



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



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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?

About 100 years	About 70 years	About 35 years	Never



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...

Cosmetics	Drugs





Pop Quiz:

Is toothpaste...

A cosmetic	A drug





Cosmetic vs. Drug Examples

Cosmetics	Drugs	Both
Moisturizer	Diaper ointment	Moisturizer w/ SPF
Deodorant	Antiperspirant	Antiperspirant/deodorant
Shampoo	Dandruff treatment	Anti-dandruff shampoo



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



**SOUTHERN
FOAMING
BUBBLE
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**FOR
THE
WHOLE
FAMILY**

**STRAWBERRY
SCENT**

CAUTION: SEE BACK LABEL

946.35 mL(32 FL OZ (1 QUART))

*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, Cocamide 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





Pop Quiz: Enforcement

True or False:

Under the law, if a cosmetic is adulterated or misbranded, FDA can order a recall.

True	False



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.
- Survey of in-store “testers,” 1989-1990
- 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





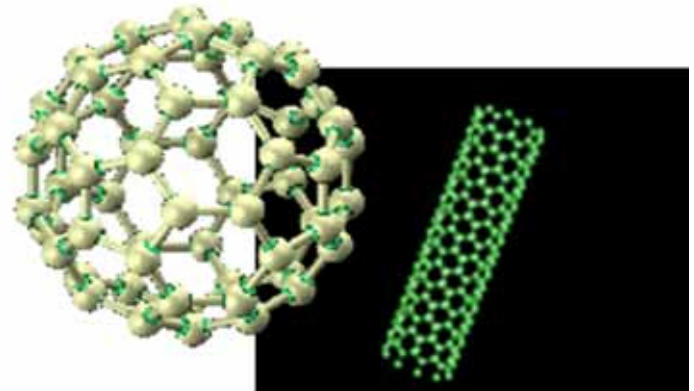
What is FDA doing?

- 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

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“Cosmetics”
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Contents

- Enforcement News**
Warning Letters to Industry, Import Surveillance, and Recalls on Cosmetic-Related Issues
- FDA Authority and Policy**
Overviews of legal, regulatory and policy issues related to cosmetics
- Cosmetic Products and Ingredients**
Information for consumers and industry
- Cosmetic Labeling and Label Claims**
What cosmetic labels can say and what they must say; what label claims mean
- Information for Industry**
Regulations, guidance, registration and other resources
- International Activities**
U.S. consumers purchase cosmetics from around the world. U.S. manufacturers export cosmetics. What is FDA's role?
- Related Sites at FDA**
Over-the-counter drugs, botanicals, cosmetic surgery, contact lenses, women's health and more



Highlights

- Nationwide Recall of Paris Dream Blonde Bleach and Lightening Care Kit Due to Misprinted Directions January 18, 2008
- FDA Develops New Tools to Further Improve the Security of Food and Cosmetics December 21, 2007
- FDA Warns Consumers Not to Use Swad Brand Sindoer: Product Contains High Levels of Lead December 15, 2007
- 1,4-Dioxane July 3, 2007
- Listing of Color Additives Subject to Certification; D&C Black No. 3
- Warning Letter to Black Henna Ink, Inc., Cites Illegal Use of Color Additive (also available in PDF) August 14, 2006

Frequently Requested Information:

- FDA Authority Over Cosmetics March 3, 2005
- Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?) July 8, 2002
- Color Additives and Cosmetics January 24, 2006
- Exporting Cosmetics August 7, 2006
- Imported Cosmetics

*PDF Readers are available for free from the Adobe web site.

Voluntary Cosmetic Registration Program (VCRP)

Cosmetic Q&A:
What is FDA's authority over cosmetics? [Answer](#)
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Quiz Yourself!
How Smart Are You About Cosmetics?
[More Special Features](#)

The term "cosmetic" means (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; except that such term shall not include soap.
— FD&C Act, Sec. 201 (i)



Web sites of Interest to Educators about Cosmetics

Cosmetics Home Page: <http://www.cfsan.fda.gov/~dms/cos-toc.html>

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,
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