



# Regulatory Update of Dietary Supplements

Corey J. Hilmas, M.D./Ph.D.

Supervisor (Acting), Regulations Implementation Team

Division of Dietary Supplement Programs,

Office of Nutrition, Labeling and Dietary Supplements,

Center for Food Safety and Applied Nutrition,

Food and Drug Administration

[corey.hilmas@fda.hhs.gov](mailto:corey.hilmas@fda.hhs.gov)



# Agenda

- The Bottom Line
- Regulatory Cases
- Definition of Dietary Supplement
- The Law
- NDIs: Identity and Safety
- Debunking
- GMPs
- AERs
- The Take Home



# The Bottom Line

- There are about **55,600** dietary supplement products on the market, and the Institute of Medicine has estimated that 1,000 new dietary supplements are introduced to the market each year, yet FDA has only received approximately 700 NDI notifications since we began reviewing NDI notifications some 16 years ago.
- We receive approximately 50 NDINs per year.
- Per the Dietary Supplement GMPs (21 CFR Part 111) **1,460** firms (including manufacturers, packagers, labelers, holders, distributors, and warehouseurs) are out there
- Consumers should have access to dietary supplements that meet quality standards, that are free from contamination and are accurately labeled. FDA's review of NDI notifications are an important preventive control mechanism to ensure that the consumer is not exposed to unnecessary public health risks in the form of new ingredients with unknown safety profiles.



# From Dec. 15, 2010 Letter to Industry

## The Role and Responsibility of Industry to Address This Problem

Manufacturers, distributors, importers and others in the supply chain of dietary supplements are responsible for ensuring that their products comply with the statutes and regulations FDA enforces. Therefore, responsible individuals should take appropriate steps to ensure that their products do not contain active ingredients that may cause the product to be an unapproved new drug, a misbranded drug and/or an adulterated or misbranded dietary supplement, such as: those in FDA-approved drugs, analogs of approved drugs, active pharmaceutical ingredients removed from the market for safety reasons, new chemical ingredients that have not been studied adequately in humans, or controlled substances.

## Dietary Supplements May Be More Regulated by the FDA

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By Jennifer Walters

If you're concerned with the quality and safety of your dietary supplements (and, really, who isn't?), there's some good news. After coming under fire for being too hands-off when it comes to the safety of diet drugs and supplements, which are currently not regulated by the Food and Drug Administration (FDA), the FDA recently released a draft of a new report that would require all manufacturers to provide evidence that all "new dietary ingredients" are safe for consumers.

According to the FDA and dietary supplements report, this change is "an important preventive control to ensure that consumers are not exposed to unnecessary public health risks from new ingredients with unknown safety profiles." To be a "new dietary ingredient" an ingredient must not have been marketed in the United States as a dietary supplement before October 15, 1994.

## FDA Attempting to Regulate Dietary Supplements

by Susan Brady, Last updated July 06, 2011



In response to recent pressures, the FDA has today issued a draft of a guidance document for the dietary supplements industry stipulating that manufacturers must notify the agency in advance when adding a "new ingredient" with an unknown safety profile to their products. The manufacturers must also provide evidence that the ingredient is safe for consumers. They consider this "an important preventive control to ensure that consumers are not exposed to unnecessary public health risks from new ingredients with unknown safety profiles."

The term "new dietary ingredient" means a dietary ingredient that was not marketed in the United States in a dietary supplement before October 15, 1994. There is no authoritative list of dietary ingredients that were marketed in dietary supplements before October 15, 1994. Therefore, manufacturers and distributors (you) are responsible for determining if an ingredient is a "new dietary ingredient" and, if not, for documenting that a dietary supplement that contained the dietary ingredient was marketed before October 15, 1994.

While this is a step forward in ensuring public safety, many believe that more rigorous testing should be required of dietary supplements, and that approval for new products should undergo review prior to landing on store shelves for public availability.

Have you had a problem with a dietary supplement? Reported it to the FDA? We'd love to hear about your experience and the response received from the FDA.





