# TABLE OF CONTENTS

## CHAPTER 1
**FOOD LABELING INTRODUCTION**

I. HISTORICAL OVERVIEW 1-1
II. GOVERNING LAWS 1-2
   a. Federal Laws 1-2
   b. State Laws 1-2
III. REGULATORY AUTHORITIES 1-3
   a. FDA 1-3
   b. USDA 1-3
   c. Customs 1-4
   d. FTC 1-4
IV. SCOPE 1-4

## CHAPTER 2
**OVERVIEW OF LABELING REQUIREMENTS**

I. GENERAL MISBRANDING PROVISIONS 2-1
II. SPECIFIC MISBRANDING PROVISIONS 2-1
   a. Foods Regulated By FDA 2-1
   b. Foods Regulated By USDA 2-2
III. NATIONAL UNIFORMITY IN FOOD LABELING 2-3
IV. TERMINOLOGY 2-3
   a. “Package” 2-3
   b. “Label” And “Labeling” 2-3
   c. “Principal Display Panel” 2-4
   d. “Information Panel” 2-4
V. PLACEMENT OF LABEL INFORMATION 2-4
VI. ENGLISH AND FOREIGN LANGUAGES 2-5
    EXEMPTIONS 2-6

## CHAPTER 3
**STATEMENT OF IDENTITY**

I. ELEMENTS OF THE STATEMENT OF IDENTITY 3-1
   a. Standards Of Identity And Common Or Usual Names 3-1
      i. Standard of Identity Regulations 3-2
      ii. Common or Usual Name Regulations and Guidance 3-2
   II. LABEL PRESENTATION 3-3
   III. OPTIONAL FORMS 3-4
   IV. “IMITATION” LABELING 3-4
CHAPTER 4
NET CONTENTS LABELING

I. ELEMENTS OF THE NET CONTENTS DECLARATION 4-1
   a. What Must Be Declared? 4-1
   b. Avoirdupois And Metric Declarations—Both Typically Required 4-2
   c. Largest Appropriate Unit of Measure Must Be Used 4-2
   d. Dual Avoirdupois Declaration 4-2
   e. Multiunit Retail Packages 4-3
   f. Prefatory Language 4-4
   g. Abbreviations 4-4
   h. Qualifying Language 4-4
   i. Supplemental Statements 4-4
   j. Miscellaneous Exceptions 4-4

II. LABEL PRESENTATION 4-5
   a. Placement On PDP 4-5
   b. Mandatory Separation From Other Information 4-6
   c. Type Style And Size 4-6

III. NET CONTENTS COMPLIANCE 4-7
   a. “Accurate” Declaration Is Required 4-7
   b. Largest Declared Value Used for Compliance 4-7

