

TABLE OF CONTENTS

CHAPTER 1: INTRODUCTION	1
I. HISTORICAL OVERVIEW	1
II. GOVERNING LAWS	3
III. REGULATORY AUTHORITIES	3
A. FDA	3
B. Federal Trade Commission and National Advertising Division	4
C. Customs	4
IV. STATUTORY DEFINITIONS	5
A. Definition of “Dietary Ingredient”	5
V. PRODUCTS THAT MAY BE DIETARY SUPPLEMENTS	6
VI. PRODUCTS THAT MAY NOT BE DIETARY SUPPLEMENTS	7
VII. DIETARY SUPPLEMENTS IN RELATION TO OTHER FDA-REGULATED PRODUCTS	9
Chapter 2: FORMULATION AND SAFETY	11
I. FORMULATION	12
A. Definition of “Dietary Ingredient”	12
B. “New Dietary Ingredients”	12
C. Articles Excluded from Use in Dietary Supplements	15
D. Other Ingredients	17
II. SAFETY	17
A. DSHEA Safety Standard	17
B. Dietary Supplements and Dietary Ingredients Prohibited	18
C. Substances Prohibited or Restricted in All Foods	19
D. FDA Import Alerts	22
E. FDA Warnings	23
F. Other Safety Issues	25
Chapter 3: LABELING REQUIREMENTS	29
I. Overview of Labeling Requirements	29
A. General Misbranding Provisions	29
B. Specific Misbranding Provisions	30
C. Terminology	31
D. Placement of Label Information	33
E. English and Foreign Languages	34
F. National Uniformity	34
II. Mandatory Label Information	35
A. Statement of Identity	35
B. Net Contents Declaration	36
C. Nutrition Labeling – “Supplement Facts”	42
D. Ingredients or Other Ingredients Declaration	67
E. Signature Line	73
III. Additional Labeling Exemptions	75
IV. Label Information Required for Certain Products	76
A. Flavor Labeling	76
B. Allergen Labeling	78

C. Warning and Notice Statements.....	80
D. Country of Origin Marking	84
V. Non-Mandatory Label Information	87
A. Claims	87
B. Other Non-Mandatory Label Information	87
CHAPTER 4: LABELING CLAIMS.....	89
I. NUTRIENT CONTENT CLAIMS.....	89
A. General Requirements and Scope.....	90
B. Permitted Nutrient Content Claims.....	91
C. Claims Authorized by FDA Regulation – Global Provisions	94
D. Claims Authorized by FDA Regulation – Definitions and Specific Eligibility Requirements	97
F. Claims Reflecting Authoritative Statements	109
G. Claims Reflecting Authoritative Statements	110
II. HEALTH CLAIMS AND QUALIFIED HEALTH CLAIMS	110
A. General Requirements and Scope	111
B. Permitted Health Claims	114
C. Health Claims Approved by FDA Regulation	117
D. Health Claims Prohibited by FDA Regulation	127
E. Qualified Health Claims – Claims Authorized by FDA	128
F. Qualified Health Claims – Claims Not Authorized by FDA	138
III. STRUCTURE/FUNCTION CLAIMS	142
A. Structure/Function Claims Differentiated.....	143
B. Substantiation	146
C. 30-Day Notification	147
D. FDA Disclaimer	147
Chapter 5: THIRD-PARTY LITERATURE	149
I. OVERVIEW OF EXEMPTION	149
II. GENERAL REQUIREMENTS.....	149
III. THIRD-PARTY LITERATURE AS EVIDENCE OF INTENDED USE	152
Chapter 6: CURRENT GOOD MANUFACTURING PRACTICES	153
I. OVERVIEW OF CGMP REQUIREMENTS	153
A. Background.....	153
B. Purpose of the CGMPs	154
C. Written Procedures and FDA Access to Records	154
D. Consequences of Failure to Follow CGMPs	154
E. Compliance Dates	155
II. GENERAL PROVISIONS	155
A. Who Is Subject to the Rule?	155
B. Definitions.....	157
III. PERSONNEL	160
A. Written Procedures	160
B. Preventing Contamination from Sick or Infected Personnel	160
C. Personnel and Supervisor Qualifications	161
D. Record Keeping and Records Access	161
IV. PHYSICAL PLANT AND GROUNDS	162

