

An Overview of FDA's Regulation of Dietary Supplements

Bob Durkin, Deputy Director, CFSAN/ODSP
"All Matters FDA"

Widener University Delaware Law School
April 3, 2019

Dietary Supplement Authority

- Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et. seq.)
 - Dietary Supplement Health and Education Act
 - Laid out the major framework for dietary supplements
 - Public Health Security and Bioterrorism Preparedness and Response Act
 - Requirement for facilities to register with FDA
 - Food Allergen Labeling and Consumer Protection Act
 - Allergen labeling requirement

Dietary Supplement Authority

- Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et. seq.)
 - Dietary Supplement and Nonprescription Drug Consumer Protection Act
 - Requirement for dietary supplement firms to submit serious adverse events to FDA
 - FDA Food Safety Modernization Act
 - Major overhaul of framework for food facilities

Dietary Supplement Authority

- Dietary Supplement Health and Education Act of 1994
 - Defined the term dietary supplement
 - Established requirements for new dietary ingredient premarket review
 - Established requirements for current good manufacturing practices
 - Included dietary supplements under the adulteration provisions

Definition of Dietary Supplement

- Product (other than tobacco) that is intended to supplement the diet
- Product that is intended for ingestion
- Contains one or more dietary ingredients
 - Vitamin
 - Mineral
 - Herb or other botanical
 - Amino acid
 - Dietary substance for use by man to supplement the diet by increasing the total dietary intake
 - A concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients

Definition of Dietary Supplement

- It does not include
 - an article that is approved as a new drug, certified as an antibiotic, or licensed as a biologic
 - an article authorized for investigation as a new drug, antibiotic, or biological for which substantial clinical investigations have been instituted and for which the existence of such investigations has been made public(unless such article was first marketed as a dietary supplement or food)

Regulatory Responsibilities

- Facility Registration
- New Dietary Ingredient Notification
- Good Manufacturing Practices
- Dietary Supplement Labeling
- Structure/Function Claim Notification
- Adverse Event Reporting

Facility Registration

- All food facilities must register with FDA
 - Domestic and foreign
 - Basic information: name, address, type of activity conducted at the facility for each food product category, responsible party
 - FDA inspection acknowledgement
- Renewal of information every even numbered year

New Dietary Ingredients

- Dietary ingredients not marketed in a dietary supplement prior to October 15, 1994
- Manufacturers must submit a safety notification to FDA at least 75 days prior to marketing
- FDA has 75 days to respond
 - Acknowledgement – not approval
 - Objection (generally based on identity or safety)
- Notification is made public after 90 days

New Dietary Ingredients

- Notification must include
 - Name and address
 - Signature of responsible party
 - Name of the ingredient
 - Description of the product(s) containing the NDI
 - Amount of the NDI in product(s)
 - Conditions of use
 - History of use or other evidence of safety establishing the NDI “will reasonably be expected to be safe”

New Dietary Ingredients

- While the requirement has been in place for 20+ years, FDA has only received ~1000 NDINs
- Important that firms know:
 - When to submit a premarket notification
 - How to prepare a premarket notification

Current Good Manufacturing Practices

- FDA published the CGMP Rule in 2007
 - 21 CFR 111
- To help ensure dietary supplement product quality, purity, consistency, and safety
 - Production and process controls
 - Testing requirements for raw materials and finished products

Current Good Manufacturing Practices

- Applies to all firms who manufacture, package, label or hold dietary supplements
 - Domestic and foreign
- Compliance confirmed by periodic inspections
 - ORA investigators

Dietary Supplement Labeling

- Dietary supplements must follow food labeling requirements (21 CFR 101)
 - Must be labeled as a “dietary supplement”
 - Must list all ingredients
 - Properly formatted Supplement Fact label
 - Name/location of manufacturer
 - Domestic contact information for submission of adverse events

Dietary Supplement Labeling

- Allowed claims
 - Nutrient content claims
 - Characterizes the level of a nutrient
 - Structure/function claims
 - Describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans
 - Health claims/qualified health claims
 - Characterizes the relationship of any substance to reducing risk of a disease