CHAPTER 5
NUTRITION LABELING

I. ELEMENTS OF NUTRITION LABELING 5-1
II. LABEL PRESENTATION 5-1
III. RDIS, DRVS, AND DVS 5-1
IV. SERVING SIZES 5-3
   a. Reference Amounts 5-3
      i. General 5-3
      ii. Products Requiring Cooking or Addition of Ingredients 5-3
      iii. Imitation, Substitute, or Altered Foods 5-4
      iv. Whipped/Aerated Foods 5-4
      v. Foods Packaged and Presented to Be Consumed Together 5-4
      vi. Nutrient Content And Health Claim Eligibility Based on Reference Amounts 5-4
   b. Determining Label Serving Sizes From Reference Amounts 5-5
      i. Label Serving Size Must Be Based on Relevant Reference Amount 5-5
      ii. Products in Discrete Units 5-5
      iii. Products in Discrete Units That Naturally Vary in Size 5-5
      iv. Products in Large Discrete Units Usually Divided for Consumption 5-5
      v. Nondiscrete Bulk Products 5-6
      vi. Products Requiring Further Preparation Before Consumption 5-6
      vii. Single-Serving Containers 5-7
      viii. “Meal Products” and “Main Dish Products” 5-7
<table>
<thead>
<tr>
<th>Section</th>
<th>Title</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ix</td>
<td>Variety Packs and Products with Multiple Compartments Containing</td>
<td>5-7</td>
</tr>
<tr>
<td></td>
<td>Different Foods</td>
<td></td>
</tr>
<tr>
<td>x</td>
<td>Variety and Assortment Foods to Be Used as Gifts</td>
<td>5-7</td>
</tr>
<tr>
<td>xi</td>
<td>Limited Availability Weight Control Foods</td>
<td>5-7</td>
</tr>
<tr>
<td>xii</td>
<td>Raw Fruits and Vegetables</td>
<td>5-8</td>
</tr>
<tr>
<td>V</td>
<td>EXPRESSION OF SERVING SIZE</td>
<td>5-8</td>
</tr>
<tr>
<td>a</td>
<td>Parenthetical Metric Declaration — Generally Required</td>
<td>5-8</td>
</tr>
<tr>
<td>b</td>
<td>“Common Household Measure” Or “Common Household Unit”</td>
<td>5-8</td>
</tr>
<tr>
<td>c</td>
<td>Hierarchy Of Household Measures</td>
<td>5-8</td>
</tr>
<tr>
<td>d</td>
<td>Household Measure — “Piece”</td>
<td>5-9</td>
</tr>
<tr>
<td>e</td>
<td>Optional Parenthetical Declaration In Oz And Fl Oz</td>
<td>5-9</td>
</tr>
<tr>
<td>f</td>
<td>Optional Clarifying Phrases</td>
<td>5-9</td>
</tr>
<tr>
<td>g</td>
<td>Calculating Percent Of Reference Amount From Net Weight Of Package</td>
<td>5-9</td>
</tr>
<tr>
<td>h</td>
<td>Rounding Of Serving Sizes</td>
<td>5-9</td>
</tr>
<tr>
<td>VI</td>
<td>SERVINGS PER CONTAINER</td>
<td>5-10</td>
</tr>
<tr>
<td>a</td>
<td>Determining Number Of Servings</td>
<td>5-10</td>
</tr>
<tr>
<td>VII</td>
<td>ADDITIONAL DECLARATIONS</td>
<td>5-10</td>
</tr>
<tr>
<td>a</td>
<td>Voluntary Secondary Nutrition Labeling On “As Prepared” Basis</td>
<td>5-10</td>
</tr>
<tr>
<td>b</td>
<td>Optional Declaration Of Nutrition Information Per 100 g, 100 mL, Etc.</td>
<td>5-10</td>
</tr>
<tr>
<td>c</td>
<td>Mandatory Secondary Nutrition Labeling Requirement For Promoted Product</td>
<td>5-11</td>
</tr>
<tr>
<td></td>
<td>Uses That Differ Significantly From Reference Amount</td>
<td></td>
</tr>
<tr>
<td>d</td>
<td>Dual Column for Products Packaged and Sold Individually that Contain</td>
<td>5-11</td>
</tr>
<tr>
<td></td>
<td>at Least 200% and Up To and Including 300% of the Applicable Reference</td>
<td></td>
</tr>
<tr>
<td>e</td>
<td>Nutrient Content Claims And Products Containing At Least 200% And Up To</td>
<td>5-11</td>
</tr>
<tr>
<td></td>
<td>An Including 300% Of The Applicable Reference Amount</td>
<td></td>
</tr>
<tr>
<td>f</td>
<td>NUTRIENTS AND OTHER INFORMATION TO BE DECLARED</td>
<td>5-12</td>
</tr>
<tr>
<td>a</td>
<td>Servings Per Container</td>
<td>5-12</td>
</tr>
<tr>
<td>b</td>
<td>Serving Size</td>
<td>5-12</td>
</tr>
<tr>
<td>c</td>
<td>“Calories”; “Calories, Total”; Or “Total Calories”</td>
<td>5-12</td>
</tr>
<tr>
<td>d</td>
<td>“Calories From Saturated Fat”</td>
<td>5-13</td>
</tr>
<tr>
<td>e</td>
<td>“Total Fat” Or “Fat, Total”</td>
<td>5-13</td>
</tr>
<tr>
<td>f</td>
<td>“Cholesterol”</td>
<td>5-13</td>
</tr>
<tr>
<td>g</td>
<td>“Sodium”</td>
<td>5-13</td>
</tr>
<tr>
<td>h</td>
<td>“Fluoride”</td>
<td>5-13</td>
</tr>
<tr>
<td>i</td>
<td>“Total Carbohydrate” Or “Carbohydrate, Total”</td>
<td>5-14</td>
</tr>
<tr>
<td>j</td>
<td>“Dietary Fiber”</td>
<td>5-14</td>
</tr>
<tr>
<td>k</td>
<td>“Soluble Fiber”</td>
<td>5-14</td>
</tr>
<tr>
<td>l</td>
<td>“Insoluble Fiber”</td>
<td>5-14</td>
</tr>
<tr>
<td>m</td>
<td>“Sugars”</td>
<td>5-15</td>
</tr>
<tr>
<td>n</td>
<td>“Added Sugars”</td>
<td>5-15</td>
</tr>
<tr>
<td>o</td>
<td>“Sugar Alcohol”</td>
<td>5-18</td>
</tr>
<tr>
<td>p</td>
<td>“Protein”</td>
<td>5-18</td>
</tr>
<tr>
<td>q</td>
<td>Vitamins And Minerals</td>
<td>5-19</td>
</tr>
<tr>
<td>r</td>
<td>Additional Declarations — Prohibited</td>
<td>5-19</td>
</tr>
</tbody>
</table>
# TABLE OF CONTENTS

