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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 Requirements 2. 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 Supplements 7. 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

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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-

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