Structure/Function Claims

- Claims made in accordance with section 403(r)(6) of the FD&C Act
 - nutrient deficiency disease claim
 - general well-being claim
 - structure/function claim
- Cannot claim to treat, cure, prevent disease
 - Disease = damage to an organ, part, structure, or system of the body such that it does not function properly, or a state of health leading to such dysfunction

Structure/Function Notification

- Firms need to
 - have substantiation that the claim is truthful and not misleading
 - notify FDA of the text of the claim no later than 30 days after marketing the product containing the claim
 - include the FDA disclaimer language
- Firms do not need to
 - provide the entire label/labeling with their notification
 - provide the substantiation

Disease Claims

- Context is CRITICAL
 - Not always possible to draw a clear line
 - Need to consider all information in labeling and elsewhere
 - No claim is likely to be always or never appropriate
- Factors to take into account
 - Guidance for Industry: Structure/Function Claims, Small Entity Compliance Guide

Adverse Event Reporting

- FDA's MedWatch program receives dietary supplement adverse events
 - Electronic portal, email, phone calls, letters
- Consumers and health care providers are encouraged to submit adverse events
- Manufacturers are required by law to submit serious adverse events to FDA within 15 business days

Adverse Event Reporting

- All dietary supplement adverse events are entered into the CFSAN Adverse Event Reporting System (CAERS) database
- Reviewer will evaluate cases
 - Identify any triggers with firms, products, ingredients
 - Determine if any follow-up information is necessary
 - Inspection, consumer warning, product recall

Regulatory Recap

- Facility (not product) Registration
- New Dietary Ingredient Notification (not approval)
- Good Manufacturing Practices
- Dietary Supplement Labeling
- Structure/Function Claim Notification (not approval)
- (Serious) Adverse Event Reporting

Dietary Supplements in FDA



[A to Z Index](#) | [Follow FDA](#) | [En Español](#)

Q

☰

Home

Food

Drugs

Medical Devices

Radiation-Emitting Products

Vaccines, Blood & Biologics

Animal & Veterinary

Cosmetics

Tobacco Products

Food

Home > Food > Dietary Supplements

Dietary Supplements	
Products & Ingredients	▼
Information for Consumers	▼
Information for Industry	▼
Report an Adverse Event	
New Dietary Ingredients Notification Process	▼