## VIII. NUTRITION FACTS’ FORMAT & GRAPHICS

a. Graphic Specifications 5-20
   i. Hairline Box 5-20
   ii. Type Style and Size Requirements 5-20
   iii. Lines, Bars and Spaces 5-21
   iv. Bolding Requirements 5-22
   v. “Reverse Type” — Discouraged 5-23
   vi. Voluntary Highlighting — Prohibited 5-23
   vii. Stacked Titles 5-23
   viii. %DV Footnote 5-23
   ix. Caloric Conversion Footnote 5-23

b. Format 5-23
   i. Standard Format 5-23
   ii. Simplified Format 5-26
   iii. Shortened Format 5-26

c. Display Option 5-26
   i. Full Display 5-26
   ii. Tabular Display 5-26
   iii. Linear Display 5-26

d. Abbreviations 5-29

e. Dual Declarations 5-29

f. Supplementary Nutrition Information – Use of Graphic Devices 5-32

g. Small Packages 5-32

## IX. EXEMPTIONS AND PRODUCTS SUBJECT TO SPECIAL REQUIREMENTS 5-33

a. Products Not Offered For Sale 5-33

b. Exemptions May Be Lost 5-33

c. Small Retail Business 5-33

d. Low-Volume Products Of Small Businesses 5-33

e. Foods For Immediate Human Consumption 5-33

f. Food Service Foods 5-33

g. “Cash-And-Carry” Stores 5-34

h. Ready-To-Eat Take-Out Foods 5-34

i. Foods That Contain Insignificant Amounts Of All Nutrients 5-34

j. Foods For Infants And Young Children 5-34

k. Bulk Foods Intended For Further Manufacturing, Processing, Labeling, Or Repacking 5-35

l. Shell Eggs 5-35

m. Multiunit Retail Food Packages 5-35

n. Food Products Sold From Bulk Containers 5-35

o. Small Packages 5-35


q. Game Meats 5-36

r. Products With Separately-Packaged Ingredients 5-36

s. Variety Packs 5-36

t. Assortments Of Food In A Gift Package 5-37

## XI. COMPLIANCE ISSUES 5-37
TABLE OF CONTENTS

a. Sampling 5-37
b. Permitted Variations 5-37
c. Analytical Procedures 5-37
d. Factors Considered 5-38
e. Databases 5-38
f. Alternate Means Of Compliance And Exemptions 5-38
g. Nutrition Label Accuracy 5-38
h. Records 5-38

XII. VOLUNTARY NUTRITION LABELING OF RAW FRUITS, VEGETABLES, AND SEAFOOD 5-39
a. Scope Of The Voluntary Nutrition Labeling Guidelines 5-39
b. Provisions Of The Guidelines 5-40
c. Substantial Compliance By Retailers 5-40

CHAPTER 6

DECLARATION OF INGREDIENTS

I. ELEMENTS OF THE INGREDIENTS DECLARATION 6-1
a. General Rule 6-1
b. Special Rules 6-1
   i. “Contains ___% or Less” 6-1
   ii. Spices 6-1
   iii. Flavors 6-1
   iv. Colors 6-2
   v. Composite Foods Used as Ingredients 6-3
   vi. Class Names 6-3
   vii. Water for Reconstitution 6-4
   viii. “And/Or” Labeling 6-4
      1. Fats and Oils 6-5
      2. Leavening Agents, Yeast Nutrients, Dough Conditioners, and Firming Agents 6-5
      3. Fish Species Used in Surimi 6-5
   ix. Chemical Preservatives 6-6
   x. Protein Hydrolysates 6-6
   xi. Caseinates 6-6
   xii. Wax and Resin Coatings on Fresh Produce 6-6
   xiii. GRAS and Food Additive Regulations 6-6
   xiv. Special Requirements for Certain Standardized Foods 6-7
   xv. Label Declaration of Optional Ingredients for Standardized Foods 6-7
   xvi. Exemption — Incidental Additives 6-7
   xvii. Assortments 6-8
   xviii. Bulk Foods 6-8
   xix. Source of Certain Ingredients 6-8
I. LABEL PRESENTATION 6-8
II. ALLERGENS

CHAPTER 7
SIGNATURE LINE

I. ELEMENTS OF THE SIGNATURE LINE
   a. Identification Of Responsible Party
   b. Relation To The Food
   c. Statement Of Place Of Business

II. LABEL PRESENTATION

III. INTERACTION WITH COUNTRY OF ORIGIN MARKING

CHAPTER 8
NUTRIENT CONTENT CLAIMS AND OTHER DESCRIPTIVE TERMS —
“FRESH,” “NATURAL,” “ORGANIC,” “GMO FREE,” “PASTEURIZED,”
“NO MSG,” AND “GLUTEN FREE”

I. NUTRIENT CONTENT CLAIMS – GENERAL SCOPE
   a. What Is A Nutrient Content Claim?
      i. “Expressed” Nutrient Content Claims
      ii. “Implied” Nutrient Content Claims
      iii. Factual Statements About Nutrient Content
   b. What Is Not A Nutrient Content Claim?
   c. Other Exemptions

II. PERMITTED NUTRIENT CONTENT CLAIMS
   a. Claims Authorized By FDA Regulation
      i. Defined Nutrient Content Claims and Synonyms
      ii. Variant Spellings
      iii. Approval of New Nutrient Content Claims or Synonyms
          1. Petition for a New Nutrient Content Claim
          2. Petition for a Synonym
          3. Petition for Use of an Implied Claim in a Brand Name
          4. Public Disclosure
   b. Claims Reflecting Authoritative Scientific Statements

