### Index

<table>
<thead>
<tr>
<th>Term</th>
<th>Pages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Actimel</td>
<td>185</td>
</tr>
<tr>
<td>Activists</td>
<td>385–387</td>
</tr>
<tr>
<td>Administrative Procedure Act</td>
<td>112, 113, 127</td>
</tr>
<tr>
<td>“significant scientific agreement” standard</td>
<td>125–126</td>
</tr>
<tr>
<td>“Administrative Provisions for New Food Source Hygiene” (China)</td>
<td>266</td>
</tr>
<tr>
<td>“Administrative Regulations for Health Foods” (China)</td>
<td>263</td>
</tr>
<tr>
<td>Adverse Event Reporting</td>
<td>222</td>
</tr>
<tr>
<td>Advertising</td>
<td></td>
</tr>
<tr>
<td>anecdotal evidence</td>
<td>158</td>
</tr>
<tr>
<td>Brazilian regulations</td>
<td>371</td>
</tr>
<tr>
<td>corrective</td>
<td>162</td>
</tr>
<tr>
<td>deceptive/misleading</td>
<td></td>
</tr>
<tr>
<td>EU regulations</td>
<td>345</td>
</tr>
<tr>
<td>FTC Act, 149–156, 161–164</td>
<td></td>
</tr>
<tr>
<td>EU regulations, 350–356</td>
<td></td>
</tr>
<tr>
<td>expert endorsements</td>
<td>158, 163–164</td>
</tr>
<tr>
<td>express claims</td>
<td>152–153</td>
</tr>
<tr>
<td>FOSHU products</td>
<td>256–257</td>
</tr>
<tr>
<td>FTC Act, 149–156</td>
<td></td>
</tr>
<tr>
<td>violations</td>
<td>161–164</td>
</tr>
<tr>
<td>implied claims</td>
<td>152–153</td>
</tr>
<tr>
<td>limiting health claims</td>
<td>187–189</td>
</tr>
<tr>
<td>nutrition-based claims</td>
<td>49–50</td>
</tr>
<tr>
<td>Spanish regulations</td>
<td>338–343</td>
</tr>
<tr>
<td>substantiating</td>
<td>156–161</td>
</tr>
<tr>
<td>truth in</td>
<td>149, 151</td>
</tr>
<tr>
<td>U.S. regulations</td>
<td>49–50, 149–156, 161–164</td>
</tr>
<tr>
<td>AGF Vitahot</td>
<td>257</td>
</tr>
<tr>
<td>Agricultural Marketing Service (AMS)</td>
<td>70, 72</td>
</tr>
<tr>
<td>Ajinomoto General Foods</td>
<td>257</td>
</tr>
<tr>
<td>Alar</td>
<td>71–72</td>
</tr>
<tr>
<td>All-Bran</td>
<td>25, 43–44, 79</td>
</tr>
<tr>
<td>All claims order</td>
<td>161</td>
</tr>
<tr>
<td>All products order</td>
<td>161</td>
</tr>
<tr>
<td>Alternative medicines</td>
<td>8</td>
</tr>
<tr>
<td>American Dietetic Association</td>
<td>107</td>
</tr>
<tr>
<td>American Heart Association</td>
<td>103–105</td>
</tr>
<tr>
<td>Amino acids</td>
<td>325–326, 374</td>
</tr>
<tr>
<td>Amurol Confections</td>
<td>185</td>
</tr>
<tr>
<td>Andean Community</td>
<td>384</td>
</tr>
<tr>
<td>Androstenedione</td>
<td>162</td>
</tr>
<tr>
<td>Anecdotal evidence, health claims advertising</td>
<td>158</td>
</tr>
<tr>
<td>Animal studies, Chinese regulations</td>
<td>274–275, 287</td>
</tr>
<tr>
<td>Animal welfare, organic standards</td>
<td>69, 70, 76</td>
</tr>
<tr>
<td>Antibiotics</td>
<td></td>
</tr>
<tr>
<td>organic standards, 69, 73, 76</td>
<td></td>
</tr>
<tr>
<td>overprescribing</td>
<td>253</td>
</tr>
<tr>
<td>Antioxidants</td>
<td></td>
</tr>
<tr>
<td>and cancer</td>
<td>15</td>
</tr>
<tr>
<td>FDA interim standard</td>
<td>117–118</td>
</tr>
<tr>
<td>ANVISA, 367–369</td>
<td></td>
</tr>
<tr>
<td>bioactives regulation</td>
<td>373–375</td>
</tr>
<tr>
<td>health claims regulation</td>
<td>371–373</td>
</tr>
<tr>
<td>“Approval Certificate of Health Foods” (China)</td>
<td>264–265, 276, 282–285</td>
</tr>
<tr>
<td>Aquafina</td>
<td>26</td>
</tr>
<tr>
<td>Arginine</td>
<td>187, 374</td>
</tr>
<tr>
<td>AriZona brand</td>
<td>25</td>
</tr>
<tr>
<td>Arizona Rx Memory Mind Elixir</td>
<td>186–187</td>
</tr>
<tr>
<td>“Article”, FFDCA definition of</td>
<td>137–138, 141–147</td>
</tr>
<tr>
<td>ASEAN, Codex interactions</td>
<td>382–383</td>
</tr>
<tr>
<td>Assessment Board for Diet-Health Information (BHK)</td>
<td>308–309</td>
</tr>
<tr>
<td>AST</td>
<td>162</td>
</tr>
<tr>
<td>Australia</td>
<td></td>
</tr>
<tr>
<td>food law</td>
<td>321–334</td>
</tr>
<tr>
<td>food safety</td>
<td>324–327</td>
</tr>
<tr>
<td>nutritional issues</td>
<td>327–329</td>
</tr>
</tbody>
</table>
Australia (continued)
  health claims regulation, 329–334
  novel foods regulation, 325–327
  vitamins/minerals regulation, 327–329
Australia New Zealand Food Authority
  (ANZFA), 321–324
  folate health claim evaluation, 47–48
Australia New Zealand Food Standards Code,
  321, 324, 329, 331–334
  “Authoritative statement” standard
   FDAMA, 111
   health claims, 83, 101, 172
Aviva, 34

