Regulatory Impact of a Shrinking Cosmetic Preservative Palette

FDA’s experience with contaminated cosmetics linked to inadequate preservation

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Disclaimer

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- Any mention of trade names or specific products should not be considered an endorsement.
Outline

• Regulation of Cosmetics
• Cosmetic Micro Issues
• Regulatory Issues
  – Warning Letters
  – Recalls
Cosmetics – Scope

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

- Multi-billion dollar industry
- Increasingly global industry
What is a Cosmetic?

• Defined in the Federal Food, Drug, and Cosmetic Act (FD&C Act), Section 201 (i)

• Articles intended for:
  – Cleansing
  – Beautifying
  – Promoting attractiveness
  – Altering the appearance

** Excludes “Soap” (alkali salt of fatty acid-CPSC)
What is a 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
OTC Drug vs. Cosmetic

**OTC Drug**
- Monograph or product-specific pre-market approval required
- Pre-market evaluation of safety & efficacy
- GMP regulations
- Establishments & products must be registered
- Serious adverse events must be reported

**Cosmetic**
- Pre-market approval not required
- No pre-market clearance of safety or efficacy
- GMP guidelines only (voluntary)
- Establishments & products not required to be registered
- Adverse events not required to be reported
Cosmetics – FDA’s Authority

• Cosmetics must not be adulterated (601) or misbranded (602) of the FD&C Act

• The law does NOT provide for FDA pre-market approval

• FDA’s authority is post-market only
Prohibited Under FD&C Act

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

- 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 Regulations

- General (21 CFR Part 700)
  - Definitions
  - Requirements for Specific Cosmetic Products

- Cosmetic Labeling (21 CFR Part 701)

- Voluntary Registration of Cosmetic Product Establishments (21 CFR Part 710)

- Voluntary Filing of Cosmetic Product Ingredient Composition Statements (21 CFR Part 720)

- Cosmetic Product Warning Statements (21 CFR Part 740)
FDA’s Tools for Monitoring Compliance and Enforcing Legal Requirements

- Targeted establishment inspections and sampling programs
- Detention/refusal (imports)
- Warning Letters (11 warning letters issued to date, in 2015)
- Seizures
- Injunctions
- Criminal prosecution
FDA Inspection of Cosmetic Facilities

- Facilities of all sizes are subject to inspection
- 100-150 U.S. facilities inspected annually
- Inspections can be routine or “for cause”
- Small number of foreign inspections
- Historical focus on manufacturing facilities
Microbiological Safety of Cosmetics - Updating and Restructuring FDA Tools

- Revise Chapter 23 of FDA's Bacteriological Analytical Manual (BAM)

- Develop/Revise FDA Compliance Guidance
  - Compliance Policy Guide (CPG)
  - Compliance Program

- Develop Guidance for Industry
  - Stakeholder input from November 2011 public meeting
  - Laboratory data and other technical information
    - In-house
    - Contract
Cosmetic Micro Standards

- BAM Chapter 23, not USP 61/62, is the standard for cosmetics
  - Eye area products: < 500 CFU/g
  - All other products: < 1,000 CFU/g
  - 7 day enrichment for all samples tested
- Many micro labs do not include enrichment testing which may lead to release of products onto market that are out of compliance
  [Link](http://www.fda.gov/food/foodscienceresearch/laboratorymethods/ucm073598.htm)
OCAC Statements on Preservatives

• “Manufacturers have the responsibility to determine shelf life for products, as part of their responsibility to substantiate product safety. FDA believes that failure to do so may cause a product to be adulterated or misbranded.” (http://www.fda.gov/Cosmetics/Labeling/ExpirationDating/default.htm)

• “Preservatives may be used in cosmetics to protect them against microbial growth, both to protect consumers and to maintain product integrity,” (http://www.fda.gov/Cosmetics/ProductsIngredients/Ingredients/ucm128042.htm)
Preservatives – New Issues

- Firms desire to enter natural, organic or no-preservative market
- Pressure from states to remove formaldehyde donors
- Pressure from NGO’s and retailers to remove effective preservatives because of potential safety concerns
  - even “next generation” preservatives may be subject to NGO challenge
- Shelf life of new products may not have been adequately evaluated
Preservative System

• Describes the combination of the unique physical properties of a cosmetic product
  – Packaging, formulation composition (including $a_w$ and pH), and the preservative chemical ingredients used in cosmetic formulations to ensure the quality of the product and microbiological safety for the consumer

• Use of “hurdle technologies” to enhance preservative system efficacy
Cosmetic Product Preservation – Principles of Preservation/Hurdle Technology

• Keeping microorganisms out of the new formula
  – Using high quality raw materials that have an acceptable bioburden
    • through risk assessment and sampling/testing frequency to demonstrate that the materials meet micro specs
  – Using validated production practices that help prevent microbial growth during manufacturing
    • involves HACCP analysis and micro validation of processes

• Retarding growth and/or killing microorganisms with “hurdles”
  – Reducing the pH to <5 or raising pH to >9
  – Lowering the $a_w$
  – Using chelating agents
  – Using multi-functional ingredients with antimicrobial properties (QACs, antioxidants, alcohols, fragrances, etc.)
  – Avoiding use of inhibitors (i.e., polysorbates if parabens are used) or adsorbing/complexing agents (i.e., talc, clay, titanium dioxide, etc.)
FDA Concerns

