Product Categories & Intended Use
“Drugs” Defined

- Drugs (§201(g)(1) of the FD&C Act, 21 USC §321(g)(1))
  - “(B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
  - (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
  - (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C).”
“New Drugs” Defined

New Drugs

- A drug that is not generally recognized as safe and effective for its labeled indications. (§201(p) of the FD&C Act, 21 USC §321(p))
- “No person shall introduce or deliver for introduction into interstate commerce any new drug, unless an approval of an application filed pursuant to subsection (b) or (j) is effective with respect to such drug” (§505 of the FD&C Act, 21 USC §355(a))

- All drugs are “new drugs” requiring approval under the FD&C Act, except for narrow exempted categories.
“Biologics” Defined

A biological product is defined, in relevant part, under the PHSA, as:

- “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, or blood component or derivative, allergenic product, or analogous product . . . applicable to the prevention, treatment or cure of a disease or condition of human beings.” (351(i), PHSA).

Note: drug definition is inclusive of biologics so we need to look for “touch points” between the FD&C Act and the PHSA.
“Medical Device” Defined

“an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article, including any component, part, or accessory, which is...

- (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment or prevention of disease…; or
- (3) intended to affect the structure or any function of the body of man…; and
- does not achieve its primary intended purposes through chemical action within the body and which is not dependent upon being metabolized for the achievement of its primary intended purposes. (201 FD&C Act, 21 USC 321(h)).
Food Defined

- §201(g) of the FD&C Act defines a "food" as:
  1. "(1) articles used for food or drink for man or other animals;"
  2. (2) chewing gum; or
  3. (3) article used for components of any such article"
“Dietary Supplement” Defined

§201(ff) of the FD&C Act defines Dietary Supplements as:

- “means a product (other than tobacco) intended to supplement the diet that bears or contains one or more of the following dietary ingredients:
  - Vitamin, mineral, herb or other botanical, amino acid, dietary substance used to supplement diet, concentrate/metabolite/constituent/extract or combination of any ingredient described above
- May not be presented as traditional food.
- May not contain ingredient approved/authorized as new drug.
- May not make drug claims.
Food Labeling vs. Drug Labeling

- Types of permissible food claims (includes dietary supplements)
  - (1) Health
    - 1990 Nutrient Labeling and Education Act (NLEA) – literature/petition
    - Authoritative Statements
    - Qualified Health Claims – emerging evidence
  - (2) Nutrient Content
  - (3) Structure/Function
    - 1994 DSHEA – role of ingredient to affect normal function

- Must not claim to treat, cure, mitigate or diagnose, or else the intended use may render it a drug
  - Dietary supplement labeling may not be false or misleading
  - must contain disclaimer that FDA has not evaluated structure/function claim.
Cosmetic Defined

- 201(i) of the FD&C Act defines a “cosmetic” as:
  - “(1) articles intended to be rubbed, poured, sprinkled or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and
  - (2) articles intended for use as a component of any such articles”

- Intended use revisited:
  - Product can be both drug and cosmetic and must comply with law governing both categories.
Importance of “Intended Use”

- Determines regulatory status of product
- 21 CFR 201.128
  - “Objective intent of persons responsible for labeling of products”
- Determined by:
  - Labeling claims (21 U.S.C. 321(k))
  - Advertising/Promotion
  - Oral/Written Statements
  - Circumstances re: Distribution
  - Consumer Expectations/Use
Analyzing Food & Drug Law Issues

- Step 1: Identify the correct product category or categories of the article;
- Step 2: For each category, outline the regulatory framework applicable
- Step 3: Define problem or issue
- Step 4: Determine compliance with statute and 21 CFR.