Balance Bar, 23
Batch production records, 64–65
Bayer, 8, 11
Bear gall powder, 274
Bee pollen, 297
Belgium
  health claims regulation, 233
  herbals/botanicals regulation, 243
  vitamins/minerals regulations, 242
Benecol, 30, 31, 34, 184, 189
  FOSHU-approved health claim, 254, 257
Berberine, 241
Beta-carotene supplements, 174
Beverages, fruit-based, 25
BfR, 309, 312, 315
Bifidobacterium, 254, 372
Bioactive substances/compounds, 4; See also
  Nutraceuticals
   Australia/New Zealand regulations, 325–326
   Brazilian regulations, 368, 369, 373–375
   clinical substantiation, 17–20
   form of, 325
   performance-enhancing properties, 326
   proprietary, 30–32
Biodiversity, and organic agriculture, 70
Biofoods, Spanish regulations, 342–343
Biologically active principles (BAPs), 241;
  See also Bioactive substances/
  compounds
Biomarkers, and health claims process, 85–86
Biotechnology
  Codex and, 383, 385–387
  traceability, 387
Black currant oil, 90, 92
Blood pressure
  and dairy peptides, 3
  potassium and, 44–45, 83, 103–105, 177
  Tropicana Pure Premium, 101–108
Books, FDA labeling restrictions, 93–94
Borage seed oil, 92
Boswellia, 19
Botanicals
  Brazilian regulations, 374
  EU regulations, 241, 242–243, 316
  Irish regulations, 243
  U.S. regulations, 12, 17–20
Bovine spongiform encephalopathy, 260
Bran Buds, 177
Bran Flakes, 79
Brazil
  advertising regulations, 371
  bioactives regulation, 373–375
  botanicals/herbals regulation, 374
  dietary supplements regulation, 373–375
  food, defined, 367
  food law, 367–370
  functional claims, 370–371
  health claims regulation, 370–373
  labeling regulations, 370–373
  performance-enhancing products, 374
Brazilian Sanitary Surveillance Agency, 369
Bristol-Meyers Squibb, 8
Bundesamt für Verbraucherschutz und
  Lebensmittelsicherheit (BVL), 309,
  312
Bundesinstitut für Risikobewertung (BfR),
  309, 312, 315
Bundesministerium für Verbraucherschutz,
  Ernährung, und Landwirtschaft, 309
Bureau of Competition (FTC), 149
Bureau of Consumer Protection (FTC), 149
Bureau of Economics, (FTC), 149
Bureau of Food and Drugs (Philippines), 296
BVL, 309, 312
Caffeine, 25
  approved uses, 185, 189
Cairns Group, 384
Calcium
  deficiency, Japan, 248
health claims, 189
and osteoporosis, 24
Calcium acetate, 92
Calcium citrate malate, 23–24, 257
Campbell Soup Company, 154
fat/cholesterol claims, 177
Tomato Soup, 188
V8 juice structure/function claim, 183
Canada
dietary supplements, 213
functional foods
market, 213–214
regulation, 216–221
natural health products (NHP)
industry, 213–214
regulation, 221–225
Canada Gazette, 218, 221, 222–224
Canadian Food and Drugs Act and
Regulations, 215
Canadian Institutes of Health Research
(CIHR), 224
Cancer
and antioxidants, 15
and fiber, 25, 43–44, 79
and phytochemicals, 24
and selenium, 15, 174
Canola oil, genetically modified, 237
Carbohydrates, EU nutrition labeling
regulations, 230
Carcinogenicity studies, 275
Cardia Salt, 187
Cardiovascular disease. See Heart disease
Carnitine, 204, 374
Carotenoids, 374
CarpalCare, 176
Cartagena Protocol on Biosafety, 383
Cease and desist order, FTC, 161
Center for Food Safety and Applied Nutrition
(CFSAN)
health claims, 14
and Pearson v. Shalala, 15
Centers for Disease Control and Prevention
(CDC), as “scientific body”, 83, 101
Central Hudson Gas & Electric Corp. v.
Public Service Commission of New
York, 112–113, 123–125
Centrum, 8, 9
Cereals, fiber health claims, 25, 43–44, 83,
172, 177
Certifying agents, organic foods, 72
Cheerios, 26
Chevron USA v. NRDC, 141–143
Chewing gum, 257, 373
Children, obesity/overweight in, 45
China
food law, 263, 264, 288–289
health foods
defined, 295
industry, 263
health foods regulation, 263–265, 297–298,
300–301
approval certificate, 264–265, 276,
282–283, 285
assessment procedure, 283–285
control/supervision, 288–289
evaluation/approval process, 266
functionality evaluation, 276–281
hygiene standards, 287
imported foods, 282–283
labeling, 283, 285, 287
packaging, 286–287
production, 286
safety control, 266–275
violations of, 289
Ministry of Health (MOH), 263–290, 298,
300–301
premarketing approval, 298
Chinese Institute of Food Science and
Technology, 263
Chinese Nutrition Society, 263
Chitosan, 372
Chlorella, 92
Cholesterol
consumer misconceptions, 353
and oat bran, 3, 25, 44, 79–80, 172, 177
and phytosterols, 30, 31, 315–316, 327
Cholestin case, 185
agency and court proceedings, 140–144
background, 139–140
implications of, 144–146
Chondroitin sulfate, 19, 20
Chromium, 205
Citrus juices, calcium-fortified, 23–24
Civil penalties, advertising violations, 161
“Claim”, defined
Codex, 351
EU, 231–232
Claim Identification Number (CIN), 220
Clif Bar, 25
Clinical trials
FOSHU products, 252
for substantiation of health claims, 85, 158–161
Swedish regulations, 307–309
CocaCola, functional foods, 25
Code of Conduct on Health Claims (Belgium), 233
Code of Practice (Netherlands), 233–234
Code of Practice (UK), 38, 41
Codex Alimentarius
claim, defined, 351
“Codex General Guidelines on Claims, 304
consumer health, 377–378
General Principles for the Addition of Essential Nutrients to Foods, 327–328
Guidelines for the Use of Nutrition Claims, 353–355, 359, 364
health claim, defined, 38
health claims regulation, 304–305
international authority of, 385–387
low fat/calories claims, 356, 359
organic foods guidelines, 70, 76
organizational interactions, 381–387
“precautionary principle”, 385–387
and SPS Agreement, 378–381
WTO dispute settlement procedures, 378–379
Codex Alimentarius Commission, establishment of, 377–378
Coenzyme Q10, 92
Cognitive dysfunction, and phosphatidylserine, 16, 174
Colors, EU regulations, 228, 241
Comfrey, 155
Commercial speech, and health claims, 109, 111–112, 121–125
Commission on Sustainable Development (UN), 383
Community Registry of Functional and Health Claims, 362
Compost, organic standards for, 73
Con Agra, soy foods, 26
Conjugated linoleic acid (CLA), 28
Conseil National de l’Alimentation, 233
Constitution of the United States of America, 126–127
First Amendment, 109, 111–112, 121–125
Fifth Amendment, 112
Consumer Advisory, FDA, 170
Consumer advocacy, and misleading health claims, 46
Consumer communication, Tropicana Pure Premium campaign, 105–108
Consumer health
Codex Alimentarius, 377–378
Food Standards Program, 378
WHO/FAO, 381–382
Consumer Health Information for Better Nutrition (FDA), 40
Consumers, dietary supplement use, U.S., 21
Consumer safety, and information disclosure, 152–156
Consumers’ Association (UK), 47
Consumer satisfaction surveys, 158
Contaminants
EU regulations, 241
preventing, 66–67
SPS Agreement, 380
Content claims, 101
Convention on Biological Diversity (CBD), 383
 Coronary heart disease. See Heart disease
Cosmetics, FDA-FTC jurisdiction, 150
Coumarin, 241
Council of Better Business Bureau, National Advertising Division, 186–187
Council of Europe, “Guidelines concerning scientific substantiation of health-related claims for functional foods”, 304
Court of Appeals for the District of Columbia Circuit, 109, 112
Court of Appeals for the First Circuit, FDA and food additives, 90
Court of Appeals for the Seventh Circuit, FDA and food additives, 90
Court of Appeals for the Tenth Circuit, 142–143
Cranberry juice, 22, 45
Creatine, 374
Credence claims, 157
Cultivation practices, organic foods, 73
Current Good Manufacturing Practices (CGMPs), 56–57
batch production records, 64–65
equipment, 60–61
expiration dating, 67
labeling, 63
laboratory operations, 65–66
manufacturing, 66–67
master manufacturing records, 63–64
packaging, 63, 66–67
personnel, 58–59
physical plant, 59–60
production, 61
quality control unit, 61–62
raw materials, 62–63
requirements, 57–58
utensils, 60

Dairy peptides, and blood pressure, 3
Dannon, 185
Deception Policy Statement, FTC, 149–156, 161–164
DeFelice, Stephen, 3
Dementia, and phosphatidylserine, 16, 174
Desert-living cistanche, 274
Designer foods, German regulations, 313–316
Dextrin, FOSHU-approved health claim, 255
DHA, 32, 372
Diabetes
adult-onset, Japan, 248
and diet, 214
and nutraceutical research, 204–205
Diacylglycerol, 256
Diet
and disease, 214
and functional foods, 303–304
Dietary Approaches to Stop Hypertension (DASH) trial, 104–105
Dietary foods, Germany, 310–312
Dietary guidelines, EU recommendations, 345
Dietary ingredients
defined