- New preservative systems may not be adequately tested – change may be premature
- Small startup brands lack scientific acumen to assure product is safe for consumer use
- Contract manufacturers may lack GMP’s which could contribute to contamination
- New players in industry lack institutional knowledge may
- Safety of imported products sometimes in question
Issues Related to Inadequate or Marginal Preservation of Cosmetics

• Firm initiated recalls of contaminated cosmetics
• Adverse events reported to FDA by consumers and health professionals through Medwatch
• Import detentions for failure to meet BAM Chapter 23 standards
• Warning letters issued when inspection indicates inadequate controls in place to assure product safety
## MicroRecalls - creams, lotions, gels

**calendar years 2014-15**

<table>
<thead>
<tr>
<th>Product</th>
<th>Cause*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Argan oil face cream</td>
<td>Enterobacter gergoviae</td>
</tr>
<tr>
<td>Organic face cream</td>
<td>Aspergillus glaucas, Penicillium</td>
</tr>
<tr>
<td>Body butter</td>
<td>Pseudomonas luteolia</td>
</tr>
<tr>
<td>Hand &amp; Body Moisturizing Lotion</td>
<td>Pseudomonas aeruginosa</td>
</tr>
<tr>
<td>Moisturizing Lotion</td>
<td>Pseudomonas aeruginosa</td>
</tr>
<tr>
<td>Massage gel</td>
<td>Yeast, Staph aureus</td>
</tr>
</tbody>
</table>

* Species determined by firm
## Micro Recalls – wipes and masks

calendar years 2014-15

<table>
<thead>
<tr>
<th>Product</th>
<th>Cause*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Baby wipes</td>
<td>High plate count</td>
</tr>
<tr>
<td>Baby wipes</td>
<td>Discoloration, odor and irritation</td>
</tr>
<tr>
<td>Wipes</td>
<td>Mold</td>
</tr>
<tr>
<td>Lavender Anti-aging Eye Mask</td>
<td>Mold</td>
</tr>
</tbody>
</table>

* Species not determined by firm
## Micro Recalls – mouthwash/rinse

*calendar years 2014-15*

<table>
<thead>
<tr>
<th>Product</th>
<th>Cause*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Mouth rinse</td>
<td>Pseudomonas aeruginosa</td>
</tr>
<tr>
<td>Admission Kit (mouthwash)</td>
<td>Pseudomonas aeruginosa</td>
</tr>
<tr>
<td>Tea Tree Mouthwash</td>
<td>Pseudomonas aeruginosa</td>
</tr>
</tbody>
</table>

* Species determined by firm
# Micro Recalls – shampoos, conditioners, soaps

calendar years 2014-15

<table>
<thead>
<tr>
<th>Products</th>
<th>Cause*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grapefruit &amp; Bergamot Foaming Soap</td>
<td>Pseudomonas aeruginosa</td>
</tr>
<tr>
<td>Liquid Hand Soap</td>
<td>High plate count</td>
</tr>
<tr>
<td>Biotin and Collagen Conditioner</td>
<td>Burkholderia Cepacia</td>
</tr>
<tr>
<td>Conditioning Shampoo</td>
<td>Pseudomonas Aeruginosa</td>
</tr>
</tbody>
</table>

* Species determined by firm
# Micro Recalls – miscellaneous

calendar years 2014-15

<table>
<thead>
<tr>
<th>Product</th>
<th>Cause*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Organic eye shadow</td>
<td>High plate count, Bacillus cereus</td>
</tr>
<tr>
<td>Tattoo ink</td>
<td>Mycobacterium chelonae</td>
</tr>
<tr>
<td>Tattoo ink</td>
<td>Microbial contamination</td>
</tr>
</tbody>
</table>

* FDA laboratory results.
Adverse Events Related to Cosmetic Micro Issues Are Rare
MedWatch reports calendar years 2014-15

• **Lotion- 1 AE**
  – Symptoms included swelling, blistering; confirmed mold growth

• **Conditioner- 1 AE**
  – Symptoms include rash
Adverse Events Related to Baby Wipes and Tattoo Ink

• **Tattoo Ink** – 31 AE’s
  – Mycobacterium chelonae infections reported

• **Baby Wipes** – 23 AE’s
  – Symptoms include diaper rash, blisters/wounds, diarrhea, fever and respiratory issues
Warning Letters

• Example: Organic eye shadow
• Reason: high levels of *B. cereus* in organic raw materials used to manufacture eye shadow
Conclusions

• Recalls and adverse events associated with inadequately preserved cosmetics are likely to continue
• Expect continued FDA attention to organic and non-traditionally preserved (or “preservative-free”) cosmetics
• Manufacturers should assure that preservative efficacy testing is validated across a broad range of products under normal conditions of product use by consumers
• Preservative efficacy cannot be accurately predicted – must be product specific and anticipate the effect of potential consumer misuse/abuse
Conclusions - continued

• Organic raw materials may not be suitable for all types of cosmetics – minimal or no processing by definition
• GMP’s become more important without traditional preservative systems
• “Use by” (or expiration) date may be beneficial for some products
• Do not change preservatives until you are certain that new preservatives work
Thank You For Your Interest!
Questions?