III. CLAIMS APPROVED BY FDA REGULATION — GLOBAL PROVISIONS
   a. General Principles
      i. “Substitute” Food
      ii. “Free” And “Low” Claims
          1. Inherent Nutrient Content Versus Modified Food — Qualification
             May Be Required
          2. Eligibility for “Free” Claims
          3. Permitted Synonyms
      iii. Relative Claims
          1. Reference Foods
          2. Accompanying Information for Relative Claims
3. Permitted Synonyms 8-13
4. “Modified” 8-13
   iv. “Meal Products” and “Main Dish Products” 8-13
v. Compliance 8-13
vi. Nutrition Labeling 8-14
b. Labeling Mechanics 8-14
   i. Typesize and Style of Claim 8-14
   ii. Disclosure Statement 8-14
   iii. Disclaimer Where Claim Eligibility Criteria Are Met Per Reference Amount But Not Per Labeled Serving Size 8-15
   iv. Typesize of Specific Statements Required with Nutrient Content Claims 8-15
IV. CLAIMS AUTHORIZED BY FDA REGULATION — DEFINITIONS AND SPECIFIC ELIGIBILITY REQUIREMENTS 8-16
   a. “High,” “Good Source,” “More,” And “High Potency” Claims 8-16
      i. “High” 8-16
      ii. “Good Source” 8-16
      iii. Meal Products and Main Dish Products 8-16
      iv. Total Carbohydrate — Claims Prohibited 8-16
      v. “More” 8-17
      vi. Dietary Fiber Claims — Fat Disclosure 8-18
      vii. “High Potency” 8-18
   b. Antioxidant Claims 8-18
   c. “Light” And “Lite” Claims 8-19
      i. Unqualified Uses 9-19
      ii. Qualified Uses 8-20
   d. Calorie Content And Sugar Claims 8-20
      i. Calorie Claims 8-20
      ii. Sugar Claims 8-21
         iii. Terms Suggesting Usefulness as Low Calorie or Reduced Calorie Foods 8-22
   e. Sodium Content And Salt Claims 8-22
      i. Sodium Claims 8-22
      ii. Salt Claims 8-23
   f. Fat, Fatty Acid, Cholesterol, Lean, And Trans Fat Claims 8-23
      i. Fat Claims 8-23
      ii. Saturated Fat Claims 8-24
      iii. Cholesterol Claims 8-25
      iv. Lean Claims 8-27
      v. Trans Fat – Claims Not Authorized 8-27
   g. Implied Nutrient Content Claims 8-27
      i. Comparative Nutrient Claims 8-27
      ii. Ingredient Claims 8-27
      iii. General Nutrition Claims 8-27
      iv. “Healthy” 8-28
         1. Definition 8-28
2. Labeling Context 8-30

V. CLAIMS REFLECTING AUTHORITATIVE STATEMENTS — GLOBAL PROVISIONS 8-30

VI. CLAIMS REFLECTING AUTHORITATIVE STATEMENTS — SPECIFIC PERMITTED CLAIMS 8-33
   a. Choline 8-33
   b. Specific Omega-3 Fatty Acids 8-33
   c. Linolenic Acid 8-33

VII. CLAIMS REFLECTING AUTHORITATIVE STATEMENTS — SPECIFIC PROHIBITED CLAIMS 8-34

VIII. RESTAURANT FOOD 8-34

IX. DESCRIPTIVE TERMS 8-35
   a. “Fresh” Claims 8-35
      i. Scope 8-35
      ii. “Fresh” 8-35
      iii. “Fresh Frozen” and “Frozen Fresh” 8-36
      iv. “Freshly Prepared,” “Fresh Squeezed” 8-36
      v. Fresh Ingredients in Processed Foods 8-36
   b. Other Claims 8-36
      i. “Natural” 8-36
      ii. “Organic” 8-37
      iii. “GMO-Free,” “non-Genetically Modified,” and Similar Claims 8-38
      iv. “Pasteurized” 8-39
      v. “No MSG” 8-39
      vi. “Gluten Free” 8-40

LISTS:
   Summary of Nutrient Content Claims for Individual Food Products 8-41
   Summary of Nutrient Content Claims for Meal and Main Dish Products 8-42
   Nutrient Content Claims Synonyms 8-44

CHAPTER 9
MODIFIED STANDARDIZED FOODS 9-1

I. GENERAL REQUIREMENTS AND SCOPE 9-1
   a. Modified Foods That Conform To A Standard Of Identity 9-1
   b. Foods That Qualify As Modified Versions Of More Than One Standardized Food 9-1
   c. Modification Necessary 9-1
   d. Implied Nutrient Content Claims 9-2
   e. Standards Of Identity Using Nutrient Content Claims 9-2
   f. Multiple Claims 9-2
   g. Noncharacterizing Changes In Standardized Foods 9-2
   h. Rule Does Not Encompass Standards Of Quality Or Fill 9-2

