Cosmetics and Color Additives

Personal Care Product Council GMP Workshop
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Cosmetics – Scope

- Used by most Americans every day
- Examples:
  - Moisturizers, other skin preparations
  - Hair care, hair dyes, hair straighteners
  - Makeup, nail polishes
  - Shaving preparations
  - Perfumes
  - Toothpastes, mouthwashes
  - Face and body cleansers, deodorants

- Over 8 billion personal care products sold in U.S. annually
- Over $60 billion in annual sales
Cosmetic

- Defined in FD&C Act, Section 201 (i)
- Articles intended for:
  - Cleansing
  - Beautifying
  - Promoting attractiveness
  - Altering the appearance
- Excludes “Soap”

Drug

- Defined in FD&C Act, Section 201 (g)
- Articles intended--
  - for use in the diagnosis, cure, mitigation, treatment, or prevention of disease
  - to affect the structure or any function of the body of man or other animals
Cosmetic vs. Drug

- Products can be cosmetics, drugs, or both
  - Antimicrobial cleanser
  - Antidandruff shampoo
  - Anticaries toothpaste
  - Antiperspirant-deodorant

- If it meets the definition of a drug, it must comply with drug requirements—even if it is also a cosmetic

- No legal definition of “cosmeceutical” or “functional cosmetic”

OTC Drug vs. Cosmetic

- **OTC Drug**
  - Pre-market approval required
  - Safety & efficacy
  - Subject to GMP regulations
  - Establishments & products must be registered
  - No prescription required
  - Symptom relief

- **Cosmetic**
  - Pre-market approval not required
  - No pre-market clearance of safety or efficacy
  - GMP guidelines only
  - Establishments & products not required to be registered
  - No prescription required
  - Cleansing, beautifying, or altering the appearance
Cosmetics – FDA’s Authority

- Cosmetics must not be adulterated or misbranded
- The law does NOT provide for FDA pre-market approval
- FDA’s authority is post-market only
- FDA bears the burden of proving a product or ingredient is unsafe before it can act to remove it from the marketplace
- “Appearance standard” for Imported products

Prohibited Under FD&C Act

- **Adulterated Cosmetics**
  - Harmful or injurious under labeled or customary conditions of use
    - Formulation
    - Container
    - Contamination
  - Unapproved Color Additive
    - “Coal Tar Hair Dye Exemption” (Sec. 601 (a))
  - Manufactured or held under “insanitary” conditions

- **Misbranded Cosmetics**
  - False or misleading labeling
  - Required information missing or presented improperly
  - Deceptive container
  - Doesn’t comply with 1970 Poison Prevention Packaging Act (Child resistant)
Cosmetics - Challenges

- Significant changes in past 5-7 years
  - Manufacturing more global
  - Increasingly sophisticated technology and complex ingredients
    - Nanotechnology
    - “Active” ingredients
    - Botanicals

FDA-Regulated Product Lines Imported Globally

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Cosmetic Product Lines
Imported Globally

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Hazards and Consequences: Examples

- **Eye Area Cosmetics**
  - **Microbial Hazards**
    - Can be introduced during packaging or repacking
    - Associated with inadequate preservative systems

- **Skin Preparations**
  - **Microbial Hazards**
    - Can be introduced during packaging or repacking
    - Associated with inadequate preservative systems
  - **Chemical Hazards**
    - Can be introduced during packaging or repacking
  - **Wide range of severity in adverse effects**
Drugs/Cosmetics –
Recent Situations with Public Health Impact

**Oral Care Products**
- **Alcohol-Free Mouthwash**: regulated as cosmetics or OTC drugs depending on intended use
  - Microbial contamination, severe illnesses, several deaths in one outbreak
  - Products recalled
- **Toothpaste**: diethylene glycol contamination
  - CNS depressant, kidney/liver toxin, vulnerable population
  - Both OTC and cosmetic products detained at U.S. border
  - Recall by distributors and importers

**Import Alerts for Cosmetics**

- **Subject to “detention without physical exam”**
- **“Transparent”: On FDA Web site**
  - Color additives – 601(e)
  - Poisonous or deleterious substances - 601(a)
  - Labeling
  - Filth/insanitary conditions
- **Import Alerts:**
  - 17-04 - Bulk High-Risk Bovine Tissue from BSE-Countries
  - 66-38 - Skin Care Products with Anti-aging claims
  - 53-06 - Cosmetics Containing Illegal Colors
  - 53-17 - Microbial Contamination of Cosmetics
Color Additives