# The Salt Lake Tribune

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## Feds plow new ground in spiked supplement case

By Matt Canham

The Salt Lake Tribune

Published: October 1, 2011 11:33PM

Updated: October 2, 2011 12:08AM

Washington • When regulators or dietary supplement executives talk about rogue companies lacing their health aides with drugs, they often describe shadowy figures creating fly-by-night operations or overseas criminals hawking spiked pills through a cheap website.

They don't tend to describe Kelly Harvey, a 20-year industry veteran who ran NovaCare, a well-known manufacturer in Murray that belongs to Natural Products Association, the nation's biggest dietary supplement trade group.

But late in September, a federal judge unsealed a 31-count felony indictment accusing Harvey of making millions of dollars from sexual enhancement pills tainted with a chemical very similar to the active ingredient in Viagra.

"It is a Utah company and that makes me cringe," said Loren Israelsen, who heads the Utah-based United Natural Products Alliance and has been outspoken in his desire to have more federal prosecutions of rogue supplement makers. "Usually they do operate on the margins and in the shadows."

To be as high profile as Harvey, he said, "is unusual."

Test case? • Harvey is the first person from the state to face prison time for allegedly spiking his products. Federal prosecutors rarely take on a case involving supplements; most of the time manufacturers or distributors pay a civil fine for violating federal laws.



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Department of Justice

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FOR IMMEDIATE RELEASE

Thursday, June 2, 2011

**Two New Jersey Dietary Supplement Companies and  
Their Principals Found Guilty of Criminal Contempt**

WASHINGTON – A Trenton, N.J., jury Wednesday found Paterson, N.J.-based dietary supplement companies Quality Formulation Laboratories Inc. and American Sports Nutrition Inc., as well as their owner, Mohamed S. Desoky, and managers Ahmad Desoky Esq. and Omar Desoky, guilty of multiple counts of criminal contempt of court for violating a consent decree, the Justice Department announced today. The decree was entered by the U.S. District Court for the District of New Jersey on March 16, 2010. The decree, which resolved a civil action filed by the Justice Department as the result of an investigation by the Food and Drug Administration (FDA), mandated Mohamed S. Desoky and the two companies shut down all manufacturing and distribution activities of food products.



## **PRESS RELEASE: Two New Jersey Dietary Supplement Companies and Their Principals Found Guilty of Criminal Contempt**

POSTED BY FREDERICA CADE - JUNE 2, 2011 - [LEAVE A COMMENT](#)

**FILED UNDER** ANALYSIS, CONGRESS, ECONOMICS, EDUCATION, ENVIRONMENT, FBI, GENERAL, HISTORY, INVESTIGATION, JUSTICE DEPARTMENT, LAWS, LOCAL NEWS, NATIONAL NEWS, NEWS, TOP STORY, WIKIPEDIA

The complaint alleged that the defendants caused misbranding of food because the food contained a major food allergen (milk) not declared on the product labels. The civil complaint went on to allege that defendants' failure to have adequate sanitizing and cleaning operations and follow their own procedures for manufacturing products on dedicated equipment, may have led to food being contaminated with this major food allergen by virtue of "cross-contamination" or "cross-contact" in the manufacturing process. The civil complaint alleged that during an FDA inspection of the defendant's facility in December 2008 and January 2009, FDA investigators observed a dead rodent – cut in half- on a blender motor platform; a dead rodent, surrounded by rodent excreta pellets in an area used to store near-finished product; and, on two occasions, a live rodent running through the blending room. Additionally, the complaint alleged that investigators observed bags of raw ingredients that were gnawed through by rodents and covered in rodent urine and excreta pellets.

mandated Mohamed S. Desoky and the two companies shut down all manufacturing and distribution activities of food products.

The defendants' businesses manufactured and distributed food products and supplements, including many varieties of protein powder mixes, as well as other powder mixes and dietary supplements. The products were distributed under the American Sports Nutrition brand and many other private labels to locations throughout the United States.

The complaint in the civil case that led to court order alleged that the defendants, which included Mohamed S. Desoky, Quality Formulation Laboratories Inc., and American Sports Nutrition Inc., adulterated food by manufacturing it without following FDA's regulations regarding current good manufacturing practice (CGMP) requirements, and causing the adulteration of food by preparing it under insanitary conditions whereby it may have become contaminated with filth (as a result of rodent activity) or may have been rendered injurious to health (as a result of cross-contamination with a major food allergen).

