- posting reminders on the FDA Web site and listserv.

FDA could also consider testing the accuracy of the information in the registry by regularly attempting to contact a sample of listed companies. This would provide FDA with information on the registry's accuracy and help determine whether the registry can work as intended in an emergency.

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<sup>30</sup> 21 U.S.C. § 350d(a)(3).

### **Seek Statutory Authority To Impose Civil Monetary Penalties on Companies That Do Not Comply With Registration Requirements**

In 2009, OIG recommended that FDA consider seeking authority to impose civil monetary penalties on food facilities, including dietary supplement companies, that either fail to register or fail to provide accurate information.<sup>31</sup> Civil monetary penalties may provide added incentive for companies to comply with registry requirements. FDA previously expressed support for this recommendation and indicated that it would be open to pursuing this authority in the future.<sup>32</sup>

### **Educate the Dietary Supplement Industry About Registration and Labeling Requirements**

Such education could lead to an increase in the number of dietary supplement companies that register and comply with labeling requirements. FDA could focus on educating the dietary supplement industry about which types of companies are required to register. FDA could also educate companies about the requirement for labels to include a complete telephone number or address for reporting adverse events. FDA could consider providing education through industry and FDA Web sites, as well as trade association publications and meetings.

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<sup>31</sup> OIG, *FDA's Food Facility Registry*, OEI-02-08-00060, December 2009.

<sup>32</sup> Ibid.

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## AGENCY COMMENTS AND OFFICE OF INSPECTOR GENERAL RESPONSE

In its comments on the draft report, FDA concurred with all of our recommendations. FDA acknowledged that its ability to ensure the safety of dietary supplements used by consumers should be improved and described its plans to address our recommendations.

FDA concurred that it should take steps to improve the accuracy of the Food Facility Registry. It noted that FSMA requires registrants to renew their registrations every 2 years, and the agency expects that this will improve the accuracy of the registry. FDA also said that it is preparing updated informational and guidance documents related to the biennial registration requirement and will make these available to facilities required to register.

FDA also concurred with our recommendation to seek statutory authority to impose civil and monetary penalties on dietary supplement manufacturers or their facilities that fail to register.

Finally, FDA concurred with our recommendation to educate the dietary supplement industry about registration and labeling requirements. In its comments, FDA focused on educating currently registered companies about the requirement to renew their registrations biennially but did not specify its plan for educating unregistered companies about the requirement to register their facilities. FDA plans to send letters to major trade associations and trade show providers regarding the new requirement to renew registrations biennially. In addition, FDA noted that in 2011, it produced a handout for industry regarding labeling requirements for adverse event reporting.

We ask that in its final management decision, FDA clarify its plans for identifying and registering unregistered facilities and increasing compliance with registration requirements overall. For the full text of FDA's comments, see Appendix B.



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## APPENDIX A:

### Information on Sampled Dietary Supplements and Companies

**Table A-1: Sampled Supplements by Source of Purchase and Supplement Type**

Supplement Source	Weight Loss Supplements	Immune Support Supplements	Total
Retail	32	35	67
Internet	28	32	60
<b>Total</b>	<b>60</b>	<b>67</b>	<b>127</b>

Source: Office of Inspector General (OIG) analysis of sampled dietary supplements, September 2011.

**Table A-2: Companies Contacted and Their Registration Status**

Company Type	Contacted	Required To Register With FDA	Registered With FDA
Retail	47	46	37
Internet	39	33	20
<b>Total</b>	<b>86</b>	<b>79</b>	<b>57</b>

Source: OIG analysis of sampled dietary supplements, September 2011.

## APPENDIX B

### Agency Comments



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration  
Silver Spring MD 20993

**Date:** August 3, 2012  
**To:** Inspector General  
**From:** Acting Associate Commissioner for Policy and Planning  
**Subject:** FDA's General Comment to OIG Draft Report on Dietary Supplements:  
Companies May Be Difficult to Find in an Emergency

FDA is providing the attached general comments to the Office of Inspector General's draft report entitled, *Dietary Supplements: Companies May Be Difficult to Find in an Emergency* (OEI-01-11-00211).

FDA appreciates the opportunity to review and comment on this draft report before it is published.

