U.S. FOOD & DRUG ADMINISTRATION

FDA's Role in Dietary Supplement Regulation

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Agenda

Regulatory Framework for Dietary Supplements

ODSP's Priorities

FDA's Steps to Modernize Regulation of Dietary Supplements

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

Distinguished from Drugs and Conventional Foods

- Does not include an article that is approved as a new drug, antibiotic, or biologic, or has been authorized for investigation
  - Unless the article was marketed as a dietary supplement or as a food before such approval or authorization. (FDCA §201(ff)(3))
- Dietary supplements may not be:
  - Represented for use as conventional food or as "sole item of a meal or the diet"

Regulatory Responsibilities

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

Facility Registration

- All food facilities must register with FDA
  - Domestic and foreign
  - Basic information: name, address, type of facility, responsible party
- Renewal of information every even-numbered year

New Dietary Ingredient Notifications

- FD&C Act 413(a)(2)
  - Established the requirement that manufacturers or distributors must submit a notification to FDA 75 days prior to introducing a new ingredient to market
  - NDI notifications must meet the requirements of 21 CFR 190.6 to be considered complete
  - Not an approval

Dietary Supplement Labeling

- Must be labeled as a "dietary supplement"
- Must list all ingredients
- Properly formatted Supplement Facts label
- Name/location of manufacturer
- Domestic contact information for submission of adverse events
- Permissible claims

Permissible Claims and Structure/Function Notifications

- 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

- Firms are required to:
  - Maintain adequate ***substantiation***
  - include disclaimer language
  - notify FDA no later than 30 days ***after*** marketing the product containing the claim

Current Good Manufacturing Practices

- Apply to all firms who manufacture, package, label or hold dietary supplements
  - Domestic and foreign
- To help ensure dietary supplement product quality, purity, consistency, and safety
  - Production and process controls
  - Testing requirements for raw materials and finished products
- Compliance confirmed by FDA inspections

Adverse Event Reporting

- Manufacturers:
  - Submit serious adverse events to FDA
  - Maintain records of adverse events
- Follow-up
  - AERs entered into the CFSAN Adverse Event Reporting System (CAERS) database for review/evaluation.
  - CAERS raw data available: https://www.fda.gov/food/complianceenforcement/ucm494015.htm#files

ODSP Priorities

Our three strategic priorities align with reasonable consumer expectations:

- Consumer safety
  - Expectation: this product will not cause illness, injury, or death
- Product integrity
  - Expectation: this product contains what the label says, in the fair amounts, and nothing else
- Informed decision-making
  - Expectation: this is some scientific basis to believe that this product will have the effect that it claims

ODSP Priorities

- Structure/function claim notifications, NDINs, and adverse event reports
- Warning letters regarding violative ingredients and disease claims
- Injunctions for violations of CGMPs
- Seizure of violative product

Steps to Modernize Regulation

- Achieve right balance between:
  - Preserving consumers' access to lawful supplements, while still upholding obligation to protect the public from unsafe and unlawful products
  - Holding accountable those actors who are unable or unwilling to comply with the requirements of the law

Steps to Modernize Regulation (continued)

- FDA launched Dietary Supplement Ingredient Advisory List

- In May 2019, FDA hosted a public meeting on Responsible Innovation in Dietary Supplements

- The Botanical Safety Consortium (BSC) was announced in November 2019

Steps to Modernize Regulation (continued)

- Engaging in a public discussion
- Mandatory Product Listing
  - Improve transparency
  - Preserve DSHEA's original vision
  - Strategic use of FDA's resources

Thank you

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