- **Color Additive (21 CFR 70.3 (f))**
  - Synthetic or natural in origin
  - Synthesized, extracted, or isolated
  - Added or applied to food, drug, or the human body
  - Color must be apparent to the naked eye
  - Includes black, white, and intermediate grays
  - Includes food ingredients deliberately used to impart color
  - Does not include food ingredients imparting their own natural color mixed with other foods

Color Additives

- **Color Additive Requirements**
  - Pre-market approval: chemistry and safety, uses and restrictions

- **Color Additives Exempt From Batch Certification**
  - 21 CFR 73 (source: mineral, animal, botanical)

- **Color Additives Subject to Batch Certification**
  - 21 CFR 74 (synthetic organic)
  - FDA certification of each batch of certifiable color additive required
Newly Listed Color Additive
“Pearlescent Pigments”

- Mica-based Pearlescent Pigments Exempt from Certification
  - Foods: Final Rule 71 FR 31927, June 2, 2006; Effective Date July 5, 2006
  - Drugs: Final Rule 70 FR 42273, July 22, 2005; Effective Date August 23, 2005

- Pigments prepared from synthetic iron oxide, mica, and titanium dioxide

- Not listed for use in cosmetics

Color Additive Compliance Issues

- Use of unapproved color additives
- Use of color additives not approved for use in certain products
- Use of certified color additives approved for “external use only” in products like douches and feminine wipes
- Use of botanical extracts that color the product, but are not approved color additives
Use of Color Index Numbers (CI) alone as color additive designations is **NOT permitted** for FDA-regulated products marketed in the U.S.

“Dual” Declaration: For products marketed both in U.S. and in EU or other foreign countries that require CI Nos.

**Examples:**
- FD&C Green No. 3 (CI 42053)
- Green 3 (CI 42053)

**Hazards and Consequences**

- **Unapproved or uncertified color additives**
  - Heavy metals, organic carcinogens – potentially high levels
  - Long term exposure – potential for severe illness
    - Tissue damage
    - Cancer
    - Neurological damage
  - Potential for widespread consequences because a single lot of color additive may be used in a large number and wide variety of products
Import Alerts for Color Additives

- IA 45-02- Illegal & undeclared color additives
- IA 53-06- Cosmetics Containing Illegal Colors

BSE

- Many bovine raw materials used in cosmetics
- Possible vehicle for “prion” infection
- Variant Creutzfeldt-Jakob Disease (vCJD)
- Abraded skin, eye area, mucous membranes
BSE in the US

- No reported cases of vCJD in the US attributed to exposure to US cosmetic products
- Only BSE case in US traced back to cow of Canadian origin
- No known cases of cosmetic adulteration with BSE in US or other countries
- Major efforts continue to assure that food, dietary supplements and cosmetic products remain free from BSE

BSE Major Areas of Concern

- Use of ingredients from high risk TSE tissues (brain, spine/spinal cord, distal ileum, eye)
- Use of ingredients from ruminants born and raised where BSE or TSE exists
- Is critical that specific tissue and country of origin is identified for all sources of bovine-derived ingredients
- Cosmetic industry is a major user of bovine (cow) sources
BSE Preventative Measures

- “Safe-sourcing” from non-BSE countries and certified BSE-free herds
- “Safe processing” conditions should be employed - Avoid “Co-mingling” and “cross-contamination”
- Avoid use of high risk material such as brain/spinal cord/eye material
- Use tallow that has been designated at least Grade III

Proposed Record-Keeping for Cosmetics With Cattle Material

- Federal Register, Vol. 69, No. 134, pgs. 42275-42285, July 14, 2004
- Manufacturers must keep records and make them available to FDA
- Importers to affirm at time of entry that those cosmetics with cattle material do not contain prohibited material
FDA Export Certificates

- Guidance for cosmetics:
  
  [http://www.cfsan.fda.gov/~dms/cos-cert.html](http://www.cfsan.fda.gov/~dms/cos-cert.html)

- A certificate is NOT a guarantee nor a certification of the product's safety and quality

- A certificates does NOT indicate the product or product labeling is approved or sanctioned by the FDA

- FDA is not required by law to issue export certificates for cosmetics

- FDA does not require companies to obtain export certificates

Thank You For Your Interest! Questions?