/S/

David H. Dorsey

Attachment

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## APPENDIX B (CONTINUED)

### **Food and Drug Administration Response to Office of Inspector General Draft Report on Dietary Supplements: Companies May Be Difficult to Find in an Emergency**

The Food and Drug Administration (FDA) welcomes the Office of Inspector General's (OIG) report as a means of calling attention to the challenges the Agency faces with respect to contacting, in the event of an emergency, facilities that manufacture, process, pack, and hold dietary supplements.

As part of its responsibility to protect the public from potential problems or emergencies associated with FDA-regulated products, FDA continues to engage with dietary supplement firms when such emergencies arise. In general, FDA agrees that the Agency's ability to ensure the safety of dietary supplements used by consumers should be improved. FDA's initial response to each of the recommendations is described below.

#### **Response to OIG Recommendations**

##### *Recommendation 1: Improve the Accuracy of the Information in the Registry*

The Agency concurs with this recommendation. Section 415(a)(2) of the Federal Food, Drug, and Cosmetic Act requires registrants to notify FDA in a timely manner of changes to information in the registry. The Food Safety Modernization Act (FSMA) now requires registrants to renew their registration every two years, and FDA expects that this new requirement will improve the accuracy of the information in the registration database. Under FSMA, the first biennial registration renewal period begins in October of 2012. The Agency is preparing updated informational materials and guidance documents related to the registration requirements, including the existing requirement to update the registration when facility information changes as well as the new biennial renewal requirement. The Agency's initial communications plan will include making these materials available to facilities that are required to renew their registration in 2012. The Agency has used registration information in the past to communicate with registered facilities and will consider what testing might be of value after the first renewal period has concluded.

##### *Recommendation 2: Seek Statutory Authority to Impose Civil Monetary Penalties on Companies That Do Not Comply With Registration Requirement*

The Agency concurs with the recommendation to consider seeking this authority. The food safety legislation (H.R. 2749, the "Food Safety Enhancement Act") passed by the House of Representatives in the 111th Congress would have authorized (in section 135) civil monetary penalties for food-related violations of section 301 (prohibited acts) of the Federal Food, Drug, and Cosmetic Act. This language would have authorized, among other things, civil penalties for failure to register food facilities (which includes dietary supplement facilities) and for the introduction or delivery into commerce of any article in violation of the registration requirements. The Administration supported H.R. 2749. However, the 111th Congress chose not to include this additional civil penalty authority

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## APPENDIX B (CONTINUED)

in the food safety legislation ultimately enacted, the "FDA Food Safety Modernization Act" (FSMA), P.L. 111-353.

FSMA did provide enhancements to the registration requirement. For example, it requires facilities to renew their registration (and thus provide updated information) on a biennial basis. This new requirement should improve the accuracy of the information in the registration database. FSMA also authorizes FDA to require additional information about food categories. FDA expects that this information will provide FDA with improved data about the types of foods and ingredients used at the facilities. Further, FSMA provides for the suspension of registration under certain circumstances. If a facility's registration is suspended, no person may introduce into commerce food from that facility. This restriction applies both domestically and to imports from foreign facilities.

Given that Congress recently chose not to provide this additional civil penalty authority when enacting, in FSMA, significant new food safety-related authorities that included these registration enhancements, FDA does not believe it is likely that Congress will provide FDA with such authority, at least in the immediate future.

*Recommendation 3: Educate the Dietary Supplement Industry About Registration and Labeling Requirements*

The Agency concurs with this recommendation. To prepare for the first biennial registration renewal period required by the FSMA, FDA intends to educate industry -- including dietary supplement firms and trade associations -- on the food facility registration requirements. Specifically, we plan to send letters to the trade associations and major trade show providers regarding food facility registration requirements before and during the biennial registration renewal period. Regarding adverse event reporting, in July of 2011, the Office of Food Defense, Communication and Emergency Response and the Office of Nutrition, Labeling and Dietary Supplements produced a handout for industry reminding them of their obligations under the Dietary Supplement and Nonprescription Drug Consumer Protection Act, including the requirement to label products with a domestic phone number or street address for adverse event reporting. This handout is available on FDA's Web site at <http://www.fda.gov/downloads/Food/DietarySupplements/GuidanceComplianceRegulatoryInformation/UCM267417.pdf>, and FDA's Office of Regulatory Affairs provides it to the dietary supplement firms it inspects.

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# Office of Inspector General

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