

# DEWITTY ON DIETARY SUPPLEMENT LAW



# DEWITTY ON DIETARY SUPPLEMENT LAW

## Including Cannabis-Derived Ingredients

**Robert M. DeWitty**

Member of the Federal Courts of the District  
of Columbia, California, and Illinois

**2022**

Copyright © 2022 Robert M. DeWitty. All Rights Reserved.

No part of this publication may be reproduced or transmitted in any form or by any means, electronic or mechanical, including photocopy, recording, or utilized by any information storage or retrieval system, without written permission from the publisher. For information about permissions or to request permissions online, visit us at [www.fastcase.com](http://www.fastcase.com), or a written request may be e-mailed to our permissions department at [support@fastcase.com](mailto:support@fastcase.com).

First published in 2022.

Printed in the United States of America

1 2 3 4 5 6 7 8 9 0

ISBN 978-1-949884-74-6

# *Dedication*

---

Thank you to my mother for spurring my education,  
the foundation upon which this project was built.

Thank you to my son, whose continuing growth  
provided me the continuing focus for this project.



# Table of Contents

---

Preface

xv

## PART I: THE UNITED STATES LEGAL STRUCTURE

<b>Chapter 1</b>	<b>THE UNITED STATES LEGAL STRUCTURE</b>	<b>3</b>
§1.1	Sources and Hierarchy of Law	4
§1.1.1	The Constitution	4
§1.1.2	Federal Legislation and Statutes	4
§1.1.3	Treaties	5
§1.1.4	Executive Agreements	5
§1.1.5	State Constitutions	5
§1.1.6	State Legislation and Statutes	6
§1.1.7	Local Statutes	6
§1.1.8	Federal, State, or Local Government Administrative Laws and Regulations	6
§1.2	The Judiciary	7
§1.2.1	Federal System of Courts	7
§1.2.1.1	The United States Supreme Court	7
§1.2.1.2	The United States Court of Appeals; the United States Court of Appeals for the District of Columbia Circuit; the Federal Circuit	8
§1.2.1.3	The United States' District Courts	8
§1.3	State Governments	11
§1.4	Judicial Review	12
§1.4.1	Court's Power of Judicial Review	12
§1.4.2	The Foundation of Judicial Review of Congressional Acts or Executive Actions	12
§1.4.3	Judicial Review of Administrative Agency Actions	13
§1.5	Arbitrary and Capricious Standard; <i>De Novo</i> Review	14
§1.6	Nature and Scope of <i>De Novo</i> Judicial Review	14
§1.7	Judicial Review of FDA Final Agency Action or Inaction ("Final Action")	16

**PART II: DEVELOPMENT OF UNITED STATES FOOD AND DRUG  
LAW; FOOD ADDITIVES; DIETARY SUPPLEMENTS**

<b>Chapter 2</b>	<b>LEGAL DEVELOPMENT PRIOR TO 1994</b>	<b>19</b>
§2.1	Defining “Food” and “Drug” Mid-to-Late 19th Century	19
§2.2	Adulteration and Misbranding Under 1906 Act	26
§2.3	Act of 1938	33
§2.4	Technology, Market Segmentation, and Food Law: 1938–1958	42
	§2.4.1 Food Additives Amendment of 1958	56
	§2.4.2 Establishing Safety for Food Additives	58
§2.5	Foods for Special Dietary Uses and Food Additives: 1970–1990	59
	§2.5.1 National Nutrition Foods Association et al. versus the Food and Drug Administration	64
	§2.5.2 Congressional Intervention in NNFA Versus FDA	66
<b>Chapter 3</b>	<b>SCIENTIFIC ASPECTS OF DIETARY SUPPLEMENTS</b>	<b>69</b>
§3.1	Natural Products and Herbs	70
	§3.1.1 Definitions: Herbs and Natural Products	70
	§3.1.2 Medicinal Plants, Herbs, Natural Products, and Their Uses	71
	§3.1.3 Classification/Nomenclature of Medicinal Plants and Herbs	72
	§3.1.3.1 Latin Binomials	72
	§3.1.3.2 Drug or Food/Dietary Supplement	73
	§3.1.4 Naming Unclassified or Newly Discovered Medicinal Plants and Herbs: The International Code of Botanical Nomenclature	74
§3.2	Method of Treatment Using Natural Products and Herbs	74
	§3.2.1 Traditional Chinese Medicine (TCM)	74
	§3.2.1.1 Yin-Yang Theory	75
	§3.2.1.2 Theory of Five Elements	75
	§3.2.1.3 Theory of Four Natures and Five Flavors	75
	§3.2.1.4 TCM Decoction	75
	§3.2.1.5 Issues and Development of TCM	76
	§3.2.2 African Traditional Medicine	76
	§3.2.3 Ayurveda Practice in India	78
	§3.2.4 North American Indigenous People’s Herbal Medicine	79
	§3.2.5 South American Indigenous People’s Herbal Medicine	80
	§3.2.6 Phytotherapy in Europe (England, Greece, France, Germany, Switzerland, and Other ESCOP Member Nations)	82