The complaint alleged that the defendants caused misbranding of food because the food contained a major food allergen (milk) not declared on the product labels. The civil complaint went on to allege that defendants' failure to have adequate sanitizing and cleaning operations and follow their own procedures for manufacturing products on dedicated equipment, may have led to food being contaminated with this major food allergen by virtue of "cross-contamination" or "cross-contact" in the manufacturing process. The civil complaint alleged that during an FDA inspection of the defendant's facility in December 2008 and January 2009, FDA investigators observed a dead rodent – cut in half- on a blender motor platform; a dead rodent, surrounded by rodent excreta pellets in an area used to store near-finished product; and, on two occasions, a live rodent running through the blending room. Additionally, the complaint alleged that investigators observed bags of raw ingredients that were gnawed through by rodents and covered in rodent urine and excreta pellets.

# What Can FDA Use?

- GMPs
- SAERs
- Labeling, Facility Registration, etc.
- New Dietary Ingredient Notifications (NDINs)
- \* NDIs are the only premarket preventive control with respect to the regulation of dietary supplements



- 25-29 B USD industry since DSHEA
- In 3 years - 3<sup>rd</sup> Decade of DSHEA
- Preventive maintenance/control – almost 400 recalls of spiked products in past 3 years + 150 Million Americans + 25% OAI on GMPs + only 50 NDINs annually = “Low-Risk?”
- 55,600 dietary supplement products on market (originally 4,000 at time of DSHEA passage)



# Statutory Authority

- Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et. seq.)
  - Dietary Supplement Health and Education Act of 1994 (Pub. L. 103-417, 108 Stat. 4325)
  - Dietary Supplement and Nonprescription Drug Consumer Protection Act (Pub. L. 109-462, 120 Stat. 3469)
  - Farm Security and Rural Investment Act of 2002 (Pub. L. 107-171, 116 Stat. 135-527)
  - Food Allergen Labeling and Consumer Protection Act of 2004 (Pub. L. 108-282, 118 Stat. 905)
  - Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Pub. L. 107-188, 116 Stat. 594)
  - **FDA Food Safety Modernization Act (Pub. L. 111-353, 124 Stat. 3885)**
  - Fair Packaging and Labeling Act
  - Public Health Service Act