II. REQUIREMENTS FOR MODIFIED STANDARDIZED FOODS 9-2
   a. Nutritional Equivalence 9-3
### TABLE OF CONTENTS

b. Performance Characteristics  
   i. Deviations from Non-Ingredient Provisions of Standard 9-3  
   ii. Label Disclosure of Significant Differences in Performance Characteristics 9-3  
   iii. Typesize and Placement 9-3  
c. Ingredients  
   i. Nutrients 9-4  
   ii. Mandatory Ingredients 9=4  
   iii. Prohibited Ingredients 9-4  
   iv. Other Safe and Suitable Ingredients 9-4  
   v. Ingredients Declaration 9-4  
   vi. Water; Fat Analogs 9-5  
   vii. Fats and Fat Analogs in Dairy Products 9-5  
   viii. Flavor Labeling 9-6  

III. SPECIFIC FOODS

#### CHAPTER 10

**HEALTH CLAIMS**

I. GENERAL REQUIREMENTS AND SCOPE 10-1  
      i. Basic Definition 10-1  
      ii. Implied Health Claims 10-2  
         1. Brand Names 10-2  
         2. Third Party References 10-2  
         3. Symbols 10-3  
      i. Drug Claims 10-3  
      ii. Classical Deficiency Disease Claims 10-3  
      iii. “Healthy” 10-3  
      iv. Special Dietary Use Claims 10-4  
      v. General Dietary Guidance 10-4  
      vi. Multiple Use Products 10-4  

II. PERMITTED HEALTH CLAIMS 10-4  
   a. Claims Authorized By FDA Regulation 10-4  
      i. Scientific Standard 10-4  
      ii. Substance Involved 10-5  
      iii. Disease or Health-Related Condition 10-5  
      iv. Petitions for Recognition of New Claims 10-5  
         1. General Requirements’ 10-5  
         2. Summary of Scientific Data 10-5  
         3. Analytical Data 10-6  
         4. Model Health Claim 10-6  
      v. Agency Action 10-6  
      vi. Public Disclosure 10-7  
   b. Claims Reflecting Authoritative Scientific Statements 10-7
<table>
<thead>
<tr>
<th>Topic</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>c. Qualified Health Claims</td>
<td>10-8</td>
</tr>
<tr>
<td>i. Scientific Standard</td>
<td>10-8</td>
</tr>
<tr>
<td>ii. Petitions for Authorization of Qualified Health Claims</td>
<td>10-9</td>
</tr>
<tr>
<td>1. General Requirements</td>
<td>10-8</td>
</tr>
<tr>
<td>2. Procedural Timeline for Qualified Health Claim Petitions</td>
<td>10-9</td>
</tr>
<tr>
<td>iii. FDA Letter of Enforcement Discretion</td>
<td>10-10</td>
</tr>
<tr>
<td>d. Disqualification From Health Claim Eligibility</td>
<td>10-10</td>
</tr>
<tr>
<td>III. CLAIMS APPROVED BY FDA REGULATION — ELIGIBILITY REQUIREMENTS</td>
<td>10-11</td>
</tr>
<tr>
<td>a. Minimum Nutrient Levels</td>
<td>10-11</td>
</tr>
<tr>
<td>b. Required Level Of Nutrient</td>
<td>10-11</td>
</tr>
<tr>
<td>c. General Labeling Requirements</td>
<td>10-11</td>
</tr>
<tr>
<td>i. Consistency with FDA’s Summary</td>
<td>10-11</td>
</tr>
<tr>
<td>ii. Disclosure Statement</td>
<td>10-12</td>
</tr>
<tr>
<td>iii. Location of Required Information</td>
<td>10-12</td>
</tr>
<tr>
<td>iv. Optional General Information</td>
<td>10-12</td>
</tr>
<tr>
<td>IV. CLAIMS APPROVED BY FDA REGULATION — SPECIFIC PERMITTED CLAIMS</td>
<td>10-12</td>
</tr>
<tr>
<td>a. Calcium And Osteoporosis</td>
<td>10-12</td>
</tr>
<tr>
<td>i. Model Claims</td>
<td>10-12</td>
</tr>
<tr>
<td>ii. Requirements</td>
<td>10-13</td>
</tr>
<tr>
<td>b. Sodium And Hypertension</td>
<td>10-13</td>
</tr>
<tr>
<td>i. Model Claims</td>
<td>10-13</td>
</tr>
<tr>
<td>ii. Requirements</td>
<td>10-14</td>
</tr>
<tr>
<td>c. Dietary Lipids (Fat) And Cancer</td>
<td>10-14</td>
</tr>
<tr>
<td>i. Model Claims</td>
<td>10-14</td>
</tr>
<tr>
<td>ii. Requirements</td>
<td>10-14</td>
</tr>
<tr>
<td>d. Dietary Saturated Fa and Cholesterol And Risk of Coronary Heart Disease</td>
<td>10-15</td>
</tr>
<tr>
<td>i. Model Claims</td>
<td>10-15</td>
</tr>
<tr>
<td>ii. Requirements</td>
<td>10-15</td>
</tr>
<tr>
<td>e. Fiber-Containing Grain Products, Fruits and Vegetables And Cancer</td>
<td>10-16</td>
</tr>
<tr>
<td>i. Model Claims</td>
<td>10-16</td>
</tr>
<tr>
<td>ii. Requirements</td>
<td>10-16</td>
</tr>
<tr>
<td>f. Fruits, Vegetables and Grain Products that Contain Fiber,</td>
<td>10-16</td>
</tr>
<tr>
<td>Particularly Soluble Fiber, and Risk of Coronary Heart Disease</td>
<td>10-16</td>
</tr>
<tr>
<td>i. Model Claims</td>
<td>10-16</td>
</tr>
<tr>
<td>ii. Requirements</td>
<td>10-17</td>
</tr>
<tr>
<td>g. Fruits And Vegetables And Cancer</td>
<td>10-17</td>
</tr>
<tr>
<td>i. Model Claims</td>
<td>10-17</td>
</tr>
<tr>
<td>ii. Requirements</td>
<td>10-18</td>
</tr>
<tr>
<td>h. Folate And Neural Tube Defects</td>
<td>10-18</td>
</tr>
<tr>
<td>i. Model Claims</td>
<td>10-18</td>
</tr>
<tr>
<td>ii. Requirements</td>
<td>10-19</td>
</tr>
<tr>
<td>iii. Food Fortification Requirements/Limitations</td>
<td>10-19</td>
</tr>
<tr>
<td>i. Dietary Noncariogenic Carbohydrate Sweeteners And Dental Caries</td>
<td>10-20</td>
</tr>
<tr>
<td>i. Model Claims</td>
<td>10-20</td>
</tr>
</tbody>
</table>

