FOOD LABELING
COMPLIANCE REVIEW

Fourth Edition
James L. Summers is a senior consultant at AAC Consulting Group, Inc., (Rockville, MD), a firm providing consulting services in food, dietary supplement, cosmetics, and other areas that fall under FDA jurisdiction. He is a former FDA food labeling expert with 32 years tenure at FDA. He has held positions as Aquatic Sampling Specialist, Supervisory Microbiologist, Public Health Sanitarian, General Biologist, FDA Inspector, Regional Shellfish Specialist, and Consumer Safety Officer (Division of Regulatory Guidance). His last position with the FDA was as Supervisory Consumer Safety Branch Officer, Branch Chief in the Office of Food Labeling, where he handled the most controversial and precedent-setting problems involving regulatory compliance issues dealing with food labeling. He participated in the development of policies and regulatory strategies regarding the enforcement of NLEA and other food labeling regulations.

Elizabeth J. (Betty) Campbell joined AAC Consulting Group, Inc., (Rockville, MD), as a Senior Food Labeling Consultant after a 35-year career with the FDA where she served as Director of Programs and Enforcement Policy in the Office of Food Labeling in the Center for Food Safety and Applied Nutrition and as Acting Director of the Office of Food Labeling. Ms. Campbell played a key role in writing the Nutrition Labeling and Education Act (NLEA) regulations and had primary responsibility for implementing those regulations.
Contents

I. Introduction
II. Overview of the History of Food Labeling
III. Definitions
IV. Changes in Food Labeling Regulations
   A. Ingredient Labeling
   B. Certified Color Additives
   C. Common or Usual Names for Nonstandardized Foods
      1. Protein Hydrolysates  (21 CFR 102.22)
      2. Beverages that Contain Fruit or Vegetable Juice  (21 CFR 101.30 and 102.23)
   D. Standardized Foods
      2. Special Varieties of Foods  (21 CFR Parts 131 through 169)
   E. Nutrition Labeling
      1. Mandatory Labeling
      2. Nutrition Labeling Exemptions
      3. Nutrient Content Declaration
      4. Nutrition Label Format
      5. Serving Sizes
      6. Daily Values – DRVs and RDIs
      7. Nutrient Content Descriptors
      8. Health Claims
   F. Descriptive Claims: Fresh, Freshly Frozen, Fresh Frozen, Frozen Fresh  (21 CFR 101.95)
   G. Others; Noncertified Color Additives, and Spices and Flavorings
H. Food and Drug Administration Modernization Act (FDAMA) of 1997 (Pub.L.105-115)

V. Outline for Compliance Review

A. Establish Jurisdiction
   1. Food 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 Sale

B. Determine the Completeness and Accuracy of the Required Label Information (21 CFR Part 101)
   1. Identity Statement (21 CFR 101.3)
   3. Ingredient Statement (21 CFR 101.4)
   4. Name and Address of the Place of Business (21 CFR 101.5)
   5. Nutrition Labeling (21 CFR 101.9)

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 Program

A. Identity Statement (21 CFR 101.3)
   1. Summary of the Requirements
   2. Questions and Responses
   3. Illustration VI.A.3 – Principal Display Panel
   4. Regulation VI.A.4 – Foods Named by Use of a Nutrient Content Claim and a Standardized Term (21 CFR 130.10)
   5. Chart VI.A.5 – Categories of Standardized Products (21 CFR Parts 131 through 169)
   7. Chart VI.A.7 – Common or Usual Names for Nonstandardized Foods (21 CFR Part 102)
   8. Regulation VI.A.8 – Identity Labeling of Food in Packaged Form (21 CFR 101.3)
Contents

9. Chart VI.A.9 – Requirements for Foods that Resemble and Substitute for Traditional Foods (21 CFR 101.3(e))


B. Designation of Ingredients (21 CFR 101.4)
   1. Summary of the Requirements
   2. Questions and Responses
   3. Illustrations VI.B.3 – Information Panel
   4. Regulation VI.B.4 – Other Common or Usual Names Specifically Prescribed by Regulations (21 CFR 101.4(b)(3) through (f))