Dietary Supplements

SHARE
 TWEET
 LINKEDIN
 PIN IT
 EMAIL
 PRINT

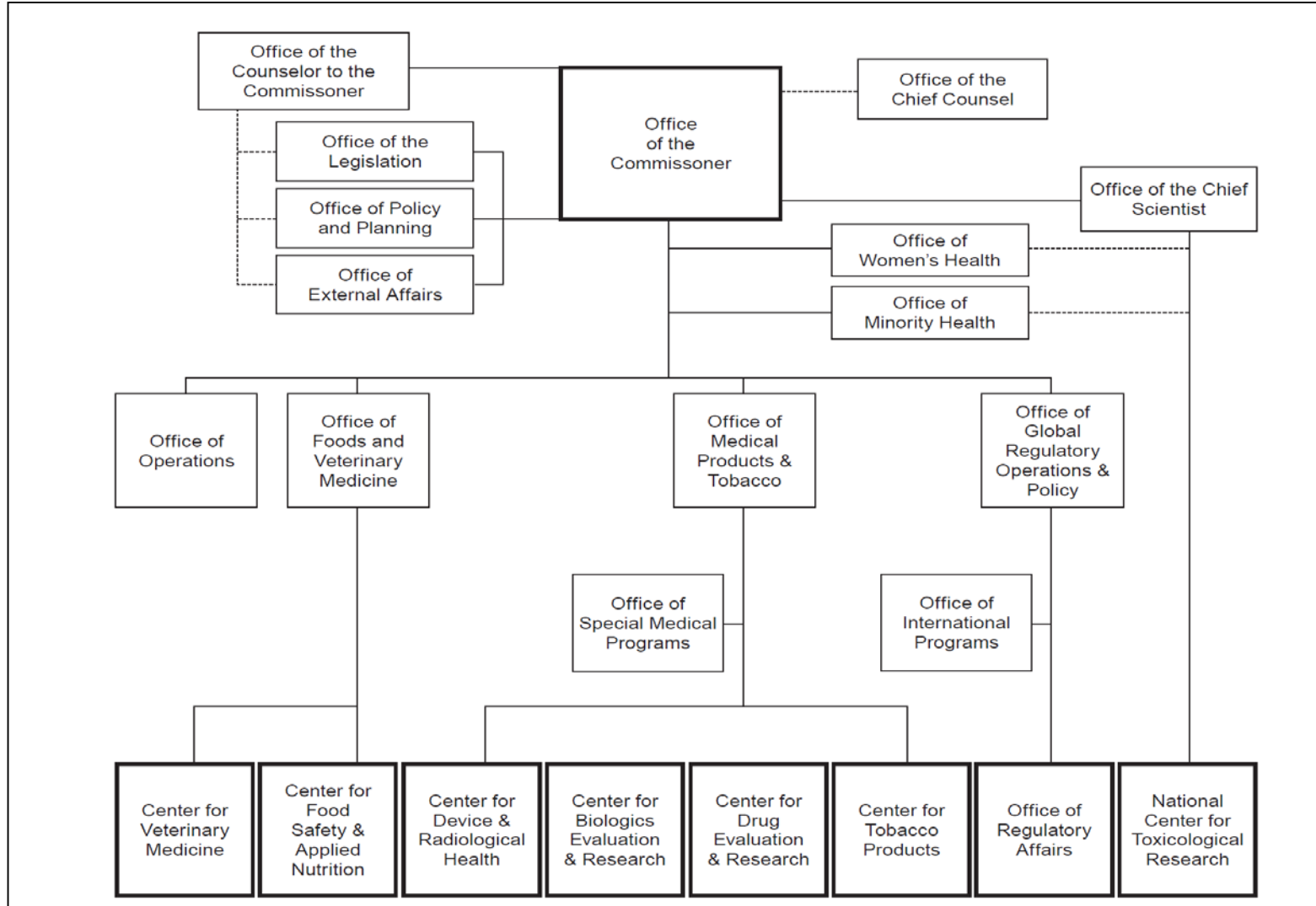
FDA regulates both finished dietary supplement products and dietary ingredients. FDA regulates dietary supplements under a different set of regulations than those covering "conventional" foods and drug products. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA):

- Manufacturers and distributors of dietary supplements and dietary ingredients are prohibited from marketing products that are adulterated or misbranded. That means that these firms are responsible for evaluating the safety and labeling of their products before marketing to