x
ii. Requirements 10-21

j. Soluble Fiber From Certain Foods And Risk of Coronary Heart Disease 10-21
   i. Model Claims 10-21
   ii. Requirements 10-22
   iii. Label Statement of Eligibility Criteria 10-22
   iv. Psyllium Husk-Containing Foods — Notice Statement 10-22

k. Soy Protein and Coronary Heart Disease 10-23
   i. Model Claims 10-23
   ii. Requirements 10-23
   iii. Methodology 10-24
   iv. Food Substance 10-24
   v. Records 10-24

l. Plant Sterol/Stanol Esters and Coronary Heart Disease 10-24
   i. Model Claims 10-24
      1. Plant sterol esters 10-25
      2. Plant stanol esters 10-25
   ii. Requirements 10-25
   iii. Substance 10-26

V. CLAIMS PROHIBITED BY FDA REGULATION 10-27
   a. General 10-27
   b. Specific Claims 10-27

VI. CLAIMS REFLECTING AUTHORITATIVE STATEMENTS — GLOBAL PROVISIONS 10-27

VII. CLAIMS REFLECTING AUTHORITATIVE STATEMENTS — SPECIFIC PERMITTED CLAIMS 10-30
   a. Whole Grain Foods/Heart Disease and Certain Cancers 10-30
      i. Claim 10-30
      ii. Requirements 10-30
      iii. Authoritative Source 10-30
   b. Potassium-Containing Foods/High Blood Pressure and Stroke 10-31
      i. Claim 10-31
      ii. Requirements 10-31
      iii. Authoritative Source 10-31
   c. Fluoridated Water and Reduced Risk of Dental Caries 10-32
      i. Claim 10-32
      ii. Requirements 10-32
      iii. Authoritative Source 10-32
   d. Saturated Fat, Cholesterol, and Trans Fat, and the Risk of Heart Disease 10-32
      i. Claim 10-32
      ii. Requirements 10-32
      iii. Authoritative Source 10-32
   e. Substitution of Saturated Fat with Unsaturated Fatty Acids and Risk of Heart Disease 10-33
      i. Claim 10-33
      ii. Requirements 10-33
      iii. Authoritative Source 10-33
VIII. CLAIMS REFLECTING AUTHORITATIVE STATEMENTS —
SPECIFIC PROHIBITED CLAIMS 10-33
IX. QUALIFIED HEALTH CLAIMS – CLAIMS AUTHORIZED BY FDA 10-34
a. Cancer-Related Claims 10-34
   i. Tomatoes and Prostate, Ovarian, Gastric, and Pancreatic Cancers 10-34
   ii. Green Tea and Breast and Prostate Cancers 10-35
b. Claims Concerning Cardiovascular Disease 10-35
   i. Monounsaturated Fats from Olive Oil and CHD 10-35
   ii. Unsaturated Fatty Acids from Canola Oil and Reduced Risk of Coronary Heart Disease 10-37
   iii. Corn Oil and Corn Oil-Containing Products and a Reduced Risk of Heart Disease 10-38
   iv. Soybean Oil and Reduced Risk of Coronary Heart Disease 10-40
   v. EPA and DHA Omega-3 Fatty Acids and CHD 10-44
      1. Claim Wording 10-41
      2. Requirements for Use of the Claim for Conventional Foods 10-41
      3. Safety Requirements 10-42
   vi. Walnuts and CHD 10-43
   vii. Certain Other Nuts and CHD 10-44
   viii. Macadamia Nuts and Reduced Risk of CHD 10-44
c. Claims Concerning Diabetes 10-45
   i. High-Amylose Maize Starch (Containing Type-2 Resistant Starch) and Reduced Risk Type 2 Diabetes Mellitus 10-45
   ii. Psyllium Husk to Reduce the Risk of Type 2 Diabetes Mellitus 10-45
   iii. Whole Grains and Reduced Risk of Diabetes Mellitus Type 2 10-56
d. Claims Concerning Peanut Allergy 10-47
X. QUALIFIED HEALTH CLAIMS – CLAIMS NOT AUTHORIZED BY FDA 10-48
XI. RESTAURANT FOOD 10-49