A. Written Procedures	162
B. Sanitation Requirements	162
C. Design and Construction Requirements	164
D. Record Keeping and Records Access	164
V. EQUIPMENT AND UTENSILS	165
A. Written Procedures	165
B. Equipment and Utensils Requirements.....	165
C. Automatic, Mechanical or Electronic Equipment.....	165
D. Record Keeping and Records Access	165
VI. PRODUCTION AND PROCESS CONTROLS	166
A. Implementing a Production and Process Control System.....	166
B. Design Requirements	166
C. Quality Control Operations.....	166
D. Establishing Specifications.....	166
E. Determining Whether Specifications Are Met	167
F. Actions Required When Specifications Not Met.....	169
G. Requirement to Collect Samples	169
H. Record Keeping and Records Access	170
VII. REQUIREMENTS FOR QUALITY CONTROL	171
A. Written Procedures	171
B. Quality Control Personnel.....	171
C. Laboratory Operations	172
D. Material Review and Disposition Decisions.....	172
E. Equipment, Instruments, and Controls	173
F. Components, Packaging, and Labels	173
G. Master Manufacturing Record, etc.	173
H. Packaging and Labeling Operations	174
I. Returns and Complaints	174
J. Record Keeping and Records Access.....	174
VIII. REQUIREMENTS FOR COMPONENTS, PACKAGING AND LABELING	175
A. Written Procedures	175
B. Components	175
C. Packaging and Labels	176
D. Product Received for Packaging and Labeling.....	176
E. Rejected Components, Packaging and Labels	177
F. Record Keeping and Records Access	177
IX. MASTER MANUFACTURING RECORD	178
A. Requirement to Establish a Master Manufacturing Record	178
B. Information Required in the Master Manufacturing Record	178
C. Record keeping and Records Access	179
X. BATCH PRODUCTION RECORD	179
A. Requirement to Prepare a Batch Production Record	179
B. Information Required in Batch Production Record	179
C. Record Keeping and Records Access	180
XI. LABORATORY OPERATIONS	181
A. Written Procedures	181
B. Laboratory Facilities	181
C. Laboratory Control Processes.....	181
D. Laboratory Methods	181

E. Record Keeping and Records Access	182
XII. MANUFACTURING OPERATIONS	182
A. Written Procedures	182
B. Design Requirements	182
C. Sanitation Requirements	182
D. Rejected Dietary Supplements	183
E. Record Keeping and Records Access	183
XIII. PACKAGING AND LABELING OPERATIONS	183
A. Written Procedures	183
B. Packaging and Labels	183
C. Filling, Assembling, Packaging, Labeling and Related Operations	184
D. Repackaging and Relabeling	185
E. Rejected Dietary Supplements	185
F. Record Keeping and Records Access	185
XIV. HOLDING AND DISTRIBUTING.....	185
A. Written Procedures	185
B. Holding Components, Dietary Supplements, Packaging and Labels	185
C. In-process Materials	186
D. Reserve Samples.....	186
E. Distribution	186
F. Record Keeping and Records Access	186
XV. RETURNED DIETARY SUPPLEMENTS	187
A. Written Procedures	187
B. Receipt of Returned Dietary Supplements	187
C. Disposal of Returned Dietary Supplements	187
D. Salvage of Returned Dietary Supplements.....	187
E. Reprocessing Returned Dietary Supplements.....	187
F. Investigating Manufacturing Processes and Other Batches.....	187
G. Record keeping and Records Access	188
XVI. PRODUCT COMPLAINTS	188
A. Written Procedures	188
B. Review and Investigation	188
C. Record Keeping and Records Access	189
XVII. RECORDS AND RECORD KEEPING	189
A. Record Keeping Requirements.....	189
B. FDA Records Access.....	189
XVIII. PETITION TO REQUEST AN EXEMPTION	190

Chapter 7: FDA INSPECTION AND ENFORCEMENT	193
I. FDA INSPECTION AUTHORITY	193
A. FD&C Act.....	193
B. Scope of Inspection.....	194
C. Refusal to Allow Inspection	195
II. REASONS FOR AN FDA INSPECTION	195
A. Routine Compliance Inspections	196
B. Complaint Follow-Up Inspections	196
C. Recall Follow-Up Inspections.....	196
D. FDA Surveys.....	197
E. Government-Wide Quality Assurance Program	197
F. Office of Criminal Investigations	197