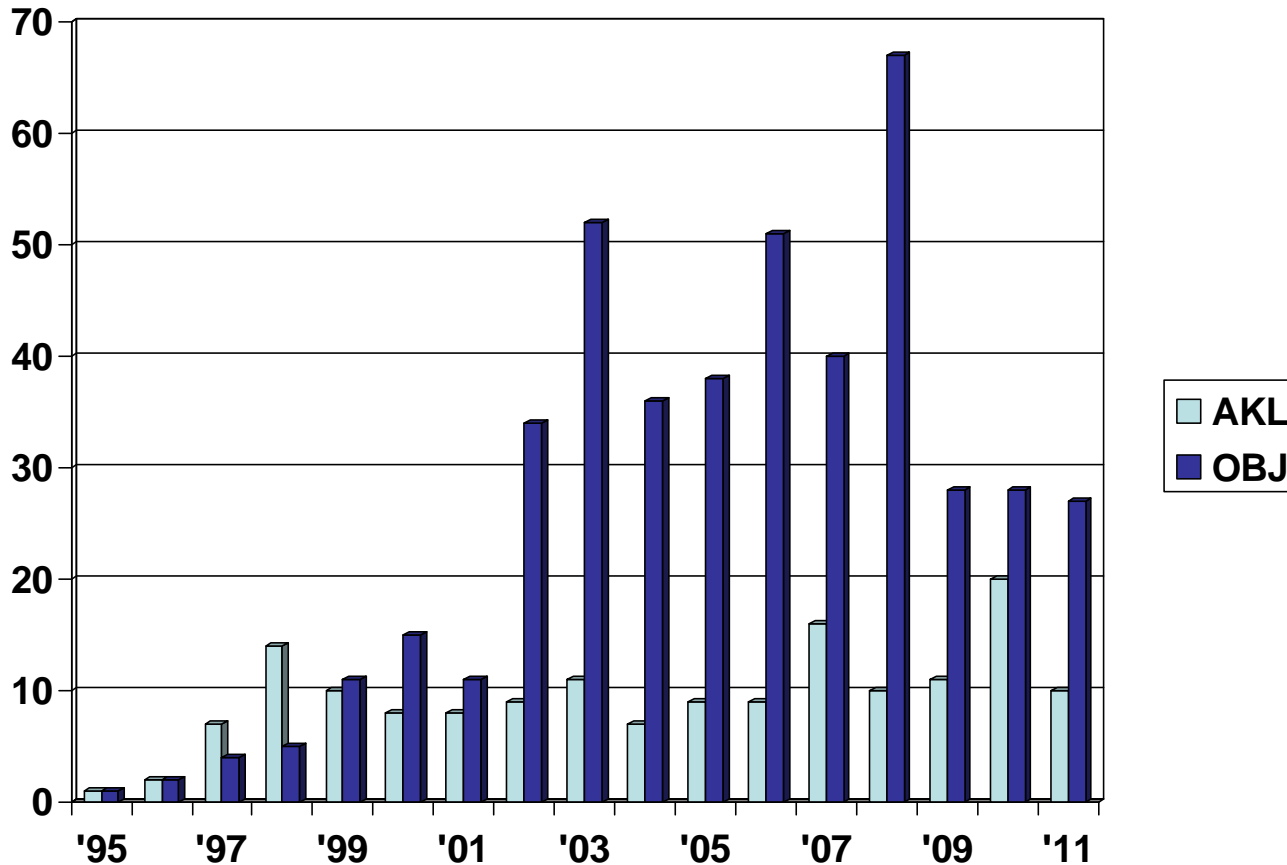
# General

- General Regulatory Paradigm
  - Very, very limited premarket review – **No Premarket approval**
  - No formulation standards
  - No product registration
  - No approval of claims
  - Manufacturer responsible for ensuring safety and compliance
- Where to find Information
  - Statutes (15, 21 & 42 U.S.C)
  - Code of Federal Regulations (Title 21)
  - Guidances

# More NDI facts

- We have “acknowledged” 162 of those notifications. An acknowledgement means that we do not object to the marketing of the ingredient in a dietary supplement under the conditions of use proposed in the notification.
- To date we have objected to 450 notifications.
- A number of objections still find their way onto the market.

# Number of Acknowledgements vs. Objections FY'95-Present





# NDI Draft Guidance

- Under the FDA Food Safety and Modernization Act (FSMA), FDA is required to publish NDI guidance not later than 180 days after the date of enactment.
- The guidance is intended to inform and assist manufacturers, distributors, and other industry entities in deciding when a premarket safety notification for a dietary supplement containing a new dietary ingredient (NDI) is necessary and in preparing premarket safety notifications.

# NDI Draft Guidance

- *“Guidance represents the FDA's current thinking on this topic. It does NOT create or confer any rights for or on any person and does not operate to bind FDA or the public.”*
- 90-day comment period, usually most draft guidance have a 60-day period

# Major Dietary Supplement provisions of the FDCA:

- “Dietary supplements” are deemed (as food)
- elements of how a food is determined to be safe are appropriate for DS
- Adulteration (safety) standard specific to supplement products and their ingredients
- DSHEA specifically exempted FAP/GRAS provisions for DS – but added new adulteration provisions – we are addressing those here in the draft guide
- Requirements for labeling and claims
- Authority for Current Good Manufacturing (cGMPs) are provided for dietary supplements
- Adverse events reports (AERs) must be kept and serious AERs reported to FDA within 15 days

# What is a “Dietary Supplement”?

- **“...a product (other than tobacco) intended to supplement the diet that bears or contains one or more... dietary ingredients”**
- **21 U.S.C. § 321(ff)(1)**

# Dietary Ingredient

- **Vitamin, mineral, amino acid**
- **Herb or other botanical**
- **Dietary substance for use by man to supplement the diet by increasing the total dietary intake**
  - **Means a substance ordinarily used as food or drink of man**