DSHEA, 55
FFDCA, 5
exemption of food additive status, 92
Generally Recognized As Safe (GRAS), 14, 20
new, 170
DSHEA regulations, 92, 96–97
EU regulations, 237–238
FFDCA definition of, 146
quality control, 62–63
safety regulations, 30, 170–171
Dietary Supplement Act, 110
Dietary Supplement Health and Education Act (DSHEA)
dietary ingredients, 92
defined, 55
new, 92, 96–97
dietary supplements
defined, 91, 138–139, 170
requirements for, 94–96
GMPs, 97
health claims
approved, 202
restrictions, 13–16
imminent hazard authority, 93, 96
passage of, xiii, 4, 5, 8–9, 89
purpose of, 89–91
safety standards, 92–93
statements of nutritional support, 94
structure/function claims, 14, 151
use of published literature, 93–94
Dietary supplements
adulterated, 95–97
background, 8–9
consumer attitudes toward, 203
consumer use, 21
defined, 5
DSHEA, 91, 138–139, 170
FFDCA, exclusionary clause, 137, 140–147
functional foods as, 183–187, 190
industry, U.S., 9–11, 13–29
market
Canada, 213
U.S., 8–9
misbranded, 95–96
and Pearson v. Shalala, 173
Dietary supplements (continued)
products considered as, 11–13
purchasing channels, 12
quality control, 55–67
statements of nutritional support, 94
structure/function claims, 175–176
truth in labeling, 95–96
Dietary supplements regulation, See also
Food supplements regulation
Brazil, 373–375
Codex and, 385
FDA, 89–98, 109
Good Manufacturing Practices (GMPs), 97
health claims, 13-16, 111-119; See also
Pearson v. Shalala
FDA-approved, 177–182
Japan, 258
legal framework, 138–139
Malaysia, 296
New Zealand, 321, 324, 329, 331–333
Pearson v. Shalala, 109–130
Pharmanex V. Shalala, 137–147
premarket approval process, 22
Singapore, 296–297
Thailand, 297
U.S., 29–34
dietary ingredients, 92
DSHEA enactment, 89–91
DSHEA prohibitions, 95–96
DSHEA requirements, 94–96
imminent hazard authority, 93, 96
new dietary ingredients, 92, 96–97
use of published literature, 93–94
violations, 96
Dietetic foods, EU regulations, 238–239, 344, 359
Diet and Health: Implications for Reducing
Chronic Disease Risk, 103–105
Dioxin-like polychlorinated biphenyls
(PCBs), EU regulations, 241
Dioxins, EU regulations, 241
Disclaimer, structure/function claims, 6
Disclosures
in advertising, 152–156
mandatory, 162
Disease
defined, 202
diet-related, 214
Disease claims
conventional foods, 110
defined, 110
Dispute Settlement Body, WTO, 379
Dispute Settlement Understanding (DSU), 379
District Court for the District of Columbia, on
FDA and Pearson v. Shalala, 112, 113–119
District Court for Utah, 137, 141–142
Doan’s Pill’s, 162
Docosahexaenoic acid, 325
Dole Juices, 25
Drug, Canadian Food and Drugs Act
definition, 215
Drug Identification Number (DIN), 215, 222–223
Dupont, 26
Echinacea
efficacy of, 203
in foods, 184, 185
standardization of, 19
E. coli 0157, 75
Econa cooking oil, 256
Eden Foods, 26
Eggland’s Best, 162–163
8th Continent™, 26
Employee training, CGMPs, 58–59
Endorsements
by experts, 163
by groups, 163
deceptive, 163
use in health claims advertising, 158
Endorsers, material connection, 163–164
Energy bars, 45
Energy drinks, 25
Australia/New Zealand regulations, 329–330
global market, 45
Enova, 256
Ensemble, 34, 182–183
EPA, in milk, 372
Ephedra, 22, 274
Ephedrine, 371
Epigallocatechin (EGCG), 11
Equipment, quality control, 60–61
European Authority, 345
Federal Trade Commission (FTC) (continued)
all products order, 161
Bureau of Economics, 49–50
cease and desist order, 161
Deception Policy Statement, 149–156, 161–164
*Dietary Supplements: An Advertising Guide for Industry*, 151
functional foods, marketing, 149–164
*Guide Concerning Use of Endorsements and Testimonials in Advertising*, 158, 163
health claims
advertising, 187–189
substantiation of, 21, 156–161
law enforcement framework, 150–152
mission, 149
“weight of scientific evidence” standard, 33
Federation of Swedish Farmers, 234, 307
Federation of Swedish Food Industries, 234
Feeding trials, animal/human, 276, 287
Fertilizers, organic standards for, 72–73
Fiber
and cancer, 25, 43–44, 79
FDA interim standard, 115
health claims, Brazil, 372, 374–375
and heart disease, 3, 25, 44, 79–80, 172, 177
First Amendment, and disease claims, 109, 111–112, 121–125
Fifth Amendment, 112
Fish liver oils, 241
Flavonoids, 374
Flavorings, 241
Flaxseed oil, 92
Folic acid
and neural tube defects, 16, 47–48, 112, 174, 177
FDA interim standard, 115–116, 118–119
pilot health claim trial, 332–333
and vascular disease, 16
Food additives
defined, 5
functional ingredients as, 190
Food additives regulations
Australia/New Zealand, 326–327
China, 266
EU, 228–229, 240–241
Japan, 248
“nutritive value” requirement, 184, 189
petitions for FDA approval, 89–92, 170
safety standards, 29–30
SPS Agreement, 380
Food Advisory Committee (FAC), UK, 235
Food and Agriculture Organization (FAO), 70, 377
Codex interactions, 381–382
Food and Drug Administration (FDA)
Center for Food Safety and Applied Nutrition (CFSAN), 14
the Constitution and, 126–127
Consumer Advisory, 170
Consumer Health Information for Better Nutrition, 40
Current Good Manufacturing Practices (CGMPs), 56–57
dietary supplements regulation, 89–98, 109
enforcement authority, 127–128
Federal Register, 80
FTC and, 150–152
GMA citizen petition, 119–121
health claims
approved, 39–41, 43, 174, 177–182
ranking system, 32–33, 174
Letter to Industry, 185–186
*Pearson v. Shalala*
application of, 125–128
conventional food labeling, 121–125
dietary supplement labeling, 110–121
impact of, 128–130
implementation of, 113–121
“significant scientific agreement” standard, 110–111
clarification of, 173
guidance document, 113
Task Force on Consumer Health Information for Better Nutrition, 40–41
Food and Drug Administration Modernization Act (FDAMA), xiii
“authoritative statement” standard, 111
enactment of, 101
health claims process, 83–84, 102–103, 171–172
“Food Hygiene Law of the People’s Republic of China”, 263, 264, 288–289

Food Industry Center (Japan), 249

Food law

Australia, 321–334
Brazil, 367–370
EU, 227–228, 231–232
Germany, 309–316
Japan, 248-249; See also FOSHU
New Zealand, 321–334
Spain, 337–343
Sweden, 305–309
U.S., 6–8

Food Policy Statement, FTC, 150–152

Food(s)

conventional
health claims in labeling, 121–125
qualified disease claims, 129–130
“significant scientific agreement”
standard, 110–111

defined
Brazil, 367
Canadian Food and Drugs Act, 215
EU, 316
dietetic
EU regulations, 238–239
FDA regulations, 174–175
hypoallergenic, 174
ingredients. See Ingredients, food
irradiation of, 242
labeling. See Labeling
marketing, FDA-FTC jurisdiction, 150
medical, 174–175, 187, 190
EU regulations, 239
new/novel. See Novel foods
organic. See Organic food
for particular nutritional uses (PARNUTS).
See PARNUTS
reduced fat, 23

