Guidance for Industry: Questions and Answers Regarding the Labeling of Dietary Supplements as Required by the Dietary Supplement and Nonprescription Drug Consumer Protection Act

Contains Nonbinding Recommendations

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staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the telephone number listed on the title page of this document.

I. Introduction

This document provides guidance to the dietary supplement industry for complying with the labeling requirements prescribed for dietary supplement manufacturers, packers, and distributors by the Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109-462, 120 Stat. 3469). The guidance covers the following topics:

(1) what "domestic address" means for purposes of the dietary supplement labeling requirements in section 403(y) of the Federal Food, Drug, and Cosmetic Act (FD&C Act);

(2) FDA's recommendation for the use of an introductory statement before the domestic address or phone number that is required to appear on the product label under section 403(y);

(3) when FDA intends to begin enforcing the labeling requirements of section 403(y).

FDA's guidance documents, including this document, do not establish legally enforceable responsibilities. Instead, guidance documents describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Background

On December 22, 2006, the President signed into law the Dietary Supplement and Nonprescription Drug Consumer Protection Act. This law amends the FD&C Act with respect to adverse event reporting and recordkeeping for dietary supplements and non-prescription drugs marketed without an approved application. This guidance document contains questions and answers relating to the new labeling requirements for dietary supplements under the Dietary Supplement and Nonprescription Drug Consumer Protection Act.

III. Questions and Answers

1. **What information must be included on the label of a dietary supplement to enable consumers to report serious adverse events associated with the use of the dietary supplement?**

   Section 403(y) of the FD&C Act (21 U.S.C. 343(y)) requires the label of a dietary supplement being marketed in the United States to include "a domestic address or domestic phone number through which the responsible person … may receive a report of a serious adverse event with such dietary supplement." If the label does not include the required domestic address or phone number, the dietary

supplement is misbranded.

When the responsible person chooses to provide a domestic address (rather than a phone number) for adverse event reporting, FDA concludes that the statute requires the product label to bear a full U.S. mailing address that includes the street address or P.O. box, city, state, and zip code of the responsible person (i.e., the manufacturer, packer, distributor, or retailer identified on the dietary supplement label). FDA finds that Congress's use of the term "domestic address" in section 403(y) is a clear and unambiguous directive that dietary supplement labels include all information necessary to enable a serious adverse event report to reach the responsible person. This reading of section 403(y) is supported by dictionary definitions of "address," which include "the indication of destination, as on mail or parcels" and "the location at which a person or an organization may be reached" (**Ref. 1**). Indeed, an address does not serve its intended purpose unless it includes all the information necessary to enable mail to reach its destination.

Similarly, when the responsible person chooses to provide a domestic phone number for adverse event reporting, FDA concludes that the statute requires the phone number on the product label to include an area code (e.g., a toll-free area code such as 800 or a local area code such as 301). Without the area code, the phone number is incomplete and does not serve its intended purpose of enabling the consumer to contact the responsible person to report a serious adverse event.

Congress's use of the phrase "through which the responsible person … may receive a report" to modify "domestic address or domestic phone number" further supports FDA's conclusion that "domestic address or domestic phone number" means a complete address or phone number (see section 403(y) of the FD&C Act (21 U.S.C. 343(y))). This phrase shows Congress's intent that the domestic address or phone number on the label be sufficient to ensure that the responsible person will actually receive the serious adverse event reports that consumers submit. If the address provided on the product label for adverse event reporting is incomplete (e.g., no street address or P.O. box), some of the serious adverse event reports that are submitted to the responsible person by mail likely will not be received. In addition, when consumers notice the incomplete address, they may decide not to submit a report to the responsible person because they believe it will not be received. Similarly, a phone number without an area code would be useless to consumers except for those who happen to be in the same area code as the responsible person.

The use of the term "domestic address" in section 403(y) contrasts with Congress's use of a different term, "place of business," in section 403(e) of the FD&C Act (21 U.S.C. 343(e)). Section 403(e) provides that foods, including dietary supplements, are misbranded unless the product label bears the name and place of business of the manufacturer, packer, or distributor of the food. FDA's regulations interpret "place of business" to require only the firm's city, state, and zip code to appear on the product label, as long as the firm's street address is listed in a current telephone directory or other city directory (21 C.F.R. 101.5(d)). The use of the term "domestic address" in section 403(y) demonstrates Congress's intent to require the responsible person's full address,

including the street address or P.O. box, to appear on dietary supplement labels when the responsible person has opted to receive serious adverse event reports by mail. If Congress had considered the less complete address already required under the "place of business" labeling regulation to be adequate for serious adverse event reporting, there would have been no need to impose a new, more specific requirement in section 403(y) for the responsible person's "domestic address" to appear on dietary supplement labels.

2. **Should the label of a dietary supplement also include language indicating that the purpose of the domestic address or phone number is to report serious adverse events associated with use of the dietary supplement?**

   Although section 403(y) does not require a label to include anything other than a domestic address or domestic phone number for the responsible person, FDA recommends that the label also bear a clear, prominent statement informing consumers that they may report serious adverse events to the domestic address or domestic phone number on the label.

   FDA would have no objection to a firm's combining the recommended statement with language informing consumers that the domestic address or phone number on the label may also be used for other purposes, as long as the information provided is not false or misleading. The responsible person can also clarify that a doctor should be called for medical advice. For example, a multi-purpose label statement might be "You should call your doctor for medical advice about serious adverse events. To report a serious adverse event or obtain product information, contact…" or other similar language.

   Responsible persons may also provide on the product label an email address or website to which reports may be made, provided that such email address or website is in addition to the domestic phone number or domestic address required by Section 403(y) of the FD&C Act (21 U.S.C. 343(y)).

3. **When do the labeling requirements in section 403(y) become effective?**

   Under section 3(d)(2) of the Dietary Supplement and Nonprescription Drug Consumer Protection Act, the labeling requirements of section 403(y) of the FD&C Act apply to all dietary supplements labeled on or after December 22, 2007. Therefore, these labeling requirements are already in effect. However, FDA intends to exercise enforcement discretion for the new labeling requirements until September 30, 2010.

   Congress provided one year after the Dietary Supplement and Nonprescription Drug Consumer Protection Act was signed into law on December 22, 2006, for affected firms to comply with its new requirements. However, due to competing priorities, FDA was not able to consider, develop and finalize guidance on the labeling requirements of Section 403(y) until now. As a result, firms did not have the benefit of FDA's guidance on how to comply with the new labeling requirements when the requirements went into effect. Although the December 2008 revised draft guidance notified industry that the agency intended to exercise enforcement discretion for the new labeling requirements until January 1, 2010, this final guidance sets forth FDA's intention to exercise enforcement discretion for the new labeling requirements for dietary supplements labeled on or after September 30, 2010, approximately one year after this final guidance issues.

This period of enforcement discretion should be adequate to enable all firms to meet the new labeling requirements for dietary supplements. FDA intends to begin enforcing the requirements of 403(y) for dietary supplements labeled on or after September 30, 2010.

IV. Paperwork Reduction Act of 1995

This guidance contains information collection provisions that are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501-3520).

The time required to complete this information collection is estimated to average 8 hours per response, including the time to review instructions, search existing data sources, gather the data needed, and complete and review the information collection. Send comments regarding this burden estimate or suggestions for reducing this burden to:

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Division of Dietary Supplement Programs, HFS-810
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An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control number for this information collection is 0910-0642 (expires 08/31/2012).

References:

1. Webster's II New Riverside University Dictionary (Houghton Mifflin 1984), p.77.

This document supercedes the previous version, issued December 2008.

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