# Dietary Ingredient

- **Concentrate, metabolite, constituent, extract or combination of any ingredient above**
- **Synthetic substances**
  - **Probably yes for “named” ingredients**
  - **Probably not if “constituents”, such as botanical-derived substances**

# **Not a dietary ingredient:**

- **Synthetic copy of a component of a plant**
- **Most newly synthesized chemicals**
- **Pathogens, contaminants and most bacteria**
- **Metabolite (without evidence)**
- **Most approved new drugs and many investigational new drugs**

# Other Requirements

- **Other Requirements**
  - Intended for ingestion
  - tablet, capsule, liquid, powder, softgel, gelcap form
  - **NOT** represented as conventional food or sole item of a meal or diet
  - Identity labeled “dietary supplement”
  
- **21 U.S.C. § 321 (ff)(2)**

# **“Represented for use as a conventional food”**

- **Think “how is it used” or “what is it a substitute for”**
  - **labeled using a common or usual food name or uses a standardized food name**
  - **uses label representations/pictures that suggest conventional food uses**
  - **packaged like a conventional food**
  - **used or represented as alternative to a food**

# What is a dietary supplement?

- **Does not include an article that:**
  - **Is approved new drug, antibiotic, or biologic**
  - **authorized investigational new drug, antibiotic, or biologic, UNLESS**
- **“Marketed as a dietary supplement or as a food before such approval or authorization”**
  - **21 U.S.C. § 321(ff)(3)**



# 201(s)(6)

- (s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific as having been adequately shown through scientific procedures training and experience to evaluate its safety, (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—
  - (6) an ingredient described in paragraph (ff) in, or intended for use in, a dietary supplement.



# 413(a)(2)

- (a) IN GENERAL.—A dietary supplement which contains a new dietary ingredient shall be deemed adulterated under section 402(f) unless it meets one of the following requirements:
- (2) There is a history of use or other evidence of safety establishing that the dietary ingredient when used under the conditions recommended or suggested in the labeling of the dietary supplement will reasonably be expected to be safe and, at least 75 days before being introduced or delivered for introduction into interstate commerce, the manufacturer or distributor of the dietary ingredient or dietary supplement provides the Secretary with information, including any citation to published articles, which is the basis on which the manufacturer or distributor has concluded that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe.

# 402(f)(1)(B)

A food shall be deemed to be **adulterated**—

(f) Dietary supplement or ingredient: safety.

- (1) If it is a dietary supplement or contains a dietary ingredient that—
- (A) presents a significant or unreasonable risk of illness or injury that—
- (B) is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury;

# How does the agency determine Unreasonable Risk for DS?

- Preamble of Ephedra rule – goes into detail on unreasonable risk
- Burden of proof is met “*when product’s risks outweigh its benefits in light of the claims and direction for use in the products labeling or conditions of use.*”
- “*In the absence of a benefit, even a small risk may be unreasonable.*”

- Our experience with potential for unreasonable risk for the category
  - Acute – *Ephedra*/Ephedrine Alkaloids
  - Chronic/Non-Acute – *Aristolochia spp.*/Aristolochic acid
  - Combination of Factors – Hydroxycut™
  
- In light of the 3 broad categories of risk, the draft guidance reflects our expectations/experience of how one determines that a supplement containing a NDI will reasonably be expected to be safe.

- In evaluating your ingredients/products, likely there is some preliminary basis of why one would reasonably expect it to be safe and what types of risks it may present:
  - What additional data is needed to fortify existing data on the ingredient?
  - Completely new, likely not enough existing data to identify predicted risk (i.e. if you have no information how do you establish a reasonable expectation of safety?)
  - History of use, likely doesn't give long term chronic data, sometimes it may not provide daily data. How can these gaps be addressed?
  - Proposed conditions of use comparable to documented history of use?