III. FDA'S RECORDS ACCESS AUTHORITY	198
A. FDA's General Records Access Authority	198
B. FDA Access to CGMP Records	198
C. FDA Access to Records of Adverse Events	198
D. FDA Records Access under the Bioterrorism Act	199
IV. THE FDA INSPECTION	200
A. Pre-Inspection Conference and Inspection	200
B. Reportable Observations	200
C. Post-Inspection Conference with FDA	202
D. Response to Form FDA-483	203
E. Establishment Inspection Report	203
V. FDA ENFORCEMENT OPTIONS	204
VI. FDA ENFORCEMENT OPTIONS	204
A. Warning Letter	204
B. Recall Request	204
C. Administrative Detention	205
D. Seizure	207
E. Injunction	207
F. Criminal Prosecution	207
G. States' Enforcement Powers	208
Chapter 8: IMPORTS	209
I. OVERVIEW	209
II. IMPORT PROCEDURES	210
III. IMPORT FOR EXPORT	211
IV. ENFORCEMENT	212
A. Admissibility Standard	212
B. FDA Inspection Authority	212
C. FDA Enforcement	213
Chapter 9: BIOTERRORISM ACT REQUIREMENTS	215
I. REGISTRATION OF FOOD FACILITIES	216
A. Definitions	216
B. Exemptions	217
C. How to Register	217
D. Foreign Facilities	218
E. Compliance	218
II. PRIOR NOTICE OF FOOD IMPORTS	218
A. Definitions	219
B. Exemptions	219
C. How to Submit Prior Notice	219
D. Timeframes for Submitting Prior Notice	221
E. Information in the Prior Notice	221
F. Compliance	222
III. RECORDKEEPING/RECORDS ACCESS	223
A. Definitions	224
B. Exemptions	224
C. Required Records	226
D. Form, Location, and Retention	227
E. Records Access	227

F. Compliance	228
IV. OTHER BIOTERRORISM ACT PROVISIONS.....	228
A. Prohibition Against Port Shopping.....	228
B. Import for Export	228
C. Debarment for Import Violations	228
D. 24-Hour Hold on Imported Food	229
E. Notification to States.....	229
F. Marking of Food Refused Admission into U.S.	229
V. FOOD SECURITY PREVENTIVE MEASURES	229
CHAPTER 10: ADVERSE EVENT REPORTING	
I. DIETARY SUPPLEMENT AND NON-PRESCRIPTION DRUG CONSUMER PROTECTION ACT	231
II. MANDATORY REPORTING OF SERIOUS ADVERSE EVENTS	231
A. Basic Reporting Requirement.....	231
B. Relationship to FDA Reportable Food Registry	232
C. How to Report.....	233
D. When to Submit Reports.....	236
E. Effect of Reporting	236
III. LABELING REQUIREMENTS	236
A. Domestic Address or Phone Number	236
B. Additional Information	237
C. Effective Date	237
IV. MAINTENANCE AND INSPECTION OF RECORDS	238
V. IMPACT ON IMPORTED DIETARY SUPPLEMENTS	238
Chapter 11: ADVERTISING.....	239
I. OVERVIEW OF ADVERTISING REQUIREMENTS	239
A. Legal Framework	239
B. Consistency with FDA Labeling Requirements	240
C. Industry Self-Regulation.....	240
II. TRUTHFUL AND NONMISLEADING ADVERTISING	241
A. Identifying Express and Implied Claims	242
B. Disclosing Qualifying Information.....	242
C. Presenting Disclosures Clearly and Conspicuously	244
III. SUBSTANTIATING ADVERTISING CLAIMS.....	245
A. Reasonable Basis for Objective Advertising Claims	245
B. “Competent and Reliable Scientific Evidence”	246
C. Establishment Claims	246
D. Comparative Claims	247
E. Testimonial and Expert Endorsement Claims	248
F. Traditional Use Claims	252
G. “Doctor Recommended” Claims	253
H. Weight Loss Claims	254
I. “Green” Claims	255
IV. NUTRIENT CONTENT CLAIMS IN ADVERTISING	256
A. Emphatic Nutrient Content Claims.....	256
B. Comparative Nutrient Content Claims	256
C. Synonyms for Nutrient Content Claims	257
D. Implied Nutrient Content Claims	257

E. Nutrient Content Claim Disclosures	258
V. HEALTH CLAIMS IN ADVERTISING	258
A. Substantiating Health Claims	258
B. Disqualifying Levels of Risk-Increasing Nutrients	259
C. Wording of Health Claims	259
VI. FTC ENFORCEMENT POWERS AND REMEDIES	260
A. Investigative and Enforcement Authority	260
B. Remedies.....	260