

between 9 a.m. and 4 p.m., Monday through Friday.

1. Committee on the Nutrition Components of Food Labeling, Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, "Nutrition Labeling, Issues and Directions for the 1990's," Washington, DC, National Academy Press, 1990.

2. Park, Y. K., I. Kim, and E. A. Yetley, "Characteristics of Vitamin and Mineral Supplement Products in the United States," *American Journal of Clinical Nutrition*, 54:750-759, 1991.

3. Moss, A. J., A. S. Levy, I. Kim, and Y. Park, "Use of Vitamin and Mineral Supplements in the United States, Current Users, Types of Products and Nutrients, Advance Data from Vital and Health Statistics of the National Center for Health Statistics," No. 174, July 18, 1989.

4. Bender, M. M., A. S. Levy, R. E. Schucker, and E. A. Yetley, "Trends in Prevalence and Magnitude of Vitamin and Mineral Supplement Usage and Correlation with Health Status," *Journal of the American Dietetic Association*, 92:1096-1101, 1992.

5. Levy, A. S. and R. E. Schucker, "Patterns of Nutrient Intake Among Dietary Supplement Users: Attitudinal and Behavioral Correlates," *Journal of the American Dietetic Association*, 87:754-760, 1987.

6. Subcommittee on the 10th Edition of the Recommended Dietary Allowances, Food and Nutrition Board, Commission on Life Sciences, National Research Council, "Recommended Dietary Allowances, 10th ed.," Washington, DC, National Academy Press, 1989.

7. Food and Nutrition Board, Institute of Medicine, National Academy of Sciences, "How Should the Recommended Dietary Allowances Be Revised," Washington, DC, National Academy Press, 1994.

8. U.S. Department of Agriculture and U.S. Department of Health and Human Services, "Nutrition and Your Health, Dietary Guidelines for Americans," Washington, DC, *Home and Garden Bulletin*, 3d ed., U.S. Government Printing Office, 1990.

9. Memorandum from C. E. Brewer, FDA, to file, nutrient content of multinutrient products, March 28, 1994.

10. Committee on Diet and Health, Food and Nutrition Board, Commission on Life Sciences, National Research Council, National Academy of Sciences, "Diet and Health, Implications for Reducing Chronic Disease Risk," National Academy Press, Washington, DC, 1989.

11. Merrill, A. H., Jr., A. Foltz, D. B. McCormick, "Vitamins and Cancer," edited by Alfin-Slater, R. B., and D. Kritchevsky, *Cancer and Nutrition*, pp. 261-320, Plenum Press, New York, 1991.

12. Olson, J. A., "Vitamin A, Retinoids, and Carotenoids," edited by Shils, M. E., J. A. Olson, and M. Shike, *Modern Nutrition in Health and Disease*, pp. 287-307, Lea & Febiger, Philadelphia, 1994.

13. Transcript to Docket 93N-0389 for FDA-initiated public conference on antioxidant vitamins and cancer and cardiovascular disease, November, 1993.

14. McCormick, D. B., "Riboflavin," edited by Shils, M. E., J. A. Olson, and M. Shike,

Modern Nutrition in Health and Disease, pp. 367-375, Lea & Febiger, Philadelphia, 1994.

15. Swendseid, M. E., and R. A. Jacob, "Niacin," edited by Shils, M. E., J. A. Olson, and M. Shike, *Modern Nutrition in Health and Disease*, pp. 376-382, Lea & Febiger, Philadelphia, 1994.

16. Thomas, J. A. "Oxidative Stress, Oxidant Defense, and Dietary Constituents," edited by Shils, M. E., J. A. Olson, and M. Shike, *Modern Nutrition in Health and Disease*, pp. 501-512, Lea & Febiger, Philadelphia, 1994.

17. Turnland, J. R., "Copper," edited by Shils, M. E., J. A. Olson, and M. Shike, *Modern Nutrition in Health and Disease*, pp. 231-241, Lea & Febiger, Philadelphia, 1994.

18. Nielsen, F. H., "Ultratrace Elements," edited by Shils, M. E., J. A. Olson, and M. Shike, *Modern Nutrition in Health and Disease*, pp. 269-286, Lea & Febiger, Philadelphia, 1994.

19. King, J. C., and C. L. Keen, "Zinc," edited by Shils, M. E., J. A. Olson, and M. Shike, *Modern Nutrition in Health and Disease*, pp. 214-230, Lea & Febiger, Philadelphia, 1994.

20. Fairbanks, V. F., "Iron in Medicine and Nutrition," edited by Shils, M. E., J. A. Olson, and M. Shike, *Modern Nutrition in Health and Disease*, pp. 185-213, Lea & Febiger, Philadelphia, 1994.

21. Levander, O. A., and R. F. Burk, "Selenium," edited by Shils, M. E., J. A. Olson, and M. Shike, *Modern Nutrition in Health and Disease*, pp. 242-251, Lea & Febiger, Philadelphia, 1994.

22. U.S. Department of Health and Human Services, "The Surgeon General's Report on Nutrition and Health," DHHS (Public Health Service) Publication No. 88-50210 (Government Printing Office Stock No. 017-001-00465-1), U.S. Government Printing Office, Washington, DC, 1988.

List of Subjects in 21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

2. Section 101.13 is amended by adding new paragraph (b)(6) to read as follows:

§ 101.13 Nutrient content claims—general principles.

* * * * *

(b) * * *

(6) The term "high potency" may only be used on the labels or in the labeling of dietary supplements as defined by

section 201(ff) of the Federal Food, Drug, and Cosmetic Act.

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3. Section 101.54 is amended by revising the section heading and adding new paragraphs (f) and (g) to read as follows:

§ 101.54 Nutrient content claims for "good source," "high," "more," and "high potency."

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(f) "High potency" claims. (1) The term "high potency" may be used on the label or in the labeling of dietary supplements to describe a nutrient that is present at 100 percent or more of the RDI for vitamins and minerals or of the DRV for protein and dietary fiber per reference amount customarily consumed.

(2) The term "high potency" may be used on the label or in the labeling of dietary supplements to describe a product that contains 100 percent or more of the RDI, or of the DRV, for at least two-thirds of the vitamins and minerals, and of the protein and dietary fiber, present in the product (e.g., "High potency multivitamin, multiminer dietary supplement tablets").

(g) "Antioxidants" claims. (1) The term "antioxidants" is defined as a collective term inclusive of vitamin C, vitamin E, and the provitamin beta-carotene when used as part of a nutrient content claim (e.g., "good source of antioxidants," "high in antioxidants") on labels or in labeling of conventional foods or dietary supplements. The levels of vitamin C and vitamin E and the level of vitamin A present as beta-carotene in the food that bears the claim all must be sufficient to qualify for the claim (i.e., for "high in antioxidants," the product must contain 20 percent or more of the RDI for vitamin C and vitamin E per reference amount customarily consumed and 20 percent or more of the RDI for vitamin A must be present as beta-carotene per reference amount customarily consumed).

(2) The term "antioxidants" may only be used on the label or in labeling of a food that does not contain each of the three antioxidants (i.e., vitamin C, vitamin E, and beta-carotene) in sufficient amounts to qualify for the claim if the food contains at least one of these nutrients at the requisite level, and the claim discloses which antioxidants in the food meet the required level (e.g., "High in antioxidant vitamins C and E").

(3) A collective claim about antioxidant nutrients (e.g., "complete antioxidant formula," "antioxidant complex") may be used on the label or in labeling of foods provided that