Food safety regulations

Australia/New Zealand, 324–327
Brazil, 370–371
China, 266–275
dietary ingredients, 92–93, 170–171
food additives, 29–30
Food Standards Australia New Zealand (FSANZ), 324–327

FOSHU products, 252
Germany, 310
Japan, 248–249, 260
organic food, 75–76
raw materials, 16–17, 62–63
SPS Agreement, 379–381
Sweden, 306
U.S., 55
White Paper (EC), 344–349
WHO/FAO, 381–382

Foods with Nutrient Function Claims, Japan, 295–296, 300
Foods for Special Dietary Uses, Brazil, 367
Foods for specific medical purposes (FSMP), EU regulations, 239

Foods for Specified Health Uses (FOSHU) - A Guideline, 252
Foods for Specified Health Uses. See FOSHU

Food Standards Australia New Zealand (FSANZ)
functional foods definition, 323–324
objectives, 322
Regulatory Principles, 328
safety, 324–327

Food Standards Program (United Nations FAO/WHO), 378

Food supplements regulation, See also
Dietary supplements regulation
EU, 231, 243–244, 347–349
Germany, 309, 310, 312
Footnotes, disclosures in, 155–156
ForMor Inc., 155
Formulated Caffeinated Beverages (FCBs), 329–330

49th Parallel Group, 385
FOSHU, 38, 43, 295–296, 299–300
advertising, 256–257
approval process, 251–252
categories, 250
concept, 249–250
definitions, 250–251
functional ingredients, 255–256, 299
labeling, 256, 258–259, 299–300
premarket approval, 256–257, 297–298
sales by health benefit claimed, 252–255
Foundation for Innovation in Medicine, 3, 203
France
health claims regulation, 233
herbals/botanicals regulation, 243
Freedonia Group, 4
Free speech, and disease claims, xiii, 109,
111-112, 121-125; See also Pearson v. Shalala
Friends of the Earth, 385
Frontier products, Spain, 337
Fruitcal, 23
FTC v. Christopher Enterprises, Inc., 155
FTC v. Pantron I Corporation, 158
FTC v. Ruberoid Company, 161
FTC v. Warner-Lambert, 162
FTC v. Western Botanicals, 155
Functional claims
Brazil, 370–371, 372–373
Codex definition of, 355
EU, 353, 359, 361
Discussion Paper, 350–358
Spain, 356–358
Functional foods
background, 22
compositional standards, 27–28
credence claims, 157
defined, 5, 22, 293
FOSHU, 250–251, 295, 299–300
FSANZ, 323–324
General Accounting Office, 169
Health Canada, 217
Philippines, 294, 302
South Korea, 294, 302
diet and, 303–304
as dietary supplements, 183–187, 190
flavor problems, 28
FOSHU, 249–258, 295
health claims, 23–24, 171–176, 191
FDA-approved, 177–182
importation of, 249, 257, 282–283
labeling, 228–229
misleading, 46–47
market for, 204
Canada, 213–214
China, 263, 289
Japan, 300
U.S., 22–24
marketing, 28–29, 176–191
general principles, 50–52
as medical foods, 187
nutrient function claims, 258–259
product benefits, 23–24
public health concerns, 45–46
structure/function claims, 175–176,
182–183
U.S. industry, 22–29, 33–35
“Functional Foods in Europe Consensus
Document”, ILSI Europe, 41–42
Functional foods regulation
Australia, 321–334
Brazil, 367–373
Canada, 216–221
China. See Health food regulation, China
EU, 228–229, 304
FOSHU, 295–300
Germany, 303, 309, 312–316
Japan, 247–249, 257, 258–259
Myanmar, 301
New Zealand, 321–334
Spain, 337–343
Sweden, 305–309
U.S., 29–34, 169–176
Functional ingredients
as food additives, 190
FOSHU, 255–256
Function claims
Australia/New Zealand, 331
China, 264–265, 300–301
Fungus, Chinese regulations, 266
FSANZ, EU regulations, 241
Gaiatsu, 249
Gatorade, 25
General Accounting Office (GAO), functional foods definition, 169
General Agreement on Tariffs and Trade (GATT), 379
General Foodstuff and Commodities Act (Germany), 309
General Law of Public Health (Spain), 338
Generally Recognized As Safe (GRAS)
defined, 6
dietary ingredients, 14, 20
food additives, 170
General Mills, 26
“authoritative statement”, 83
functional foods, 25
health claims proposals, 172
oats and heart health campaign, 44, 177
*General Principles for the Addition of Essential Nutrients to Foods*, Codex Alimentarius, 327–328
Genetically modified organisms (GMOs)
EU regulations, 237, 238, 244, 314, 315
“GMO free” designation, 74
Japanese regulations, 249
Genetic engineering, and organic foods, 73–74
Genetic toxicity tests, 275
German Food Law, 309–310
Germany
dietary foods, 310–312
food authorities, 309–310
food supplements, 309, 312
functional foods, 312–316
health claims regulation, 303, 309–316
herbals/botanicals regulation, 243, 318
vitamins/minerals regulations, 242
Ginger, 19
Ginkgo biloba
efficacy trials, 20
in foods, 185
standardization of, 19
Gluconolactones, 25
Glucosamine, 19, 20
Glucosamine/Chondroitin Arthritis Intervention Trial (GAIT), 20
“GMO free” designation, 74
Good Manufacturing Practices (GMPs), 56–57; *See also* Current Good Manufacturing Practices (CGMPs)
Chinese regulations, 286
dietary supplement regulation, 97
Grape polyphenols, 19
GRAS. *See* Generally Recognized as Safe
Green Giant, 177
Greenpeace, 384, 385
Green tea, FOSHU potential, 257–258
Grocery Manufacturers of America (GMA), citizen petition, 119–121
Grocery Manufacturers of Sweden, 234

*Guide Concerning Use of Endorsements and Testimonials in Advertising*, FTC, 158, 163
Guidelines for the Use of Nutrition Claims, Codex Alimentarius, 353–355, 359
Gum, chewing, 257, 373