	§3.2.7	Complementary and Alternative Medicine (CAM) in the United States	87
	§3.2.8	Hahnemann Theories	88
§3.3		Chemicals in Plants and Food (e.g., Fertilizers and Preservatives)	90
	§3.3.1	Chemicals	90
	§3.3.2	Preservatives or Additives in Foods	93
§3.4		Dietary Supplement Market in the United States	96
	§3.4.1	Growth	96
	§3.4.2	Present Day	97
	§3.4.3	Future Growth	98

**PART III: THE 1994 DIETARY SUPPLEMENT AND HEALTH EDUCATION ACT; NEW DIETARY INGREDIENTS; PRE-MARKET NOTIFICATION**

<b>Chapter 4</b>	<b>LEGISLATION LEADING TO DSHEA: 1990–1994</b>	<b>101</b>
§4.1	Enactment of NLEA	101
§4.2	Judicial Rulings	102
§4.3	Enactment of the Dietary Supplement and Health Education Act of 1994 (DSHEA)	103
<b>Chapter 5</b>	<b>PRE-MARKET NOTIFICATION</b>	<b>107</b>
§5.1	“Pre-market Notification” for New Dietary Ingredients	108
§5.2	“A dietary supplement . . .”	109
	§5.2.1 “ . . . a vitamin; a mineral . . .”	109
	§5.2.2 “ . . . an herb or other botanical . . .”	110
	§5.2.3 “ . . . an amino acid . . .”	110
	§5.2.4 “ . . . dietary substance . . . to supplement the diet by increasing the total dietary intake . . .”	111
	§5.2.5 “ . . . a concentrate, metabolite, constituent, extract, or combination of any ingredient describe [in the above clauses] . . .”	111
	§5.2.6 “ . . . new dietary ingredients . . .”	112
§5.3	“ . . . shall be deemed adulterated . . .”	112
§5.4	“ . . . under Section 402(f) unless it meets on of the following . . .”	113
§5.5	First Scenario to Overcome Assumption of Adulteration: “ . . . contains . . . dietary ingredients . . . which have been present in the food supply . . . in a form . . . [that] has not been chemically altered . . .”	114

§5.6	Second Scenario to Overcome Assumption of Adulteration: Pre-market Notification Filing	114
§5.6.1	“... history of use or other evidence ...”	115
§5.6.2	“... when used under the conditions recommended or suggested in the labeling of the ... supplement ...”	115
§5.6.3	“... reasonably be expected to be safe ...”	116
§5.7	The Manufacturer’s or Distributor’s Conclusion	116
<b>Chapter 6</b>	<b>FILING PRE-MARKET NOTIFICATIONS—FDA PROCEDURAL REGULATIONS (HENCEFORTH “MANUFACTURER”)</b>	<b>117</b>
§6.1	Name and Complete Address of Manufacturer or Distributor (Henceforth “Manufacturer”)	117
§6.2	The Name of the New Dietary Ingredient and the Latin Binomial Name (Including Author) of Any Herb or Other Botanical	118
§6.3	A Description of the Dietary Supplement Containing the New Dietary Ingredient	118
§6.4	Submission of Information Showing History of Use or Other Evidence of Safety	118
§6.5	Signature of Person Designated by Manufacturer	119
§6.6	Method of Filing Pre-market Notifications—COSM	120
<b>Chapter 7</b>	<b>POST-NOTIFICATION FILINGS</b>	<b>121</b>
§7.1	After Submission	121
§7.1.1	Acknowledgment	121
§7.1.2	Amendments	122
§7.1.3	90-Day Publication and Trade Secret Protection	122
§7.1.4	Failure of FDA to Respond to Notification	122
§7.2	“Approval” Letter or “Rejection” Letter?	122
§7.3	Responding to Communications Received from FDA	125
§7.3.1	Petition to Commissioner	125
§7.3.2	Request for Reconsideration	126
§7.4	<i>De Novo</i> Judicial Review	126
§7.4.1	Basis for <i>De Novo</i> Review	126
§7.4.2	Ripeness for <i>De Novo</i> Review	126
§7.4.3	Scope of <i>De Novo</i> Review	127
§7.4.4	Jurisdiction	127
§7.4.5	Judicial Progression	127

