FDA/NSTA Web Seminar:
Teach Science Concepts and Inquiry with Food and Cosmetics

Tuesday, May 6, 2008
Cosmetic Safety:
From Personal Choice to Public Health

Beth Meyers, FDA
Goals

• How has the safety of cosmetics been viewed historically in the United States?

• How is cosmetic safety regulated now?

• What are some of the cosmetic safety issues FDA has tackled?
Cosmetics -18th & 19th Centuries:

- Not always “respectable”
- Sometimes dangerous
  - Lead
  - Mercury
- Personal choice
  - Not “necessary”
  - Use at your own risk
How long have cosmetics been subject to Federal law? What’s your guess?

<table>
<thead>
<tr>
<th>About 100 years</th>
<th>About 70 years</th>
<th>About 35 years</th>
<th>Never</th>
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Food & Drugs Act of 1906

Attempt to include cosmetics failed. Why?

- Small part of the economy
- Used by a limited segment of the population
- Still viewed as frivolous, not respectable; use at your own risk
What changed?

- Film industry
- Manufacture, marketing
- Women in the workforce
  - Discretionary income
  - Makeup helps land a job

Makeup goes mainstream!
1920s-1930s: Personal Choice? Public Health?

• Use of makeup and other cosmetics is "normal"
• Consumer safety concerns persist

But--
• Still no federal oversight over cosmetics
• Little if any state or local oversight
Lash Lure

- Aniline dye for eyelashes
- >20 adverse events reported in JAMA
- At least one case of permanent blindness, possibly one death
Consequences

• Cosmetic safety pushed to forefront as public health priority
• Injuries led to inclusion of cosmetics in consumer legislation:
  – Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938
Let’s Pause for Two Questions from the Audience
The FD&C Act...

• Defines cosmetics:
  – Cleansing (except soap), beautifying, promoting attractiveness, altering the appearance

• Defines drugs:
  – For example, affecting the structure or function of the body; treating, mitigating, or preventing disease
Pop Quiz:

Under the FD&C Act, are sunscreens...

<table>
<thead>
<tr>
<th>Cosmetics</th>
<th>Drugs</th>
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Pop Quiz:

Is toothpaste...

<table>
<thead>
<tr>
<th>A cosmetic</th>
<th>A drug</th>
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## Cosmetic vs. Drug Examples

<table>
<thead>
<tr>
<th>Cosmetics</th>
<th>Drugs</th>
<th>Both</th>
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</thead>
<tbody>
<tr>
<td>Moisturizer</td>
<td>Diaper ointment</td>
<td>Moisturizer w/ SPF</td>
</tr>
<tr>
<td>Deodorant</td>
<td>Antiperspirant</td>
<td>Antiperspirant/deodorant</td>
</tr>
<tr>
<td>Shampoo</td>
<td>Dandruff treatment</td>
<td>Anti-dandruff shampoo</td>
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The FD&C Act...

*Does not* subject cosmetics to premarket approval, except for most color additives

*Does* prohibit marketing of cosmetics in interstate commerce if they are...

- adulterated or
- misbranded
What makes a cosmetic adulterated?

- Harmful under labeled or customary conditions of use (except for coal-tar hair dyes, with caution and patch test labeling)
- Contaminated with filth
- Produced or held under “insanitary” conditions
- Misuse of color additives
- Unsafe due to container
What makes a cosmetic misbranded?

• Labeling is false or misleading
• Required information missing or not properly displayed
• Deceptive packaging
• Packaging doesn’t comply with 1970 Poison Prevention Packaging Act
  • “Special” (Child Resistant) Packaging
An all purpose foaming detergent bubble bath for use by the whole family. Delightful strawberry scent.

DIRECTIONS: Pour one or two capfuls into running bath water. Add or decrease as desired.

INGREDIENTS: Water, Sodium Laureth Sulfate, Cocomide MEA, PEG-7, Glycerl Cocoate, Aloe Vera Gel, Fragrance, Methylparaben, Propylparaben, Disodium EDTA, Green #5, Yellow #10

CAUTION: Keep out of reach of children except under adult supervision. Use only as directed. Excessive use or prolonged exposure may cause irritation to skin and urinary tract. Discontinue use if rash, redness, or itching occurs. Consult your physician if irritation persists.

Manufactured for Southern Laboratories, Inc. Athens, Georgia 30306
True or False:
Under the law, if a cosmetic is adulterated or misbranded, FDA can order a recall.
What actions can FDA take?

- Seizures
- Injunctions
- Prosecutions
- Warning Letters
- Import Alerts, Import Refusals
- Inspections

Recalls are voluntary. Firms choose to recall a product to avoid worse consequences. FDA monitors recalls to make sure they’re effective.
Let’s Pause for Two Questions from the Audience
Prohibited Ingredients

- Bithionol, Halogenated salicylanilides
  - Photo-contact sensitization

- Chloroform, Methylene chloride, Vinyl chloride
  - Carcinogenic

- Zirconium-containing complexes
  - Toxic to lungs

- Prohibited cattle materials
  - Bovine spongiform encephalopathy (BSE)

- Chlorofluorocarbon propellants
  - Environmental concerns (EPA)
Restricted Ingredients

• **Hexachlorophene**
  – Toxic, penetrates skin. Use only when an alternative preservative is not as effective. NTE 0.1 percent; not on mucous membranes (e.g., lips)

• **Mercury compounds**
  – Absorbed through the skin; allergic reactions, skin irritation, neurotoxic. Eye area only, NTE 65 parts per million, only if no other effective and safe preservative is available.