SUMMARY OF APPROVED AND PROHIBITED HEALTH CLAIMS 10-49

CHAPTER 11
STRUCTURE/FUNCTION CLAIMS

I. STRUCTURE/FUNCTION CLAIMS DIFFERENTIATED FROM DISEASE/DRUG CLAIMS 11-1
II. STRUCTURE/FUNCTION CLAIMS FOR CONVENTIONAL FOODS MUST BE BASED ON NUTRITIVE VALUE 11-3
III. SUBSTANTIATION 11-4

CHAPTER 12
FLAVOR LABELING

I. REPRESENTATION OF CHARACTERIZING FLAVOR 12-1
II. “NATURAL FLAVOR” AND “ARTIFICIAL FLAVOR” 12-2
CHAPTER 13
JUICE

I. PERCENT JUICE DECLARATION 13-1
   a. Scope 13-1
      i. General 13-1
      ii. Wine Coolers and Fruit-Flavored Soft Drinks 13-1
      iii. Exemption for “Flavored” Products with Minor Amounts of Juice 13-1
      iv. Products with No Juice 13-2
      v. Dehydrated Juices 13-2
   b. Elements Of The Percent Juice Declaration 13-2
      i. Total Percent Juice Declaration Required 13-2
      ii. Non-Juice Ingredients in “100% Juice” Products 13.2
      iii. Juice Not from Concentrate 13-3
      iv. Juice from Concentrate 13-3
      v. Brix Calculation for Citrus Juices 13-3
      vi. Brix Calculation for Juices with Added Sweeteners 13-3
      vii. Modified Juices 13-3
      viii. Reduced-Sugars Juices 13-3
      ix. Alternate Percent Fruit Content Declaration for Nectars 13-4
   c. Label Presentation 13-4
      i. Placement And Prominence 13-4
      ii. Optional Declaration On PDP 13-4
   d. Prohibition On Other Percentage Declarations 13-4

II. COMMON OR USUAL NAMES FOR JUICES AND DILUTED JUICE BEVERAGES 13-4
   a. Qualifying Term Required For Diluted Juice Beverages 13-4
   b. Order Of Juices In Common Or Usual Name 13-5
   c. Nonrepresented Juices 13-5
   d. Modified Juices 13-5
   e. Reconstituted Products — “From Concentrate” Required 13-6
   f. Use Of Dehydrated Ingredients 13-6
   g. Vegetable Cocktail Products 13-6
   h. Vignettes 13-7

III. WARNING STATEMENT REQUIRED FOR SOME JUICE PRODUCTS 13-7

CHAPTER 14
WARNING AND NOTICE STATEMENTS

I. PRODUCT-SPECIFIC STATEMENTS 14-1
   a. Protein Products 14-1
   b. Self-Pressurized Containers 14-2
   c. Food Containing Or Manufactured With A Chlorofluorocarbon Or Other Ozone-Depleting Substance 14-2
   d. Juice Beverages That Are Not Specifically Processed To Control Pathogenic Microorganisms 14-2
TABLE OF CONTENTS

e. Shell Eggs 14-3
f. Irradiated Foods 14-3
g. Safe Handling Instructions — Foods Needing Refrigeration 14-4

II. INGREDIENT-SPECIFIC STATEMENTS 14-5
a. Aspartame 14-5
b. Sorbitol 14-5
c. Mannitol 14-5
d. Psyllium Husk 14-5

CHAPTER 15
STATEMENTS OF GEOGRAPHIC ORIGIN—COUNTRY OF ORIGIN MARKING/“MADE IN THE U.S.A.”

I. COUNTRY OF ORIGIN MARKING 15-1
a. Customs Regulations 15-1
   i. Elements Of Country Of Origin Marking 15-1
   ii. Label Presentation 15-2
   iii. Need To Provide Country Of Origin Information To Retail Consumers 15-2
   iv. Special Marking Rules 15-3
      1. NAFTA Language Rule 15-3
      2. Major Supplier Marking of Imported Juice Concentrates 15-3
b. USDA Regulations 15-4
   i. Establishments Subject to COOL Requirements 15-4
   ii. Covered Commodities 15-4
   iii. Labeling Requirements 15-5
      2. Ground Meat: Chicken, Lamb, and Goat 15-5
      4. Fish & Shellfish 15-6
   iv. Supplier Responsibility 15-6
   v. Records Retention 15-7
II. “MADE IN THE U.S.A.”- TYPE LABEL STATEMENTS 15-8
III. OTHER GEOGRAPHICAL REPRESENTATIONS IN LABELING 15-9