*Häagen-Dazs Company*, 156
Hain Food Group, 26, 184–185
Hartman Group, 4
Hazard Analysis and Critical Control Points (HACCP), 55, 286
Health, defined, 201
Health benefits
NREA definition of, 208
overstating, 160
Health Canada, 217
approved health claims, 218–219
*Interim Guidance Document on Preparing a Submission for Foods with Health Claims*, 220
product-specific health claims, 219–221
standards of scientific evidence, 218–219
Health claims, *See also under individual claims*
anecdotal evidence for, 158
audience targeting, 50–51, 154
bioactives, 4, 17–20, 30–32, 326, 374, context of, 51
conventional food, 121–125
defined, 6, 79, 176, 201
Codex Alimentarius, 38, 304–305
NREA, 208–209
Spain, 340–341
Sweden, 306
dietary supplements, 13–16
direct, 39, 219
DSHEA-approved, 202
European Food Safety Authority (EFSA), 364–365
exclusivity, 30–32
express, 152–153
fat-free, 353
FDA-approved, 39–41, 43, 174, 177–182
and First Amendment, 109, 111–112, 121–125
Health claims (continued)
foods for special dietary use, 173–174
FOSHU products, 253–255
functional claims, China, 264–265,
300–301
functional foods, 23–24, 171–176, 191
qualification of, 154–155
general well-being, 363
generic, 39
Health Canada-approved, 218–219
history of, US, 79–80
implied, 152–153
indirect, 39, 219
marketing, 13–16, 42–45, 50–52
medical foods, 173–174, 190
misleading, 46–47
misrepresentation of, 149–156
NLEA-authorized, 80–84
nutrition-based, 49–50, 173
preliminary studies and, 174
product-specific, 39
Canada, 219–221
Sweden, 307–308
purpose of, 101–102
qualified, 6, 14–16, 32–33, 84–85, 174
structure/function claims. See Structure/
function claims
substantiation of, 17–20, 39–42, 85, 109
Canada, 218–219
EU, 236, 360
FTC Act, 156–161
Tropicana Pure Premium, 101–108
unqualified, 6, 14, 32–33
Health claims regulations, See also Labeling
advantages of, 51
advertising. See Advertising
Australia/New Zealand, 329–334
“authoritative statement”, 83, 101, 172
bandwagon approach, 52
Belgium, 233
Brazil, 370–373
Canada, 215–216, 221–225
clinical trials, 17–20, 39–42, 85, 109
Codex Alimentarius, 304–305
disadvantages of, 51–52
approval procedure, 362
general well-being claims, 363
substantiation of claims, 236, 360
FDA, 39–41, 43
-approved, 39–41, 43, 174, 177–182
Modernization Act (FDAMA), 83–84,
102–103, 171–172
ranking system, 32–33, 174
France, 233
FTC, 21, 150–164, 187–189
Germany, 303, 309–316
“ignorant, unthinking, and credulous
consumer” standard, 109
Japan, 38, 43, 48–49, 258–259; See also
FOSHU system
Netherlands, 233–234
and public health, 45–47
“reasonable consumer” standard, 109
regulatory principle, 37
“significant scientific agreement” standard,
110, 111–121, 125–126, 172, 173
Spain, 234, 338–343
Sweden, 41, 234–235, 303, 305–309
UK, 38, 41, 235–236
U.S., 39–41, 43, 85–86
“weight of scientific evidence” standard,
32–33, 109
Health drinks, 257–258
HealthFocus International, 4
Health Food Control Act (Taiwan), 298
Health foods
defined, China, 264, 295
industry, China, 263
Health foods regulation
China, 263–265, 297–298, 300–301
approval certificate, 264–265, 276,
282–283, 285
assessment procedure, 283–285
control/supervision, 288–289
evaluation/approval process, 266
functionality evaluation, 276–281
hygiene standards, 287
imported foods, 282–283
labeling, 283, 285, 287
packaging, 286–287
production, 286
safety control, 266–275
Index

violations of, 289
Taiwan, 298
Health Functional Food (HFF), South Korea, 295
Health Products and Foods Branch, 218–219
Health Protection Branch (HPB), 215
   Food Directorate, 216
Healthy Woman, 9
HeartBar, 161, 187, 189
Heart disease
   and diet, 214
   and fiber, 3, 25, 44, 79–80, 172, 177
   and nuts, 15, 174
   and oats, 3, 25, 44, 79–80, 172, 177
   and omega-3-fatty acids, 15, 174
   and plant sterols/stanols, 172, 177, 315–316
   and potassium, 24, 44–45, 83, 103–105, 177
   and soy, 25
Heavy metals
   Chinese regulations, 287
   EU regulations, 241
   Heckler v. Chaney, 127–128
Heinz, lycopene campaign, 45, 188
Herbals
   Brazilian regulations, 374
   EU regulations, 241, 242–243, 316, 317–318
   German regulations, 303, 318
   Irish regulations, 243
   medicinal, 184–185
   Swedish regulations, 303, 318
   U.S. regulations, 12, 17–20
Heterochemical Corporation v. FDA, 128
HMG-CoA reductase inhibitors, 140
Honeywell, Inc., 160
Hormone replacement therapy (HRT), 34
Hormones, and organic meat production, 69, 73
Hygiene License, China, 286, 289
Hygienic practices, 58
   SPS Agreement, 380
Hypertension
   diet and, 104–105
   potassium and, 24, 44–45, 83, 103–105, 177
Hypoallergenic foods, 174
ILSI SE Asia Region survey
   definitions/regulations, 294–299, 302
   methodology, 293–294
   objective, 293
   premarking approval, 297–299
   products/claims, 299–301
   respondents, 294
Imagine Foods, 26
Importation
   functional foods
      China, 282–283
      Japan, 249, 257
   “Increased”, Codex Guidelines, 354
Indonesian National Agency for Drug and Food Control (NADFC), 296
Infant Formula Quality Control Procedures, 55
Infant formulas, 174
   Codex regulations, 385
   DHA in, 32
   EU regulations, 238–239
Infomercials, 163
Information, disclosure of, 152–156
Ingredients
   dietary. See Dietary ingredients
   food, See also Dietary ingredients
   Australia/New Zealand regulations, 325–327
   Brazilian regulations, 373
   form of, 325
   functional
      as food additives, 190
      FOSHU, 255–256
   GRAS, 5
   proprietary, 30–32
Inspectors, organic foods, 72
Institute of Medicine (IOM)
   scientific support for health claims, 174
   Tolerable Upper Intake Levels, 33
Institute of Nutrition and Safety (China), 282
Insulin resistance, 205
Intellectual property, nutraceuticals and, 30–32
Intergovernmental organizations (IGOs), 47
   Codex process interactions, 381–387
International Association of Consumer Food Organizations, 47
International Federation of Organic Agriculture Movements (IFOAM), 70, 73, 76
International Life Sciences Institute (ILSI), 368
China Focal Point, 263
Europe, 41–42, 304
International Office of Epizootics, 378, 380
International Organization for Standardization (ISO), 384
International Plant Protection Convention, 378
Internet, and health claims, 186
Interstate Bakeries Corporation, 160
Ireland
herbals/botanicals regulation, 243
vitamins/minerals regulations, 242
Irradiation
EU regulations, 242
organic foods, 73
Isoflavones, 9, 374
standardization of, 19
Italy, vitamins/minerals regulations, 242
Japan
birth rates, 247
food law, 248–249
Foods with Nutrient Function Claims, 295–296, 300
FOSHU system, 38, 43, 249–258, 295–300
marketing, 256–257, 259–260
functional foods
defined, 295
regulation, 247–249
future regulations, 259–260
GMOs regulations, 74, 249
health care costs, 247
longevity of population, 247
Ministry of Health, Labor, and Welfare (MHLW), 247–250
Food Sanitation Law, 248–249
Office of Health Policy on Newly Developed Foods, 251
nutrient function claims, 258–259
premarketing approval process, 297–298
Japan Food Additives Association, 248
Japan Health Food and Nutrition Food Association (JHNFA), 48, 250–258
“Jelly Bean Rule”, 173
Johnson & Johnson, 9
Joint Health Claims Initiative (JHCI), 235–236
Code of Practice, 38, 41
Karada Shien, 257
Kava, 170, 185
Kellogg, 34
Ensemble line, 182–183
fiber campaign, xi, 25, 43–44, 79, 176–177
folic acid health claim, 47–48, 177, 183
soy foods, 26
Kellogg Japan, 257
Kitchen Prescription, 184–185
Klondike Lite ice cream bars, FTC labeling challenge, 151
KPMG Consultants, 214
Kraft Foods, 23
“authoritative statement”, 83
functional foods, 25
soy foods, 26
Labeling, See also Health claims regulation
biotech, 387
Brazilian regulations, 370–373
Canadian regulations, 218
Codex guidelines, 305
conventional food, 121–125
dietary supplements, 95–96
EU regulations, 343–356
food, 228–229
functional claims, 361
GMOs, 244, 315
nutrition, 229–231
weight reduction foods, 363
false or misleading, 46–47, 128
FOSHU products, 256, 258–259
and free speech, 111–112
FTC and, 150–152
German regulations, 313–316
health claims restrictions, 14
health claims, types of, 101
health foods, China, 283, 285, 287
“ignorant, unthinking, or credulous consumer” standard, 33
logos and, 47
organic food, 69–71, 74
quality control, 63
“reasonable consumer” standard, 33
Spanish regulations, 339–343
statements of nutritional support, 94
structure/function claims, 175–176
truth in, 95–96
use of books/publications, 93–94
U.S. regulations, 4–8
Web sites and, 186
Laboratory operations, quality control, 65–66