• **Sunscreens**
  – If used only to protect the product, must be identified with a qualifying phrase (e.g., “to protect product color”)
Rio “Natural”
Hair Color/Straightener

• Imported from Brazil
• Low pH → Injuries, including scalp burns, hair loss (1990s)
• Import Alert since 1995
Microbial Contamination

- Contaminated mascara, 1970s—serious eye infections. Need for adequate preservative system.
- Import Alert since 1995
- Microbiological test methods, published 2001
- Eye makeup remover, recalled 2001
- Alcohol-free mouthwash—Recall, Warning Letter, Press Release—2005
Shared Use: “Testers”

Safety Concerns:

- Preservative systems designed for single user, hours between applications
- Multiple users →
  - more opportunity for contamination
  - less time for preservatives to act between applications
Alpha Hydroxy Acids (AHAs)

• Used for decades to adjust pH
• 1990s
  – Marketed as exfoliants (remove top layer of skin cells, “anti-aging” claims), usually glycolic or lactic acid
  – Reports of adverse events
• FDA action:
  – Research: Increased susceptibility to sunburn, even at concentrations <10%
  – Guidance issued for sunburn label warning, 2005
Eyelash Growth Enhancer

• Mascara-like product containing bimatoprost, used to treat glaucoma

• Seizure of $2 million+ worth of products, November 2007
Tattoos

- **Inks**: Cosmetics
- **Pigments**: Color additives; none approved for injection into the skin
- **Practice**: State and local regulation
- **Risks**: Infection, allergies, scarring, granulomas, MRI complications; rare
Poll Question: Tattoos

Yes or No:
One or more students at my school have tattoos.

YES (√)
NO (X)

Use the poll voting buttons to respond to this question.
What’s changed?

- Vast number of pigments in use (~150?)
- Mainstream use; no longer “exotic”
- 2003: 150 reported adverse reactions to a line of permanent makeup inks—recalled
What is FDA doing?

• Issued public advisory (“Talk Paper”) on permanent makeup recall
• Published consumer information on tattoos on the Internet
• Evaluating adverse events, conducting research
• Will consider whether further actions are needed to protect public health
Nanotechnology

• Like other cosmetic ingredients, required by law to be safe as used

• Currently used in few cosmetics, but use may increase

• Will nanoparticles pass through the skin? Research underway
Outreach

www.fda.gov

Scroll down to “Cosmetics” on the left
Web sites of Interest to Educators about Cosmetics


Cosmetics Q&A http://www.cfsan.fda.gov/~dms/qa-topco.html
(A good intro to a variety of topics)

Quiz Yourself: How smart are you about cosmetics:
http://www.cfsan.fda.gov/~dms/costf-1.html

FDA Authority and Policy: http://www.cfsan.fda.gov/~dms/cos-206.html

Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?)
http://www.cfsan.fda.gov/~dms/cos-218.html

Cosmetic Products and Ingredients: http://www.cfsan.fda.gov/~dms/cos-prd.html

Nanotechnology: http://www.fda.gov/nanotechnology

Novelty makeup (face paint): http://www.cfsan.fda.gov/~dms/cos10-31.html
Summing Up:

• What history teaches:
  – Cosmetic safety is a matter of personal choice AND public health

• What the law says:
  – Cosmetics must be safe as used, properly labeled

• What FDA does:
  – Keeps abreast of emerging safety issues
  – Conducts research
  – Provides resources for consumers and industry
  – Takes enforcement action as resources and public health priorities permit
Let’s Pause for Two Questions from the Audience
Thanks to our presenter, Beth Meyers and to the FDA for sponsoring this program.
Welcome to Your Professional Development

The Learning Center is NSTA's e-professional development portal to help you address your classroom needs and busy schedule. You can gain access to more than 2,600 different resources that cater to your preference for learning. Over 700 hundred resources, such as journal articles, science objects and web seminars are available for free. A suite of practical tools such as My Library, My Transcript, and My Professional Development Plan and Portfolio tool help you organize, personalize, and document your growth over time.

Explore Learning Opportunities

<table>
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<tr>
<th>By Subject</th>
<th>By Grade Level</th>
<th>By State Standards</th>
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<tbody>
<tr>
<td>Earth &amp; Space Science</td>
<td>Elementary</td>
<td>Find resources based on their correlation to your state standards.</td>
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<tr>
<td>Life Science</td>
<td>Middle School</td>
<td>Coming Soon!</td>
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<tr>
<td>Physical Science</td>
<td>High School</td>
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<td>College</td>
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Do-It-Yourself Learning

Learn at your own pace online with these 1-2 or 6-10 hour interactive activities.

Live Online Seminars & Classes

Learn online from certified instructors with your colleagues. 1-2 hour seminars, week and month long courses are available. Earn state

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