# **New Dietary Ingredients (NDIs)**

- **Those that were not marketed as a dietary supplement in the U.S. prior to Oct. 15, 1994**
- **Notification vs. Review Process**
- **FDA notification required before introducing a product with an NDI, unless exempt**
- **There is no authoritative list of “old” dietary ingredients**

**21 U.S.C. § 413**

# NDIs and NDI Guidance to Industry

- ❖ **Notifications are not optional: A dietary supplement marketed without a notification is adulterated.**
- ❖ **The NDI provision represents a major safety “gate”: there must be adequate evidence about the safety of supplements containing new dietary ingredients.**
- ❖ **IOM estimated the introduction of 1000 new supplements every year.**
- ❖ **FDA receives 40-50 notifications per year, ~700 since 1994.**

# **A dietary supplement is adulterated if it:**

- ❖ **Poses a significant or unreasonable risk of illness or injury when used as recommended/suggested in the product's labeling**
- ❖ **Poses an imminent hazard to public health or safety**
- ❖ **Contains a poisonous or harmful substance**
- ❖ **Others (contaminants, etc.)**

**FDCA § 402(f)(1)**



# **A dietary supplement containing an NDI is adulterated if it:**

**“is a[n] NDI for which there is inadequate information to provide reasonable assurance that such ingredient does not present a significant or unreasonable risk of illness or injury.”**

**FDCA § 402(f)(1)**



# **A dietary supplement containing an NDI is adulterated unless:**

- ❖ **The dietary supplement contains only dietary ingredients that have been present in the food supply as an “article used for food” in a form in which the food has not been chemically altered**

**or**

**FDCA § 413(a)**



# A dietary supplement containing an NDI is adulterated unless:

- ◆ The dietary supplement contains only dietary ingredients that have been present in the food supply as an “article used for food” in a form in which the food has not been chemically altered

or

- ◆ The manufacturer or distributor submits a pre-market notification to FDA that contains history of use or other evidence of safety establishing that the supplement “will reasonably be expected to be safe” when used as recommended/suggested in the product’s labeling

FDCA § 413(a)



# What to Submit:

- **Who submits? Manufacturer or distributor.**
- **Must be filed at least 75 days before the product is introduced into interstate commerce**
- **Confidential for 90 days, then placed on the public docket (trade secrets, etc are redacted)**
- **Table of contents or fillable form (no electronic submission yet)**

# Safety Responsibilities

- The manufacturer or distributor of a supplement product is responsible for ensuring that it is safe before it is marketed in the U.S.
- FDA is responsible for taking action against any unsafe products after they are marketed in the U.S.

# NDIs - Identity

- **FDA cannot determine the safety of a substance that is not clearly described**
- **What to submit?**
  - ❖ **Composition of the ingredient and the supplement**
  - ❖ **Manufacturing information**
  - ❖ **Composition and exposure estimates for historically consumed materials**

# Composition:

- ◆ **Extraction ratios**
- ◆ **Standardization to one or more components**
- ◆ **Special cultivars or harvest conditions**



# Manufacturing:

- ◆ **Raw materials**
- ◆ **Manufacturing method**
- ◆ **Process controls**

# Specifications:

- ◆ **List of analytical tests...**
- ◆ **...with acceptance criteria**
- ◆ **Full description of the methods...**
- ◆ **...including reference standards**

# History of Use or Other Evidence of Safety

- ❖ **Basis for the conclusion that the dietary supplement containing the NDI is reasonably expected to be safe**
- ❖ **Can be just history of use**
- ❖ **Can be just “other evidence of safety” (e.g. clinical trials or toxicology)**
- ❖ **Can be both**

# History of Use

- **Documentation should compare the NDI to historically consumed material including:**
  - **Composition**
  - **Conditions of use (dose/duration/frequency)**
  - **Size and characteristics of the consuming population**
  - **Use standard methods for calculating the Estimated Daily Intake (EDI) in a well described population**

# Other Evidence of Safety

- **Generally means toxicology studies (90 day subchronic) and clinical studies also can be helpful.**
- **The less history of use available, the more other evidence is needed.**

# Debunking Draft Guide Myths, Misstatements and Hyperbole

- Chemically altered
- Synthetics
- Redundant resubmissions
- Pre-DSHEA ingredients

# Chemically altered

Legislative agreement: 'chemically altered' does not include:

- minor loss of volatile components
- dehydration
- lyophilization
- milling
- tincture or solution in water
- slurry
- powder
- solid in suspension