*Lactobacillus*, 372
*Lactobacillus casei*, 253
Lactoferrin, GRAS status, 20
Lean Cuisine, 156
Lebensmittel und Bedarfsgegenstände-Gesetz (LBMG), 309–310
“Less”, Codex Guidelines, 354
Licensing agreements, 31
Licorice root, 274
Linseed oil, 92
alpha-Lipoic acid, 205
Lipovitan, 258
Lipton teas, 26
Listerine, 162
Lobelia, 92
Logos
  approved health food, China, 265
  on food labels, 47
  FOSHU, 250, 257
organic foods, 72, 74–75
Lovastatin, 140–141, 143–144, 185
“Low”
  Codex Guidelines, 353
  EC guidelines, 353
Lutein, 9, 20
Lycopene, 20, 45, 188
Malaysian Food Regulations, 296
Managed care, and nutraceuticals, 34–35
Manufacturing, quality control, 63–64, 66–67
Manure, organic standards, 73, 75, 76
*Marbury v. Madison*, 126–127
Margarine substitutes, 184, 372
Marketing
  and deceptive advertising, 163
  FOSHU products, 256–257, 259–260
  functional foods, 28–29, 176–191
  and health claims, 13–16
    benefits of, 43–45
    general principles, 50–52
    importance of, 42–43
    public health concerns, 45–47
    health and wellness, 34
    and information disclosure, 162–156
  Swedish Code of Practice, 308–309
  target audience, 154
  Tropicana Pure Premium, 105–108
Martek Bioscience, 32
Material connection, experts/endorser, 163–164
3-MCPD, EU regulations, 241
Mead Johnson, 9
Meal replacement products, EU regulations, 238–239
Meat production, organic management, 73
Medical devices, FDA-FTC jurisdiction, 150
Medical-disease claim, defined, 201
Medical foods
  defined, 175
  EU regulations, 239
  functional foods sold as, 187
  German regulations, 311
  health claims for, 173–174, 190
Medicinal product, EU definition, 360
Medicinal Products Agency (MPA), Sweden, 318
Medicine, defined, EU, 317
Meiji Dairies, 254
Mercosur, 384
Methylen chloride, 154
MetrRx, 162
Mevacor, 140–141
Mevinolin, 140
Mice, feeding trials, 276
Microbiological testing, Chinese regulations, 287
Micronutrients
Codex Guidelines, 354
EU regulations, 230, 242
Milk, organic standards for, 73
Milk products, fermented, 45
Milo milk, 257
Minerals
Australia/New Zealand regulations, 325–329
Irish regulations, 242
Italian regulations, 242
Spanish regulations, 343
U.S. market, 12
Ministerio de Sonidad y Consumo, 234
Ministry for Consumer Protection, Nutrition
and Agriculture (Germany), 309
Ministry of Health (Brazil), 370
Ministry of Health (China), 263–290
“Administrative Provisions for New Food
Source Hygiene”, 266
function claims, 300–301
premarketing approval, 298
“Standards for Toxicological Assessment of
Health Foods”, 274
Ministry of Health and Consumption (Spain),
339–343
Ministry of Health and Welfare (Japan),
premarketing approval, 297–298
Miracle products, Spain, 337
“More”, Codex Guidelines, 354
Morinaga Milk Industries, 254
Myanmar, functional foods regulation, 301
Mycotoxins, EU regulations, 241
Myocardial ischemia, 205

NAFTA, 384
National Academy of Sciences
Diet and Health: Implications for Reducing
Chronic Disease Risk, 103–105
Institute of Medicine (IOM), 17, 174
Tolerable Upper Intake Levels, 33
as “scientific body”, 83, 101
National Advertising Division, Council of
Better Business Bureau, 186–187
National Cancer Institute, xiii, 8
fiber health claims, 43–44, 79
“5-A-Day” program, 24
National Center for Complementary and
Alternative Medicine (NCCAM),
19–20
National Consumer Council (UK), 47
National Dietary Council (France), 233
National Institutes of Health (NIH)
Botanical Centers, 17
National Center for Complementary and
Alternative Medicine (NCCAM),
19–20
Office of Dietary Supplements (ODS),
19–20
as “scientific body”, 83, 101
“National List, The”, 73
National Nutritional Foods Association, 9
National Nutrition Survey in Japan, The,
248
National Organic Program (NOP), 69–71
GMO standards, 74
organic labels, 74
National Organic Standards Board, 73
National Sanitary Surveillance Agency
(ANVISA), 367–369
Natto, 254
Natural foods
defined, 6
U.S. market, 9, 22–23
Natural Health Products Directorate (NHPD),
217
health claims regulation, 221–225
nutraceuticals definition, 221
Natural Health Products (NHP), Canada
industry, 213–214
regulation, 221–225
Natural Health Products Research Program
(NHPRP), 224
Natural product number (NPN), 222
Natural products, Brazilian market, 367,
372–373
Nestle, 23
Nestle Japan, 257
Netherlands, health claims regulation,
233–234
Netherlands Nutrition Center, 233–234
Neural tube defects
and folic acid, 16, 47–48, 112, 174, 177
pilot health claim trial, 332–333
New Drug Application (NDA), 204
New Zealand
dietary supplements regulation, 321, 324, 329, 331–333
food law, 321–334
food safety, 324–327
health claims regulation, 329–334
novel foods regulation, 325–327
vitamins/minerals regulation, 327–329
Nippon Lever Co., 257
NiteBite, 187
Nitric oxide, 187
Nongovernmental organizations (NGOs), Codex process interactions, 381–387
Norelco Clean Water Machine, 153–154
North American Philips Corporation, 153–154
Novartis, 34
Novartis v. FTC, 162
Novel foods regulation
Australia/New Zealand, 325–327
Brazil, 370
EU, 237–238, 314–315
Nucleic acids regulation
Australia/New Zealand, 325–326
China, 266
Numex Corporation, 164
Nutraceutical Research and Education Act, 204, 206–212
Nutraceuticals
defined, 3–5, 6, 201
Brazil, 368
DSHEA, 55
Health Canada, 217
NREA, 208
EU regulations, 228–229
German regulations, 313–316
intellectual property, 30–32
and managed care, 34–35
marketing, 50–52, 203–206
proprietary protection, 204, 205