CHAPTER 16
USDA FOOD LABELING REQUIREMENTS

I. LABEL PRE-APPROVAL 16-1
II. REQUIRED LABEL INFORMATION 16-1
   a. Statement Of Identity 16-3
   b. Net Contents Labeling 16-4
   c. Ingredients Declaration 16-5
   d. Signature Line 16-6
TABLE OF CONTENTS

CHAPTER 17

LABELING OF RESTAURANT AND FOODSERVICE FOODS

I. RELEVANT LABELING EXEMPTIONS 17-1
   a. Exemptions Applicable to Unpackaged Foods 17-1
   b. Exemptions from Nutrition Labeling 17-3
      i. Foods Served in Restaurants and Other Establishments in Which Food Is Served for Immediate Human Consumption 17-3
      ii. Ready-to-Eat Take-Out Foods 17-4
      iii. Foodservice Distributor Foods 17-5
      iv. Other Exemptions May Apply 17-5
   c. Loss of Exemption from Nutrition Labeling 17-5
   d. Voluntary Nutrition Labeling 17-6

II. FLEXIBILITIES IN NUTRITION LABELING OF RESTAURANT FOODS 17-6

III. NUTRIENT CONTENT CLAIMS AND HEALTH CLAIMS FOR RESTAURANT FOODS 17-7
   a. Nutrient Content Claims 17-7
   b. Health Claims 17-8
   c. Other Claims 17-8

IV. STATE LABELING REQUIREMENTS APPLICABLE TO RESTAURANT FOODS 17-10

V. MENU LABELING 17-11
   a. Applicability 17-11
      i. Covered Establishments 17-11
      ii. Covered Foods 17-12
      iii. Menu or Menu Board 17-12
      iv. Exemptions 17-12
   b. Requisite Information 17-13
      i. Calories 17-13
      ii. Succinct Statement 17-14
      iii. Statement of Availability 17-14
      iv. Additional Nutrition Information 17-15
### TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>v. Special Requirements</td>
<td>17-16</td>
</tr>
<tr>
<td>1. Variable Menu Items</td>
<td>17-16</td>
</tr>
<tr>
<td>2. Combination Meals</td>
<td>17-17</td>
</tr>
<tr>
<td>3. Self-service Foods and Foods on Display</td>
<td>17-18</td>
</tr>
<tr>
<td>c. Recordkeeping</td>
<td>17-19</td>
</tr>
<tr>
<td>d. Voluntary Program</td>
<td>17-20</td>
</tr>
<tr>
<td>e. Compliance and Enforcement</td>
<td>17-20</td>
</tr>
<tr>
<td>f. Federal Preemption</td>
<td>17-20</td>
</tr>
<tr>
<td>g. Compliance Date</td>
<td>17-2</td>
</tr>
</tbody>
</table>

### APPENDIX A

FDA and USDA Headquarters - Food Labeling Contacts

### APPENDIX B

FDA Food Labeling References

### APPENDIX C

USDA Food Labeling References

### APPENDIX D

Other Rules that May Impact Food Labeling

xvi
## COMMONLY USED ABBREVIATIONS

<table>
<thead>
<tr>
<th>Abbreviation</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>C.F.R.</td>
<td>Code of Federal Regulations</td>
</tr>
<tr>
<td>Customs or CBP</td>
<td>U.S. Customs and Border Protection</td>
</tr>
<tr>
<td>DRV</td>
<td>Daily Reference Value</td>
</tr>
<tr>
<td>DV</td>
<td>Daily Value</td>
</tr>
<tr>
<td>FALCPA</td>
<td>Food Allergen Labeling and Consumer Protection Act</td>
</tr>
<tr>
<td>FDA</td>
<td>Food and Drug Administration</td>
</tr>
<tr>
<td>FDC Act</td>
<td>Federal Food, Drug, and Cosmetic Act</td>
</tr>
<tr>
<td>Fed. Reg./FR</td>
<td>Federal Register</td>
</tr>
<tr>
<td>FMIA</td>
<td>Federal Meat Inspection Act</td>
</tr>
<tr>
<td>FPLA</td>
<td>Fair Packaging and Labeling Act</td>
</tr>
<tr>
<td>FSIS</td>
<td>Food Safety and Inspection Service</td>
</tr>
<tr>
<td>FTC</td>
<td>Federal Trade Commission</td>
</tr>
<tr>
<td>NLEA</td>
<td>Nutrition Labeling and Education Act</td>
</tr>
<tr>
<td>PDP</td>
<td>Principal Display Panel</td>
</tr>
<tr>
<td>PPIA</td>
<td>Poultry Products Inspection Act</td>
</tr>
<tr>
<td>RDI</td>
<td>Reference Daily Intake</td>
</tr>
<tr>
<td>USDA</td>
<td>U.S. Department of Agriculture</td>
</tr>
</tbody>
</table>