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Food

Dietary Supplement Labeling Guide

April 2005

Guidance for Industry

A Dietary Supplement Labeling Guide

Contains Nonbinding Recommendations.

This document also available en Español (Spanish).[1]

Comments and suggestions regarding this document may be submitted at any time. Submit comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.fda.gov/dockets/ecomments. All comments should be identified with the Docket Number 2004D-0487.

For questions regarding this document contact Susan Thompson at the Center for Food Safety and Applied Nutrition, (Tel) 301 436-1784, (Fax) 301 436-2639,(301) 436-2375 (Updated phone: 240-402-2375).

Additional copies are available from:
Office of Nutritional Products, Labeling and Dietary Supplements
Center for Food Safety and Applied Nutrition, HFS-810
Food and Drug Administration, 5100 Paint Branch Parkway
College Park, MD 20740
http://www.cfsan.fda.gov/guidance.html

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Food Safety and Applied Nutrition (CFSAN)
April 2005

Guidance for Industry[(1)]
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> This guidance represents the Food and Drug Administration's (FDA's) current thinking on the topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

Introduction

The Food and Drug Administration (FDA) receives many questions about the labeling of dietary supplements. These questions are a consequence of the activity in this area over the past several years. Some of the important events relating to the labeling of dietary supplements include:

- The Nutrition Labeling and Education Act of 1990 amended the Federal Food, Drug, and Cosmetic Act (the act) in a number of important ways. Notably, by requiring that most foods, including dietary supplements, bear nutrition labeling.
- The Dietary Supplement Health and Education Act of 1994 (the DSHEA) amended the act, in part, by defining "dietary supplements," adding specific labeling requirements for dietary supplements, and providing for optional labeling statements.
- On September 23, 1997 (62 FR 49826), we implemented the DSHEA by publishing several key regulations on the statement of identity, nutrition labeling, ingredient labeling, and nutrient content and health claims for dietary supplements. On June 5, 1998 (63 FR 30615), we amended the regulations pertaining to the nutrition labeling of extracts used in dietary supplements.
- On January 15, 1997 (62 FR 2218), we published regulations that require a label warning statement on dietary supplements with added iron. These regulations also required the unit-dose packaging of supplements containing 30 milligrams or more, but this requirement has been eliminated as a result of a court challenge in January, 2003.
- On July 11, 2003 (68 FR 41434), we published a final regulation that amended the labeling requirements for dietary supplements, as well as for conventional foods, that would make the declaration of trans fat mandatory in nutrition labeling. This regulation requires that, when present at 0.5 g or more, trans fat be listed in the Supplement Facts panel of dietary supplements on a separate line under the listing of saturated fat by January 1, 2006.

We have prepared this guide to help assure that the dietary supplements sold in the United Stated (U.S.) are properly labeled. This guide applies to dietary supplements produced domestically as well as those produced in foreign countries. Under our regulations, label approval is not required to import or distribute a dietary supplement.

We have included the most frequently raised questions about the labeling of dietary supplements using a "question and answer" format. If you have a question not addressed in this guide, please contact an FDA District Office (see Appendix A of this guide) or the:

Division of Dietary Supplement Programs (HFS-810)
Office of Nutritional Products, Labeling, and Dietary Supplements
Center for Food Safety and Applied Nutrition
Food and Drug Administration
5100 Paint Branch Parkway
College Park, MD 20740-3835
(301) 436-2375 (Updated phone: 240-402-2375)

Please be advised that you must comply with any requirements for dietary supplements that may publish after this booklet is issued. New regulations are published in the Federal Register prior to their effective date and are compiled annually in Title 21, Part 101 of the Code of Federal Regulations (21 CFR 101). Summaries of our new regulations (proposed regulations and final regulations) are posted on our Internet Website (http://www.fda.gov).

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances 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 guidances means that something is suggested or recommended, but not required.

April 2005

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(1) This guidance has been prepared by the Office of Nutritional Products, Labeling and Dietary Supplements (ONPLDS) in the Center for Food Safety and Applied Nutrition (CFSAN) at the U.S. Food and Drug Administration.

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