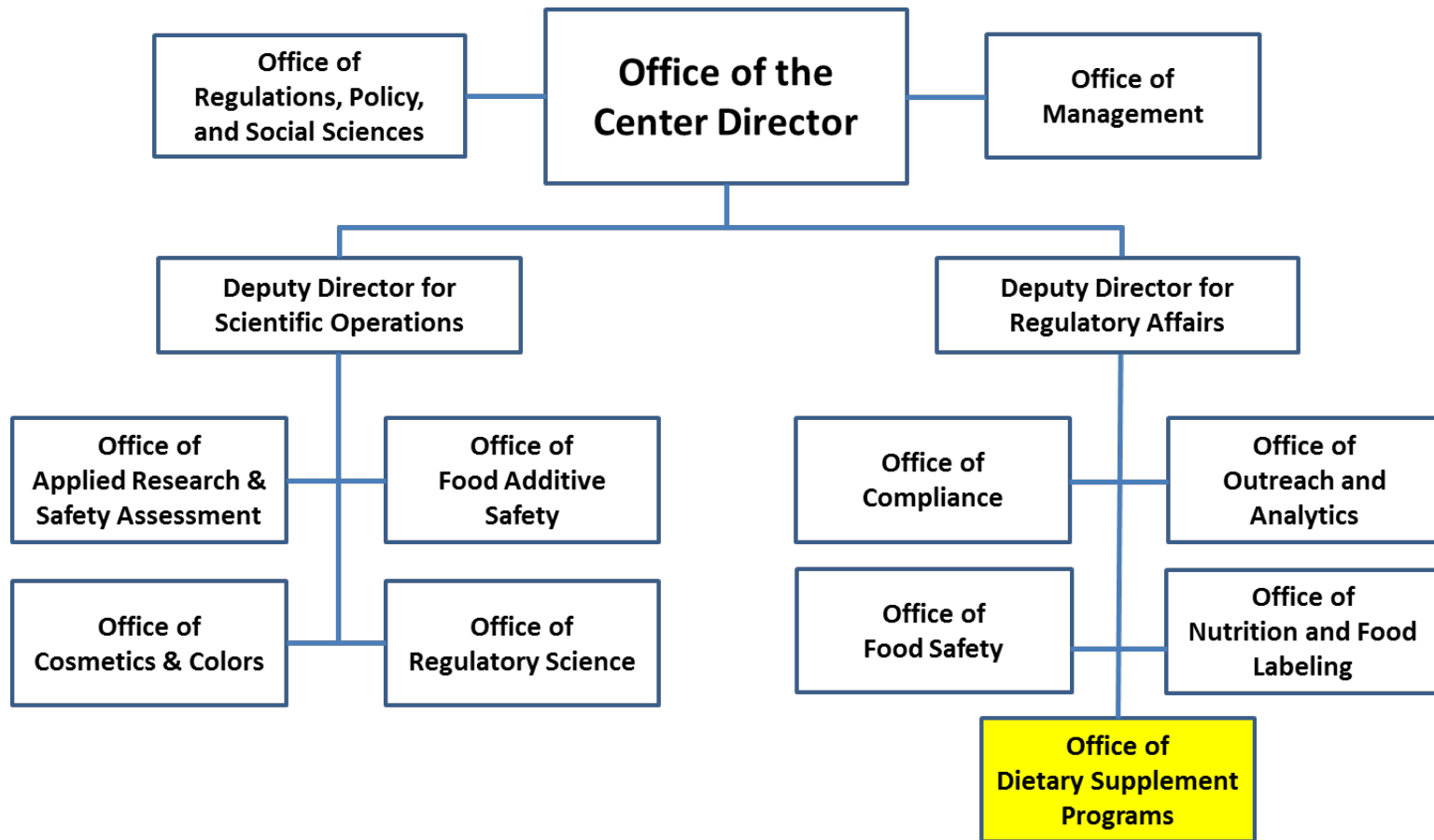
Popular Topics

- [Public Meeting to Discuss the Development of a List of Pre-DSHEA Dietary Ingredients](#)
- [Safety Alerts and Advisories](#)
- [Recalls, Outbreaks & Emergencies](#)
- [Methylsynephrine in Dietary Supplements](#)
- [What's New in Dietary Supplements](#)

FDA Organization



CFSAN Organization



CFSAN's ODSP

- 26 FTE's
- Program priorities
 - Protect consumers
 - Identifying and removing dangerous products
 - Ensure product integrity
 - Ensure products contain what they're supposed to contain
 - Promote informed decision-making

ODSP Priorities

- Protect consumers
 - Identifying and removing dangerous products
- Ensure product integrity
 - Enhance CGMP and NDIN compliance through education and enforcement
- Promote informed decision-making

Dietary Supplement Market Size

1994

- 600 manufacturers
- 4,000 products
- \$4 billion

Today

- 7,000 registered facilities
- 75,000+ products*
- \$40 billion*

Thank you!

Office of Dietary Supplement Programs
Center for Food Safety and Applied Nutrition
Bob Durkin, Deputy Director
robert.durkin@fda.hhs.gov