<b>Chapter 8</b>	<b>INTELLECTUAL PROPERTY PROTECTION AND ANCILLARY ISSUES RELATING TO DIETARY SUPPLEMENTS AND NEW DIETARY INGREDIENTS</b>	<b>129</b>
§8.1	Intellectual Property (IP) Backgrounder	129
§8.1.1	Patent Primer	130
§8.1.1.1	Acquiring Patent Rights	131
§8.1.1.2	Enforcing Patent Rights	131
§8.1.2	Trademark Primer	131
§8.1.2.1	Acquiring Trademark Rights	131
§8.1.2.2	Enforcing Registered Trademarks	132
§8.1.3	Copyright Primer	132
§8.1.3.1	Formal Copyright Registration	133
§8.1.3.2	Enforcing Copyrights	133
§8.1.4	Trade Secret/Confidential Business Information	133
§8.2	Petition for Issuance of Order	135
§8.3	Affect of “Rejected” Notification on Dietary Supplement with New Dietary Ingredient Importation	135
<b>Chapter 9</b>	<b>MARKETING MATERIAL, LABELING, AND LABELS FOR DIETARY SUPPLEMENTS WITH NEW DIETARY INGREDIENTS</b>	<b>137</b>
§9.1	Scientific Studies as Marketing Material	137
§9.2	Structure/Function Claims	138
§9.3	Health Claims	140
§9.3.1	<i>Pearson v. Shalala</i>	141
§9.3.2	FDA Current Health Claim Regulation	141
§9.4	Formatting Dietary Ingredient Labels and Labeling	142
§9.4.1	“Dietary Supplement” as Part of the Statement of Identity	143
§9.4.2	Nutrition Information and Dietary Ingredient Information	143
§9.4.3	Botanicals	144
§9.4.4	Proprietary Blends	144
§9.4.5	“Serving Size”; “Amount per Serving”	144
§9.4.6	Label Formatting Examples	145
<b>Chapter 10</b>	<b>PERTINENT U.S. FEDERAL AGENCIES AND OFFICES</b>	<b>147</b>
§10.1	U.S. Department of Justice (DOJ)	147
§10.2	Food and Drug Administration (FDA)	148

§10.3	Center for Food Safety and Applied Nutrition (CFSAN)	148
§10.4	Office of Nutritional Products, Labeling, and Dietary Supplements (ONPLDS)	148
	§10.4.1 Office of Dietary Supplement Programs	148
	§10.4.2 Food Labeling and Standards Staff	149
	§10.4.3 Nutrition Programs and Labeling Staff	149
§10.5	National Institute of Health (NIH)	149
§10.6	Office of Dietary Supplements	149
§10.7	U.S. Customs & Border Protection (CBP)	150
	§10.7.1 Necessary Information for Prior Notice	150
	§10.7.2 Time for Filing Prior Notice	151
	§10.7.3 Method of Submitting Prior Notice	151
§10.8	Federal Trade Communication (FTC)	151

## PART IV: SPECIAL TOPICS

<b>Chapter 11</b>	<b>BRIEF: CODEX ALIMENTARIUS (CODEX) COMMISSION</b>	<b>155</b>
<hr/>		
§11.1	History	155
§11.3	Food for Special Dietary Uses	157
§11.4	Claims	158
	§11.4.1 Prohibited Claims	158
	§11.4.2 Misleading Claims	158
	§11.4.3 Claims Subject to Conditions (Conditional Claims)	158
§11.5	Nutrient Claims	159
<b>Chapter 12</b>	<b>CANNABIS-DERIVED PRODUCTS AS DIETARY SUPPLEMENTS</b>	<b>161</b>
<hr/>		
§12.1	Overview	163
	§12.1.1 Cannabis Sativa L.	163
	§12.1.2 Marketing Overview for Cannabis-Derived Products in Dietary Supplements	164
§12.2	Enforcement and Regulation of Cannabis-Derived Ingestible Products	165
	§12.2.1 Enforcement and Regulation of Cannabidiol (CBD)	166
	§12.2.2 Enforcement and Regulation of Hemp-Derived Ingestible Dietary Supplements; Dehulled Hemp Seed, Hemp Seed Oil, Hemp Protein Powder, and CBD	168
	§12.2.3 Enforcement and Regulation of Tetrahydrocannabinols (“THC”)	169

	§12.2.3.1 0.3% THC as Definitive of “Hemp”	169
	§12.2.3.2 Natural Tetrahydrocannabinols Versus Synthetic Tetrahydrocannabinols	170
§12.2.4	FTC Regulatory and Enforcement Action for Cannabis Sativa L.-Derived Ingestible Products	171
§12.2.5	USDA Regulatory and Enforcement Action for Cannabis Sativa L.-Derived Ingestible Products	172
§12.3	State Regulation of Cannabis-Derived Ingestible Products, Including Hemp-Derived Supplements, CBD Containing Products, and THC Containing Products	172
§12.3.1	Overview	172
§12.3.2	The States and Territories	173
	Alabama	173
	Alaska	174
	Arkansas	174
	Arizona	175
	California	175
	Colorado	176
	Connecticut	177
	Delaware	178
	District of Columbia	178
	Florida	178
	Georgia	179
	Guam	180
	Hawaii	180
	Idaho	180
	Illinois	181
	Indiana	181
	Iowa	182
	Kansas	182
	Kentucky	183
	Louisiana	183
	Maine	184
	Maryland	184
	Massachusetts	184
	Michigan	185
	Minnesota	185
	Mississippi	186
	Missouri	186
	Montana	187
	Nebraska	187

Nevada	188
New Hampshire	188
New Jersey	189
New Mexico	189
New York	190
North Carolina	190
North Dakota	191
Ohio	192
Oklahoma	192
Oregon	193
Pennsylvania	193
Puerto Rico	194
Rhode Island	194
South Carolina	195
South Dakota	195
Tennessee	196
Texas	196
Utah	197
Vermont	198
Virginia	199
Washington	199
West Virginia	200
Wisconsin	200
Wyoming	201
<i>Table of Cases</i>	203
<i>Index</i>	213