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Nota di contenuto	DIETMY SUPPLEMENT LABELING COMPLIANCE REVIEW; Contents; I. Introduction; II. Overview of Dietary Supplements Labeling; III. Definitions; IV. Need for Specific Regulations Governing Dietary Supplements; A. Safety of Dietary Supplements; B. New Dietary Ingredients; 1. New Dietary Ingredients; 2. Premarket Notification for a New Dietary Ingredient; V. Outline for Compliance Review of Dietary Supplement Labels; A . Establish Jurisdiction; 1. Dietary Supplement is Subject to the Requirements of the Federal Food, Drug, and Cosmetic Act, as Amended (FD&CA) 2. On Requests for Information on a Label Review and Certificate of Free SaleB. Determine the Completeness and Accuracy of the Required Label Information; C. Determine the Degree of Compliance with Applicable Regulations; D. Advise Responsible Firm of Label(s) Needing Corrections; 1. Untitled Letter; 2. Product Recall; 3. Warning Letter; 4. Seizure; 5. Citation; 6. Prosecution; 7. Injunction; 8. Release with Comment Notices (Import); 9. Detention (Import); VI. Compliance Label Review; A. Identity Statement; 1. Summary of the Requirements for

Dietary Supplements; 2. Questions and Responses

3. Illustrations of the Principal Display Panel4. Identity Labeling Regulations; 5. Flavor Labeling Regulations; B. Designation of Ingredients; 1. Summary of the Requirements for Dietary Supplements; 2. Questions and Responses; 3. Illustrations of the Information Panel; 4. Food: Exemptions from Labeling; C. Name and Place of Business; 1. Summary of the Requirements for Dietary Supplements; 2. Questions and Responses; D. Net Quantity of Contents Statement; 1. Summary of the Requirements for Dietary Supplements; 2. Questions and Responses; E. Nutrition Labeling for Dietary Supplements 1. Summary of the Nutrition Labeling Requirements2. Questions and Responses; 3. Illustrations of Supplement Facts Boxes; (i) Multiple Vitamins; (ii) Multiple Vitamins for Children and Adults; (iii) Multiple Vitamins in Packets; (iv) Dietary Supplement Containing Dietary Ingredients with and without RDIs and DRVs; (v) A Proprietary Blend of Dietary Ingredients; (vi) Dietary Supplement of an Herb; (vii) Dietary Supplement of Amino Acids; (viii) Format Split and Continued to the Right; 4. Daily Values for Nutrition Labeling; 5. Illustration of Format Using Dots 6. Reference Amounts Customarily Consumed Per Eating Occasion for Dietary Supplements7. Rounding Rule Table for Serving Sizes; 8. Nutrition Labeling Exemptions/Special Labeling Provisions; (i) Exemptions under 21 CFR 101.9(j); (ii) Exemptions under 21 CFR 101.36(h); (iii) Special Labeling Provisions under 21 CFR 101.36(i); 9. Type Size Requirements for Nutrition Labeling; 9.1 Illustration of Supplement Facts Box with Arrows Showing Type Size; 10. Rounding Rule Table for Declaring Nutrients; 11. Guidelines for Determining Metric Equivalence of Household Measures; F. Nutrient Content Claims 1. Summary Statements

Sommario/riassunto

Consultant and long-time FDA food and dietary supplement labeling expert James Summers offers a comprehensive guide to understanding and complying with the dietary supplement labeling requirements of the Food and Drug Administration (FDA) in Dietary Supplement Labeling Compliance Review, Third Edition. Available in book or searchable CD-ROM (view CD-ROM version) formats, this updated review is composed of three essential parts: Sections I through V consist of the introduction and how-to information. Sections VI through IX consist of the compliance step-by-