Congressional Record October 7, 1994 page S14801



# Botanical Synthetics

- Precedent – Ephedra rule, memo to DEA on Ephedrine alkaloids, response to homotaurine petition



# Dietary Supplement versus Dietary Ingredient – redundant submissions

- End of 413 (a)(2) - .....”*that a dietary supplement containing such dietary ingredient will reasonably be expected to be safe”*

# Pre-DSHEA ingredients

- Biostratum response- *The most obvious way to show that an article has been "marketed as a dietary supplement or as a food" is with evidence that the article itself has been sold or offered for sale in the U.S. as a dietary supplement or as a food. For example, a catalog listing a product identified as a "pyridoxamine supplement" would establish the marketing of pyridoxamine as a dietary supplement. Similarly, business records documenting that pyridoxamine was offered for sale or sold as an ingredient for use in manufacturing baked goods or other conventional foods would establish the marketing of the substance as a food.*
- “Independent, verifiable” standard

# Pre-DSHEA ingredients

- 413 (d) DEFINITION.—For purposes of this section, the term “new dietary ingredient” means a dietary ingredient that was not marketed in the United States before October 15, 1994 and does not include any dietary ingredient which was marketed in the United States before October 15, 1994.
- CRN in 1998\* - *“The best policy is for any company to maintain its own records confirming long term use of an ingredient.”*

\*- <http://www.fda.gov/ohrms/dockets/dockets/05p0305/05p-0305-cr00001-04-Council-For-Responsible-Nutrition-vol1.pdf>

# Current Good Manufacturing Practice (CGMP)s

- **Identity, purity, quality issues**
  - Identification
  - Contaminants (chemical, filth, pesticides, micro, drugs)
  - Economic adulteration
- **Apply to all domestic/foreign firms**
- **Do not apply to raw material manufacturers**

Rule at <http://www.cfsan.fda.gov/~dms/ds-ind.html>

# Adverse Event Reporting

- **Mandatory reporting to FDA of “Serious” adverse events**
  - **Death**
  - **Life-threatening experience**
  - **Inpatient hospitalization**
  - **Persistent or significant disability or incapacity**
  - **Congenital anomaly or birth defect**
  - **Requires, based on reasonable medical judgement, medical or surgical intervention to prevent an outcome above**



# Adverse Event Reporting

- **Report to FDA within 15 business days**
- **Any subsequent medical information received within one year**
- **Must make and maintain records for 6 years**
- **For non-serious adverse events**
  - **No notification of FDA**
  - **Must maintain records**

# Other Requirements

- **General and nutrition labeling (21 CFR Part 101)**
  - 21 CFR § 101.3(g) – Identity labeled as DS
  - **Supplement Facts (mixing of (b)(2) and (b)(3) ingredients**
  - **101.9 (incorrect nomenclature), 101.36 (ordering)**
  - 21 CFR § 101.15(c) product labels contain information in two languages but does not appear to repeat
  - **AER label statement (domestic address/phone) ... 403(y)**
- **Import prior notice**
- **Facilities registration**

# The Take Home

- Consumers should have access to dietary supplements that meet quality standards, that are free from contamination and are accurately labeled. FDA's review of NDI notifications are an important preventive control mechanism to ensure that the consumer is not exposed to unnecessary public health risks in the form of new ingredients with unknown safety profiles.
- 700 NDINs in approximately 17 years.



# Thanks

- DDSP: Daniel Fabricant
- Sumit Sen
- ONLDS: Barbara Schneeman, Mary Poos
- OCC: Carie Jasperse
- ORPSS: Ken Smith, Marquita Steadman, Sonali Gunawardhana, Susan Bernard



- To look at previous NDI notifications and FDA responses at [regulations.gov](https://www.regulations.gov) docket FDA-1995-S-0039
- Read (and comment on) the NDI guidance at [regulations.gov](https://www.regulations.gov)
- Questions about a notification:  
NDI Consumer Safety Officer:  
[CFSANddspNDI@fda.hhs.gov](mailto:CFSANddspNDI@fda.hhs.gov)  
240-402-1756