C. Name and Place of Business (21 CFR 101.5)
   1. Summary of the Requirements
   2. Questions and Responses

D. Net Quantity of Contents (21 CFR 101.105)
   1. Summary of the Requirements
   2. Questions and Responses

E. Nutrition Labeling (21 CFR 101.9)
   1. Summary of the Requirements
   2. Questions and Responses
   3. Chart VI.E.3 – Format Style Chart for Nutrition Labeling
   4. Illustrations VI.E.4(i) through (xiii) – Nutrition Facts Box Formats
      (i) Full Vertical Format
      (ii) Full Vertical with Footnote to the Side
      (iii) Full Vertical Dual Declaration
      (iv) Full Vertical Bilingual Label Declaration
      (v) Full Vertical Aggregate Declaration
      (vi) Simplified Vertical Format
      (vii) Shortened Vertical Format
      (viii) Full Tabular Format
      (ix) Tabular Format for Small Packages
      (x) Simplified Tabular Format
      (xi) Linear Formats
      (xii) Format: Food Represented for Children Less Than 2 Years of Age
      (xiii) Format: Food Represented for Children Less Than 4 Years of Age
   5. Chart VI.E.5 – Reference Amounts for Infant and Toddler Foods (21 CFR 101.12, Table 1)
   6. Chart VI.E.6 – Reference Amounts for the General Food Supply (21 CFR 101.12, Table 2)
7. Regulation VI.E.7 – Nutrition Information for Separately Packaged Ingredients/Foods *(21 CFR 101.9(h))*
8. Chart VI.E.8 – Rounding Rule Table for Declaring Nutrients
9. Chart VI.E.9 – Rounding Rule Table for Serving Size
10. Chart VI.E.10 – Nutrition Labeling Summary Sheet
13. Illustration VI.E.13(i) – Illustration of Type and Point Sizes
14. Chart VI.E.13(ii) – Graphic Enhancements Used by FDA

F. Nutrient Content Claims *(21 CFR 101.13)*
   1. Summary Comments
   2. Questions and Responses
   3. Chart VI.F.3 – Definition of Nutrient Content Claims *(21 CFR 101)*
   5. Chart VI.F.5 – Conditions for Use of “Healthy”

   1. Summary Comments
   2. Questions and Responses

H. Statements Made Concerning the Effect of Product on the Structure or Function of the Body
   1. Summary Comments
   2. Regulation VI.H.2 – Notification Procedures for Certain Types of Statements on Dietary Supplements *(21 CFR 101.93(a) through(e))*
   3. Regulation VI.H.3 – Certain Types of Statements for Dietary Supplements *(21 CFR 101.93(f) and (g))*
   4. Regulation VI.H.4 – Other Evidence that the Intended Use of a Product is for the Diagnosis, Cure, Mitigation, Treatment, or Prevention of a Disease *(21 CFR 201.128)*
   5. Chart VI.H.5 – Examples of Disease Claims and Allowable Structure/Function Claims for Dietary Supplements *(21 CFR 101.93 (g))*

I. Authoritative Statements (FDAMA)
   1. Summary Comments
   2. Regulation VI.I.2 – Notifications for Health Claims Based on “Authoritative Statements” *(Proposed 21 CFR 101.90)*
Contents


4. Statements VI.I.4 – Allowable Authoritative Statements by Action of the Status

J. Labeling of Foods in Special Categories (21 CFR 105)
   1. Foods for Special Dietary Uses (21 CFR Part 105)
   2. Questions and Responses
   4. Infant Formula (Infant Formula Act)
   5. Restaurant Foods (21 CFR 101.10)
   6. Dietary Supplements (Not Included)

VII. Administrative Rules, Decisions, and Special Labeling Requirements
   A. Salt and Iodized Salt (21 CFR 100.155)
   B. Fresh, Freshly Frozen, Fresh Frozen, Frozen Fresh (21 CFR 101.95)
   C. Natural (FR., Vol. 58, 1/6/93, p. 2407)
   D. Organic (FR., Vol. 58, 1/6/93, p. 2408)

VIII. Exemptions from FDA Requirements for Foods
   A. Procedures for Requesting Variations and Exemptions from Required Label Statements (21 CFR 1.23)
   B. Exemptions from Required Label Statements (21 CFR 1.24)
   C. Petitions Requesting Exemption from Preemption for State or Local Requirements (21 CFR 100.1)
   D. Exemptions when it is Technologically Impracticable to Nutrition Label (21 CFR 101.9 (g)(9))
   E. Nutrition Labeling of Food: Exemptions/Special Labeling Provisions (21 CFR 101.9(j))
   F. Food: Exemptions from Labeling (21 CFR 101.100)
   G. Temporary Exemption for Purposes of Conducting Authorized Food Labeling Experiments (21 CFR 101.108)
   H. Temporary Permits for Interstate Shipment of Experimental Packs of Food Varying from the Requirements of Definitions and Standards of Identity (21 CFR 130.17)

IX. Compliance Provisions
   A. Failure to Reveal Material Facts (21 CFR 1.21)
   B. Misleading Containers (21 CFR 100.100)
   C. Food with a Label Declaration of Nutrients (21 CFR 101.9(g))
   D. Food Subject to Nutrition Labeling (21 CFR 101.9(k))
   E. Food: Prominence of Required Statements (21 CFR 101.15)
   F. Misbranding of Food (21 CFR 101.18)
G. Substantial Compliance of Food Retailers with the Guidelines for the Voluntary Nutrition Labeling of Raw Fruits, Vegetables, and Fish (21 CFR 101.43)

X. Special Food Labeling Issues
   A. Food Allergy
      1. Summary Comments
      2. Compliance Policy Guide
   B. Food Bioengineering
      1. Summary Comments
      2. Guidance for Industry
   C. Botanical and Other Novel Ingredients in Conventional Foods
      1. Summary Comments
      2. Letter to Manufacturers