quality control, 55–67
Spanish regulations, 342–343
toxicity issues, 203, 204
U.S. regulations, 29–34
Nutraceuticals World, 4
Nutrient/nutritional claims, 38–39
Codex guidelines, 355, 364
comparative, 354
EU, 229–231, 351–354
Japan, 258–259
Spain, 356–358
U.S., 49–50
Nutrients, recommended intake, 17
Nutrition
EU Discussion Paper, 350–358
EU recommendations, 345
Nutritional Outlook, 4
Nutritional profile, EU, 363
Nutrition Business Journal, 4
“Nutrition Claims and Functional Claims”, EU, 304
Nutrition industry, growth of, 4–8
Nutrition labeling, EU regulations, 229–231
Nutrition Labeling and Education Act (NLEA), xiii, 49
authorized health claims, 80–84
health claims for functional foods, 171–174
intent of, 101
“significant scientific agreement” standard, 110
statements of nutritional support, 94
Nutritive substances, regulation,
Australia/New Zealand, 325–326
“Nutritive value” requirement, food additives, 184, 189
Nuts, and heart disease, 15, 174
Oats, and cholesterol, 3, 25, 44, 79–80, 172, 177
Obesity
global prevalence of, 45
Japan, 248
Observer status, nongovernmental organizations (NGOs), 381
Ocean Spray, 45
Office of Dietary Supplements (ODS), 19–20
Office of Natural Health Products, 221
Official Journal of the European Communities, 347
Ohtsuka Pharmaceutical, 258
Olestra, 190
Omega-3-fatty acids
  Brazilian regulations, 372
  FDA interim standard, 116–117
  German regulations, 313
  health benefits, 24
  and heart disease, 15, 174
One-A-Day, 8, 11
Oranamin C, 258
Orange juice
calcium-fortified, 23-24; See also
  Tropicana Pure Premium
and nutrition, 103
US market, 106–107
Organic, definition, 70
Organic Farming Research Foundation, 75
Organic foods
certifying agents, 72
defined, 6, 69
EU regulations, 71, 76
health and safety, 75–76
inspectors, 72
Japanese market, 249
labeling, 74
U.S.
  industry, 22–23
  market, 69
  regulations, 69–77
Organic Foods Production Act, 69
Organization for Economic Cooperation and Development (OECD), 383
Organosulfur compounds, 374
Orotate compounds, 92
Orphan Drug Act, 204
Osteoarthritis, 20
Osteoporosis, and calcium intake, 24
Over-the-Counter drugs
  FDA-FTC jurisdiction, 150
  market, 204
Overweight, global prevalence of, 45
Pacific Foods, 26
Package labeling. See Labeling
Packaging
  Chinese regulations, 286–287
  quality control, 63, 66–67
  Tropicana Pure Premium, 105–108
Pallone, Frank, 204
Panda Herbal International, Inc., 155
PARNUTS, 228, 238–240
  EU regulations, 238–240, 359
  Germany, 310–311
PASSCLAIM, 42, 236, 304
Patents, 31
Pearson v. Shalala
  background, xiii, 110–121
  CFSAN and, 15
  and dietary supplements, 173
  and FDA authority over health claims, 173
  First Amendment and food labeling,
    121–125
  impact of, 128–130
  interpretation/application by FDA, 125–128
  qualified health claims, 8–85
PepsiCo., functional foods, 25
Performance-enhancing products
  Australia/New Zealand, 326
  Brazil, 374
Personnel, quality control, 58–59
Pesticides
  EU regulations, 241
  Japanese regulations, 249
  organic standards for, 71–73
  SPS Agreement, 380
Pfizer, 11
Pfizer factors, 157–158
Pharmaceuticals, market, 204
Pharmafoods, Spanish regulations, 342–343
Pharmanex I, 141–142
Pharmanex II, 138, 142–143
Pharmanex III, 137–138, 139, 143–144
Pharmanex v. Shalala, 137–138, 146–147, 185
  agency and court proceedings, 140–144
  background, 139–140
  implications of, 144–146
Philippines
  Bureau of Food and Drugs, 296
  functional foods, 294, 302
Phosphatidylserine, and cognitive dysfunction and dementia, 16, 174
Phospholipids, 374
Physical plants, quality control, 59–60
Phytochemicals
and cancer, 24
and cholesterol, 31, 315–316, 327
Phytonutrients, defined, 6
Phytosanitary standards, harmonization of, 379–380
Phytosterols, 325, 372, 374
and cholesterol, 31, 315–316, 327
Phytotherapeutics, Brazil, 367, 368, 372
Pillsbury, health claims, 177
Plant Protection Convention, 380
Polycyclic Aromatic Hydrocarbons (PAH), 241
Polydextrose, 257
Polyols, EU regulations, 241
Polyphenols, 374
Pork and Beans, 177
Potassium
and blood pressure, 24, 44–45, 83, 103–105, 177
intake, US, 105
and stroke, 24, 83, 177
Tropicana Pure Premium health claim, 101–108
PowerBar, 23
Prebiotics, Brazilian regulations, 373, 374
“Precautionary principle”, Codex Alimentarius, 385–387
Premarketing approval
China, 298
FOSHU products, 256–257, 297–298
functional claims, 355
ILSI SE Asia Region survey, 297–299
U.S.
dietary supplements, 22
food additives, 170
Prevention, self-care survey, 203
Prior market clause, 137–139, 144–147
Proanthocyanidins, 22
Probiotics
Brazilian regulations, 372, 373, 374
Chinese regulations, 266
European market, 45
German regulations, 313
“Process for the Assessment of Scientific Support for Claims on Foods” (PASSCLAIM), 42, 236, 304
Process controls, quality control, 61
Procter & Gamble, Fruitcal, 23–24
Product 19, 177
Product benefits. See Health claims
Production, quality control, 61
Production permits, China, 286
Product labeling. See Labeling
Product License, natural health products, 222
Product-specific health claims, 39
Canada, 219–221
Sweden, 307–309
Proprietary Medicinal Products (EU), 316
Proprietary products, 30–32
Proprietary protection, nutraceuticals, 204, 205
Protein content, EU nutrition labeling regulations, 230
Protein Technologies International, 26
Psyllium, 25, 176–177, 189
Publications, FDA labeling restrictions, 93–94
Public health, and health claims regulation, 45–47
Quaker Oats Company, 25, 44, 177
Quality control
batch production records, 64–65
Current Good Manufacturing Practices (CGMPs), 57–67
equipment, 60–61
expiration dating, 67
issues in, 55–57
labeling, 63
laboratory operations, 65–66
manufacturing, 66–67
master manufacturing records, 63–64
packaging, 63, 66–67
personnel, 58–59
physical plant, 59–60
process controls, 61
production, 61
raw materials, 16–17, 62–63
testing, 65–66
Quality control (continued)
  unit, 61–62
  utensils, 60
Quanterra™, 11
Quigley Corp., 160
QVC, Inc., 160

Raisin Bran, 79
Raisio Group, 31
Rama ProActive margarine, 257
Rats, feeding trials, 276
Raw materials
  Chinese safety regulations, 266–275
  quality control, 16–17, 62–63
Real Decreto (RD), 337–343
Recaldent, FOSHU approval, 257
Recommended Daily Allowance
  nutrition labeling, EU regulations, 231
  vitamins/minerals, 354
Recommended Daily Intake, 328
Red Bull GmbH, 25
“Reduced”, Codex Guidelines, 354
Red yeast rice, 139–140, 143–144
Reference Daily Intake, 173
Reference Daily Value, 173
“Regulation of the European Parliament and
  of the Council on Nutrition,
  Functional and Health Claims Made
  on Foods”, EU, 304
Research, to substantiate health claims,
  158–161
Research-based Dietary Ingredient
  Association (RDIA), 32
Restitution, to consumers, 161
Risk-assessment techniques, SPS Agreement,
  380
Risk-reduction claims
  Australia/New Zealand, 331
  Canada, 216
  Royal jelly, 297
  Rutin, 91

