

Developments in Cosmetics Regulation: A Historical Overview

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July 21, 2017

Queen Nefertiti



Status of Cosmetics 19th Century U.S.

- Obvious makeup not considered “respectable”
- Lotions, etc. marketed to enhance natural beauty
- Shampoos, makeup, lotions - often homemade
- None regulated and some dangerous

**Laird's Bloom of Youth:
Dangerous lead content: ca. 1860**



**Early 1900s -
Push for Federal Consumer Legislation**

Some Reasons:

- Increasing variety of consumer goods on the market—some dangerous
- Patchwork of state laws made interstate commerce and enforcement difficult

1906 Food and Drugs Act

- Also called "Pure Food and Drugs Act"
- Did not include cosmetics

Influence of Film Industry



Women Entering the Workforce



First International Congress of Working Women, Washington, D.C., 1919 (National Photo Company, Library of Congress collection)

Cosmetics Marketing

- Elizabeth Arden
- Madame C.J. Walker
- Helena Rubenstein
- Max Factor

He make-up Artist
for film

→ had

Polish vs Elizabeth Arden
Same time
Wear Paint play
Book 2003

Legal Status, 1930s:

- No federal oversight
- Little if any state or local oversight

Lash Lure

- Aniline dye for eyelashes
- More than 20 adverse events reported in the *Journal of the American Medical Association*
- At least one case of permanent blindness, possibly one death

Lash Lure



Effect on Legislation

- Lash Lure was not illegal.
- Injuries led to inclusion of cosmetics in consumer legislation:
 - Federal Food, Drug, and **COSMETIC** Act (FD&C Act or the Act) of 1938

FD&C Act

Defines cosmetics* by their *intended use*:

- cleansing,
- beautifying,
- promoting attractiveness, or
- altering the appearance

*does not include soap

FD&C Act

- Defines drugs:
 - Example: If intended to
 - affect the structure or function of the body, or
 - treat or prevent disease



1960's Consumer Activism

- Concern about packaged goods in general, including cosmetics
- Demand for information in making purchasing decisions

only country require
color testing.



Color Additive Amendments of 1960

- Color additives became subject to more stringent safety criteria
- Specific requirements for safe use
- Many previously approved color additives were "delisted"—including some used in cosmetics



Fair Packaging and Labeling Act (FPLA)

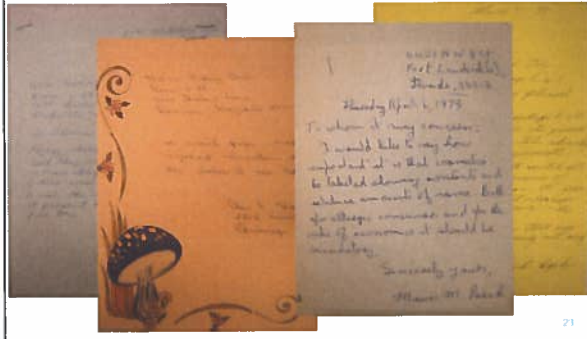
- Packages and labels should enable consumers to obtain accurate information and should facilitate value comparisons
- Applies to products sold at retail to consumers
- *Does not* require ingredient labeling, but--
- *Does* authorize the "promulgating authority" to require ingredient declarations on labeling

Cosmetic Ingredient Labeling: An Uphill Battle

- Strenuously opposed by some members of the cosmetic industry
- Perceived need for “trade secrets”
- Proposed alternative: Voluntary reporting of cosmetic formulations

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We Get Letters!



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Cosmetic-Related Adverse Events

- Rash
- Hair Loss
- Allergic Reaction
- Skin Irritation



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Top Products Reported



- Hair straightening treatments (formaldehyde)
- Deodorants
- Hair dyes
- Hair cleansing conditioners
- Tattoos
- Anti-aging creams

Enforcement Actions



- Warning letters: Skin and hair preparations marketed with drug claims; Brazilian Blowout—containing methylene glycol, releasing formaldehyde when heated; microbial contamination
- Seizures: Tanning pills, eyelash enhancers
- Import alerts: Kohl, color additive violations, microbial contamination, drug claims, more

Recent and Emerging Issues



- Nanotechnology
- Alternatives to Animal Testing
- Tattoos and Permanent Makeup



Other Current Issues



- Microbiological safety
- Preservative safety
- Trace contaminants
- Reporting of adverse events:
 - MedWatch:
<http://www.fda.gov/Safety/MedWatch>
 - Consumer Complaint Coordinators:
<http://www.fda.gov/Safety/ReportaProblem/ConsumerComplaintCoordinators>

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FDA Cosmetics Home Page

www.fda.gov – click on “Cosmetics”



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