XI. Charts/Illustrations/Statements/Regulations
XII. Index to the January 6, 1993 Federal Register Preamble and the Final NLEA Regulations (FR., Vol. 58, 1/6/93)
XIII. Index for Food Labeling Technical Amendments; August 18, 1993 (FR., Vol. 58, 8/18/93, 44020-44096)
XIV. Table of Contents for Chapter 5 – Foods, Colors, and Cosmetics for the Compliance Policy Guide
XV. Table of Contents for “Food Labeling Questions and Answers for Guidance” to Facilitate the Process of Developing or Revising Labels for Foods Other than Dietary Supplements, August 1993
XVI. Table of Contents for “Food Labeling Questions and Answers”, Volume II, A Guide for Restaurants and Other Retail Establishments, August 1995

Index
Bibliography
Preface

The “Food Labeling Compliance Review” manual is a comprehensive compliance food labeling guide designed to aid in understanding the requirements of the Food and Drug Administration (FDA) as it relates to foods other than dietary supplements. This invaluable tool can assist regulatory officials, industry personnel, and others responsible for assuring that the label and labeling of food products in interstate commerce comply with the requirements of the Federal Food, Drug, and Cosmetic Act, as amended, and its regulations.

The manual, authored by James L. Summers, former FDA food labeling expert in the Office of Food Labeling, is a practical, hands-on, user-friendly tool that contains information based on provisions published in the Federal Food, Drug, and Cosmetic Act, as amended; the regulations issued under the act; and FDA’s policies and interpretations.

Disclaimer

The information contained in this manual is accurate to the best of the author’s knowledge. However, laws, regulations, policies, and official interpretations are subject to change. Since conditions under which the information presented in this manual is used are beyond the control of the author and publisher, we assume no responsibility for the usage of this information. Therefore, no expressed or implied warranty or guarantee should be construed from the content of this manual or its periodic revisions.

Acknowledgement

The publication is dedicated to my devoted wife, Annie B., and my three daughters, Vilecia C., Kiea Y., and Narvia M. Summers.

Special thanks are also given to: Nannie Rainey for her technical and editorial writing skills, and Edward A. Steele and Elizabeth J. Campbell of AAC Consulting Group, Inc. for their significant contribution toward bringing this project to a successful conclusion.
Chapter I
Introduction

The mission of the Food and Drug Administration (FDA) is to enforce laws enacted by the U.S. Congress and regulations promulgated by the Agency to protect the consumer’s health, safety, and pocketbook.

The Federal Food, Drug, and Cosmetic Act (FDCA) is the basic food and drug law of the United States. With numerous amendments, it is the most extensive law of its kind in the world. Many of the individual States have laws similar to the Federal law, and some have provisions to automatically add any new Federal regulations established under it.

The FDCA is intended to assure the consumer that foods are pure and wholesome, safe to eat, and produced under sanitary conditions, and that all labeling and packaging is truthful, informative, and not deceptive. Other acts concerned with the labeling of food products are the Fair Packaging and Labeling Act (FPLA), which affects the content and placement of information required on the packaging, and the Nutrition Labeling and Education Act of 1990 (NLEA), that amended the FDCA and requires nutrition labeling for most foods. The NLEA also authorizes the use of nutrient content claims and appropriate FDA-approved health claims on the label and labeling of food products.

The purpose of the NLEA is simple: to clear up the confusion that has prevailed on supermarket shelves for years, to help consumers choose more healthful diets, and to offer an incentive to food companies to improve the nutritional qualities of their products. The implementation of the NLEA has been described as embodying “sweeping reform,” “a major overhaul,” or “revolutionary change” in the food label. The enactment of the NLEA fundamentally altered the governing philosophy and legal rules of the game for providing health-related information on food labels. In a speech, Michael Taylor, then Deputy Commissioner for Policy at FDA, stated that “the fundamental philosophical and legal shift embodied in the NLEA...is that a major share of the discretion previously enjoyed by food marketers in deciding the appropriate use of various nutrient descriptors and claims has been transferred from the food companies to FDA. This is the core, unavoidable legal reality of NLEA. Henceforth, the presence of nutrition labeling on packaged foods will not be left to the discretion of the food company. It will be mandatory.”

The FDCA prohibits the distribution within or importation into the United States of articles that are adulterated or misbranded. The term “adulterated” refers to products that are defective, unsafe, filthy, or produced under unsanitary conditions, but also includes economic adulteration which would involve product labeling. “Misbranding” includes statements, designs, or pictures in labeling that are false or misleading, as well as failure to provide required information on the label or in labeling.

FDA is responsible for protecting the integrity of the food label. The Agency has advised that it intends to evaluate any health claims that appear in labeling on a case-by-case-basis, and that it is prepared to take action against products that make false or misleading health claims.