Safrole, 241
St. John’s Wort, 92
  efficacy, 20, 155, 203
  as a food ingredient, 184, 185
  standardization of, 19
Sanitarium, folate health claim, 47–48
Sanitary and Phytosanitary (SPS) Agreement
  risk-assessment techniques, 380
  role of Codex standards/guidelines,
    378–381
Sardines Panel, WTO, 366–367
Saw Palmetto, FDA interim standard, 119
Scandinavian Journal of Nutrition, 305
Schering-Plough Healthcare Products, 160
Scientific Committee on Food (SCF), EU,
  237
Secretary of Health and Human Services, 93,
  96
Selenium, and cancer, 15, 174
Senate Committee on Labor and Human
  Resources, 89
Sewage sludge, 73
Shark cartilage, 19, 91
“Significant scientific agreement” standard,
  172
  Administrative Procedure Act, 125–126
  after Pearson v. Shalala, 111–121
  dietary supplements, 110, 111, 126
  FDA clarification of, 173
  FDA guidance document, 113
  NLEA, 110
Silver Anvil Award for Integrated
  Communications, 107
Simeon Management Corp. v. FTC, 158
Singapore, dietary supplements regulation,
  296–297
Site licensing, NHP companies, 222
Sitostanol ester, 30
Snow brands milk, 260
SoBe, 26
Sodium, health claims, 353, 359
Sodium nitrate, 76
Soft drinks
  functional, 45
  Japan, 257
South Korea
  functional foods, defined, 294, 302
  Health Functional Food (HFF), 295
Soyatech Inc., 34
Soy foods, 26–27, 374
  and heart disease, 25
  U.S. market, 34
Soy isoflavones, 9
standardization of, 19
Soy milk, 26
Spain
functional foods regulation, 337–343
health claims regulation, 234
vitamins/minerals regulations, 242, 343
Spanish Federation of Food and Drink Manufacturers, 234
Spanish Federation of Industries of Food and Beverages (FIAB), 339–343
Spanish Ministry of Health, 234
Specialty supplements, standardization of, 17–20
Specifications and Standards for Foods, Food Additives, etc. under The Food Sanitation Law, 248
SPINS, 4, 21
Sports nutrition products, EU regulations, 239–240
Spreads, cholesterol-lowering, 30, 31, 184, 372; See also Stanols; Sterols
Standard Operating Procedures (SOP), laboratory testing, 65–66
“Standards for Toxicological Assessment of Health Foods”, (Chinese Ministry of Health), 274
Stanols, plant, 30, 31, 172, 177
GRAS status, 20, 184
State Food and Drug Administration (SFDA), China, 263–265
Division of Traditional Medicine Protection, 283–285
Stay Alert Caffeine Supplement Gum, 185
Sterols, plant, 177, 315–316
GRAS status, 20
Stouffer Foods Corp., 156
Stroke
potassium and, 24, 83, 177
Tropicana Pure Premium, 101–108
Structure/function claims, 39, 101
defined, 6, 79, 176
DSHEA, 14, 151
functional foods, 175–176, 182–183
regulating, 191
scientific evidence for, 176
Sugars, EU nutrition labeling regulations, 230
Superscript, for disclosures, 155–156
Sweden
approved health claims, 41
functional foods regulation, 305–309
health claims regulation, 234–235, 303, 305–309
herbals regulation, 318
Swedish Code of Practice, 303, 306
labeling, 306, 308–309
marketing, 308–309
Swedish Cooperative Union, 307
Swedish Federation of Trade, 307
Swedish Food Federation, 307
Swedish Food Retail Association, 234, 307
Swedish Nutrition Foundation (SNF), 303, 305, 307–309
Sweeteners, 172, 228, 241
D-Tagatose, and tooth decay, 172
Taisho Pharma, 258
Taiwan, health foods regulation, 298
Take Control, 30, 184, 189
Tall oils, 325
Task Force on Consumer Health Information for Better Nutrition, FDA, 40–41
Taurine, 25, 374
Tea extracts, 19
Teas, flavored, 25, 26
Technical Barriers to Trade (TBT) Agreement, role of Codex standards/guidelines, 378–379
Technical-Sanitary Regulations, Spain, 340
Technical Scientific Advisory Commission on Functional Foods and New Foods (CTCAF), 369
Testimonials, use in health claims advertising, 158, 159
Testing, quality control, 65–66
Thailand, dietary supplements regulation, 297
Theragran, 8
Therapeutic claims, Canada, 216
Therapeutic Products Directorate (TPD), 215
Thompson v. Western States Medical Center, 124
Tolerable Upper Intake Levels, NAS/IOM, 33
Tooth decay, and D-Tagatose, 172
Toxicity testing, Chinese health foods, 274–275
Traceability, biotechnology, 387
Trade agreements, 378–379; See also Codex Alimentarius Commission; World Trade Organization (WTO)
Trade regulations, WHO/FAO, 381–382
Traditional Chinese Medicine (TCM), 263
TraumaCal Liquid, 175, 187
Travasorb Hepatic Powder, 175, 187
Treaty of Rome, 227
Traditional Chinese Medicine (TCM), 263
Turmeric, standardization of, 19

Unilever, 30
United Kingdom Food Standards Agency, 242
United Kingdom (UK)
consumer advocacy, 47
health claims regulation, 38, 41, 235–236
herbals/botanicals regulation, 243
United Nations (UN)
Commission on Sustainable Development, 383
Conference on Environment and Development (UNCED), 383
Food and Agriculture Organization (FAO), 70, 377
United States
Codex process interactions, 381–387
Constitution, 126–27
First Amendment, 109, 111–112, 121–125
Fifth Amendment, 112
Court of Appeals for the District of Columbia Circuit, 109, 112
Court of Appeals for the First Circuit, 90
Court of Appeals for the Seventh Circuit, 90

Court of Appeals for the Tenth Circuit, 142–143
Department of Agriculture (USDA)
Agricultural Marketing Service (AMS), 70, 72
Foreign Agricultural Service (FAS), 263
Organic seal, 74
Department of Health and Human Services, “Healthy People 2010”, 23
dietary supplements
companies, 9–11
consumer use of, 21
industry, 9–11, 13–29
market, 11–13
regulation, FDA, 89–98
District Court for the District of Columbia, on FDA and Pearson v. Shalala, 112, 113–119
District Court for Utah, 137, 141–142
FDA. See Food and Drug Administration
food law, 6–8
food sanitation regulations, 55
food supply safety, 32
functional foods
industry, 22–29
products/companies, 25–27
regulation, 169–176
health claims
advertising, 49–50
approved, 177–182
process, 85–86
qualified, 84–85
regulation, 39–41
natural food industry, 22–23
nutraceuticals regulation, 29–34
nutrition labeling, 4–8
organic foods
industry, 22–23
regulation, 69–77
Secretary of Health and Human Services, 93, 96
Unither Pharma, Inc., 160–161, 189
Utensils, quality control, 60–61

V8 juice, 183
Vascular disease, and B vitamins, 16
Veterinary drugs, SPS Agreement, 380
Viactiv, 9
Victor, Stephen, 163
Vitamin B, FDA interim standard, 117–118
Vitamin B6, 16
Vitamin B12, 16
Vitamin E, efficacy of, 203
Vitamin-fortified drinks, German regulations, 314
Vitamins regulations
  Australia/New Zealand, 325–326, 327–329
  EU, 242, 348–349, 353–354
  nutrition labeling, 230–231
  Ireland, 242
  Italy, 242
  Spain, 343
  U.S., 12
Vitasoy USA, 26
Voedingscentrum, 233
Voltaire, 201
Warner Lambert, 11, 257
Warning labels, EU regulations, 229
Washington Legal Foundation (WLF), 186
Weider Nutrition International, Inc., 172
Weight reduction foods, 174
  EU labeling regulations, 363
  German regulations, 311
“Weight of scientific evidence” standard, 32–33, 109
Welch Foods, antioxidants claims, 188
Wellness drinks, German regulations, 314
Wexler, Patricia, 163
Whitaker v. Thompson, 129, 130
White Paper on Food Safety, (EC), 227–228, 339, 344–349
White Wave, 26
WonderBread, 189
World Health Organization (WHO)
  Codex Alimentarius Commission, 377–378
  Codex interactions, 381–382, 386–387
  dietary practices, 45
  organic foods guidelines, 70
World Summit on Sustainable Development (WSSD), 383
World Trade Organization (WTO)
  Dispute Settlement Body, 379
  establishment of, 378
  Sardines Panel, 366–367
Wyeth, 8, 9
Xuezhikang, 140
Xylitol, 373
“Yakult” lactic acid beverage, 253, 257
Yogurt, 254
Zbars, 187
Zhi-Tai, 140