U.S. FOOD & DRUG ADMINISTRATION

Dietary Supplements

膳食补充剂

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Dietary Supplement Authority
膳食补充剂监管授权

- Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et. seq.)
- 联邦食品药品化妆品法（美国联邦法典第21章第301 et. Seq条）
  - Dietary Supplement Health and Education Act
  - 膳食补充剂健康教育法
    - Laid out the major framework for dietary supplements
    - 为膳食补充剂建立了基本框架
  - Public Health Security and Bioterrorism Preparedness and Response Act
  - 公众健康安全和生物恐怖主义应急法
    - Requirement for facilities to register with FDA
    - 要求企业与FDA进行注册
  - Food Allergen Labeling and Consumer Protection Act
  - 食品过敏原标签和消费者保护法
    - Allergen labeling requirement
    - 过敏原标签要求

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- 联邦食品药品化妆品法（美国联邦法典第21章第301 et. Seq条）
  - Dietary Supplement and Nonprescription Drug Consumer Protection Act
  - 膳食补充剂和非处方药消费者保护法
    - Requirement for dietary supplement firms to submit serious adverse events to FDA
    - 要求膳食补充剂企业向FDA报告严重不良事件
  - FDA Food Safety Modernization Act
  - FDA食品安全现代化法
    - Major overhaul of framework for food facilities
    - 食品工厂监管框架的重要修改

Dietary Supplement Authority
膳食补充剂监管授权

- Dietary Supplement Health and Education Act (DSHEA) of 1994
- 1994年颁布的膳食补充剂健康和教育法(DSHEA)
  - ✓Defined the term dietary supplement
  - ✓定义了膳食补充剂
  - ✓Established requirements for new dietary ingredient premarket review
  - ✓制定了新膳食原料上市前审核的要求
  - ✓Established requirements for good manufacturing practices
  - ✓制定了良好生产规范要求
  - ✓Included dietary supplements under the adulteration provisions
  - ✓增加了膳食补充剂的掺杂条款

Definition of Dietary Supplement
膳食补充剂的定义

- Product (other than tobacco) that is intended to supplement the diet
- 用于补充膳食的产品（除烟草外）
- Product that is intended for ingestion (*sublingual, topical or injected products are prohibited*)
- 可以食用的产品（*严禁含有舌下含服、局部施用、或注射使用的产品*）
- Contains one or more dietary ingredients
- 含有一种或多种膳食成分

  - Vitamin/维生素
  - Mineral/矿物质
  - Herb or other botanical/草本植物或其他植物
  - Amino acid/氨基酸

  - Dietary substance for use by man to supplement the diet by increasing the total dietary intake
  - 人类用于增加总膳食摄入量的膳食物质
  - A concentrate, metabolite, constituent, extract, or combination of any of the above dietary ingredients
  - 以上所列膳食成分的浓缩物、代谢物、组分、提取物或混合物。

Dietary Supplement- Serving Forms
膳食补充剂-服用形式

- Pill (ex. Tablet, capsules)/片剂（例如，片剂，胶囊）
- Powder/粉末
- Liquid (See Final Guidance)/液体（参见最终版指南）
- Tea/茶叶
- “Candy bar” (cannot be the entire meal), etc.*/“糖果棒”（不能作为全餐），等等*

*FD&C Act, Section 411(c)(1)(B)(ii): if not intended for ingestion in such a form, is not represented as conventional food and is not represented for use as a sole item of a meal or of the diet

*《食品药品化妆品法》第411(c)(1)(B)(ii)条：如果不是以以上形式摄入的，就不是传统食品，也不能作为一餐中的单一项目或膳食使用。

Current Good Manufacturing Practices
现行良好操作规范

- FDA published the cGMP Rule in 2007
- FDA在2007年发布了cGMP法规
  - 21 CFR 111
  - 联邦法典第21章第111部分
- Helps ensure dietary supplement product quality, purity, consistency, and safety
- 确保膳食补充剂产品的质量、纯度、一致性、安全性
  - Production and process controls
  - 生产和工艺控制
  - Testing requirements for raw materials and finished products
  - 原材料和最终产品的检测要求
- Applies to all firms who manufacture, package, label or hold dietary supplements
- 适用于所有的生产、包装、贴标、或储存膳食补充剂的企业
  - Domestic and *foreign*
  - 国内和*国外的*
- Compliance confirmed by FDA inspections
- 通过FDA检查来确认合规性

Dietary Supplement Labeling
膳食补充剂标签

- Dietary supplements must follow food labeling requirements (21 CFR 101)
- 膳食补充剂必须符合食品标签要求（联邦法典第21章第101部分）
  - Must be labeled as a “dietary supplement”
  - 必须标示为“膳食补充剂”
  - Must list all ingredients
  - 必须列明所有成分
    - Properly formatted Supplement Fact label
    - 适当格式的补充事实标签
  - Name/location of manufacturer
  - 生产商的名称/地址
  - Domestic contact information for submission of adverse events
  - 为报告不良反应事件，需标明美国国内联系方式

Dietary Supplement Identity* (Label Identification)
膳食补充剂的身份*（标签标识）

- The term "dietary supplement" must be part of the statement of identity on the label
- “膳食补充剂”这个字眼必须包含在标签的产品说明中
- The term “dietary” may be replaced with name of the dietary ingredient, (e.g., calcium supplement) Or,
- “膳食”这个字眼可以用膳食成分的名称替代（例如：补钙/钙补充剂），或者，
- with an appropriately descriptive term indicating the type of dietary ingredient(s) in the dietary supplement product (e.g., herbal supplement with vitamins).
- 在膳食补充剂产品上有适当的描述性术语表明膳食成分的类型（例如，含有维生素的草本补充剂）

***21 CFR 101.3(g)**
***联邦法典第21章第101部分第101.3(g)条**

Dietary Supplement Labeling Claims
膳食补充剂标签声称

- Allowed claims
- 允许的声称
  - Nutrient content claims
  - 营养成分声称
    - Characterizes the level of a nutrient
    - 描述一种营养成分的程度
  - Structure/function claims
  - 结构/功能声称
    - Describes the role of a nutrient or dietary ingredient intended to affect the structure or function in humans
    - 描述一种营养或膳食成分作为影响人体的结构或功能的角色
  - Health claims/qualified health claims
  - 健康声称/合格的健康声称
    - Characterizes the relationship of any substance to reducing risk of a disease
    - 描述任何物质与减少疾病风险之间的关系

New Dietary Ingredients
新膳食成分

- Dietary ingredients not marketed in a dietary supplement in the U.S. prior to October 15, 1994
- 在1994年10月15日前未在美国上市的膳食补充剂中使用的膳食成分
- Manufacturers must submit a notification to FDA at least 75 days prior to marketing
- 生产商必须在上市前至少75天前向FDA提交通报
- FDA has 75 days to respond
- FDA将在75天内作出回复
  - Acknowledgement – not approval
  - 确认 ---- 并非批准
  - Objection
  - 拒绝

  -Based on identity or safety

  基于其特性或安全性
- Notification is made public after 90 days
- 90天后通报将公布于众

New Dietary Ingredient (NDI) Notification
新膳食成分（NDI）通报

- Notification must include
- 通报必须包含
  - Name and address
  - 企业名称和地址
  - Signature of responsible party
  - 责任方签名
  - Name of the ingredient
  - 成分名称
  - Description of the product(s) containing the NDI
  - 含有新膳食成分的产品的说明
  - Amount of the NDI in product(s)
  - 新膳食成分在产品中的含量
  - Conditions of use
  - 使用条件
  - History of use or other evidence of safety establishing the NDI “will reasonably be expected to be safe”
  - 使用历史或其他证明该新膳食成分“按照合理的预期将是安全的”的安全性证据

Wrap-Up
总结

- FDA's responsibilities largely focused after the product enters the marketplace
- FDA的责任很大程度上是关注产品进入市场后的情况
- Post-market surveillance includes
- 上市后监控包括
  - cGMP Compliance
  - 现行良好操作规范合规情况
  - Product Labeling
  - 产品标签
  - Adverse Events
  - 不良反应事件

Educational Materials
学习资料

- FDA internet site /FDA官网
  - www.fda.gov

- Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues
- 行业指南草案：膳食补充剂：新膳食成分通报和相关事项
  - http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm257563.htm

- Guidance for Industry: Distinguishing Liquid Dietary Supplements from Beverages
- 行业指南：区分液体膳食补充剂和饮料
  - https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm381189.htm

- Food, Drug and Cosmetic Act (The Act)
- 食品药品化妆品法
  - https://www.fda.gov/RegulatoryInformation/LawsEnforcedbyFDA/FederalFoodDrugandCosmeticActFDCAct/default.htm

- Code of Federal Regulations
- 联邦法典
  - www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm