The Regulation of Cosmetics

FDLI Introduction to Food Law and Regulation

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Agenda

- What is a Cosmetic?
- How are Cosmetics Distinguished from other FDA-Regulated Products?
- What are Cosmetic Labeling Requirements?
- When is a Cosmetic Misbranded?
- When is a Cosmetic Adulterated?
- Self Regulatory Programs
- Enforcement Trends
- What's Next?

What is a Cosmetic? And What is not?

What is a Cosmetic?

- Article *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, [components]; except for soap (FDCA 201(i))
  - "Soap" defined narrowly in FDA's regulations
  - Examples: skin moisturizers, perfumes, lipsticks, nail polishes, eye and facial makeup, cleansing shampoos, hair colors, and deodorants

What is a Cosmetic?

- Contrast with intended use as a “drug”:
  - Intended to affect the structure or function of the body
  - Intended to diagnose, cure, treat, mitigate, or prevent a disease
- Issues
  - When is a product intended to affect the structure or function of the body?
  - What if a product is intended for use as both a cosmetic and a drug?

What is a Cosmetic?

- Intended Use
  - directed or prescribed use as determined primarily from the statements made on a product's label or labeling
  - consumer's perception of the meaning of a label statement
  - labeling = labels/websites/other materials
  - FDA can also look outside of labeling for evidence of intended use → promotional activities (e.g., facebook, twitter)
  - FDA can also look to nature/effect of ingredients: *"Prostaglandin analogs are well known to have an effect on the structure or function of the body.* ***The presence of the prostaglandin analog, isopropyl cloprostenate, along with appearance claims*** *such as "enhance the appearance of your lashes and brows," "fuller healthier-looking lashes," and "fuller healthier-looking brows" indicate that your products are intended to affect the structure or function of the body."*
    (FDA 2011 WL)

What is a Cosmetic?

Examples

- Deodorant v. Anti-Perspirant
- Oral care products
- Acne products
- Moisturizing shampoo v. Anti-Dandruff shampoo
- Decorative Contact Lenses
- Sunscreens
- Anti-aging products

Cosmetic or Drug? Or both?

“improves the appearance of wrinkles and fine lines”	“acne cleanser”	“rebuild collagen to help plump out lines and wrinkles”	“reduces under eye sagging”
“helps reduce the appearance of dark spots”	“exfoliating treatment”	“reduces visible redness and sensations of discomfort”	“moisturizer with SPF”

Cosmetic v. Device

Can a tool be a "cosmetic"? Is it intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the body?

Controversy over decorative contact lenses – FDA concluded categorically devices

Senate Report accompanying FDCA: "[T]he definition of the term cosmetic does not include devices . . . ."

More recently: microneedling products

- FDA will consider both product claims and product design/technical characteristics in determining a microneedling product's intended use.
- Could intended use apply to tool *and* topical products marketed for use with tool?

Cosmetic Labeling Requirements

When is a Cosmetic Misbranded?

- false or misleading labeling
- name and place of business of manufacturer, packer, or distributor
- net quantity of contents
- prominence requirement
- misleading container or fill

Cosmetic Labeling Requirements

- Fair Packaging & Labeling Act:
  - Applies only to outer retail package of “consumer commodities”
    - consider professional use products
  - Statement of Identity
  - Ingredient listing
- FDCA
  - Name and place of business
  - Net quantity
  - Warning statements

Cosmetic Labeling Requirements

Key Issues

- Ingredient names
- Labeling of drug-cosmetic products
- Size constraints
- Voluntary claims

Cosmetic Safety Requirements

When is a Cosmetic Adulterated?

- poisonous or deleterious substance, but not “coal-tar hair dye” with a warning label
- filthy, putrid, decomposed substance, or prepared, packed, or held under unsanitary conditions [like food provision – but no CGMP requirements]
- container is composed of poisonous or deleterious substance with leaching risk
- unsafe color additive

When is a Cosmetic Adulterated?

Frequent Issues:

- microbial contamination
  - tattoo ink
- unsafe ingredients
  - conditions of use
- unapproved color additives

Safety Requirements

- A cosmetic must have adequate safety substantiation – or bear warning telling consumers it does not
- No CGMP regulations – just guidance
- No facility registration requirements – voluntary program
- No adverse event reporting requirements – voluntary program
- Premarket review only of color additives

Self-Regulatory Programs

Self-Regulatory Programs

Cosmetic Ingredient Review

- Reviews and assesses safety of ingredients used in cosmetics
- Established in 1976 by the industry with the support of FDA
- Funded by trade association but review process is independent

Self-Regulatory Programs

Cosmetic Ingredient Review

- How relates to FDA?
  - FDA safety assessments
  - FDA safety panel liaison
  - Regulatory impact in practice

Self-Regulatory Programs

FDA voluntary registration (VCRP)

- Cosmetic products *sold* to *consumers* in United States
- Manufacturers can register establishments
- Cosmetic product ingredient statements (FDA assigns CPIS number)

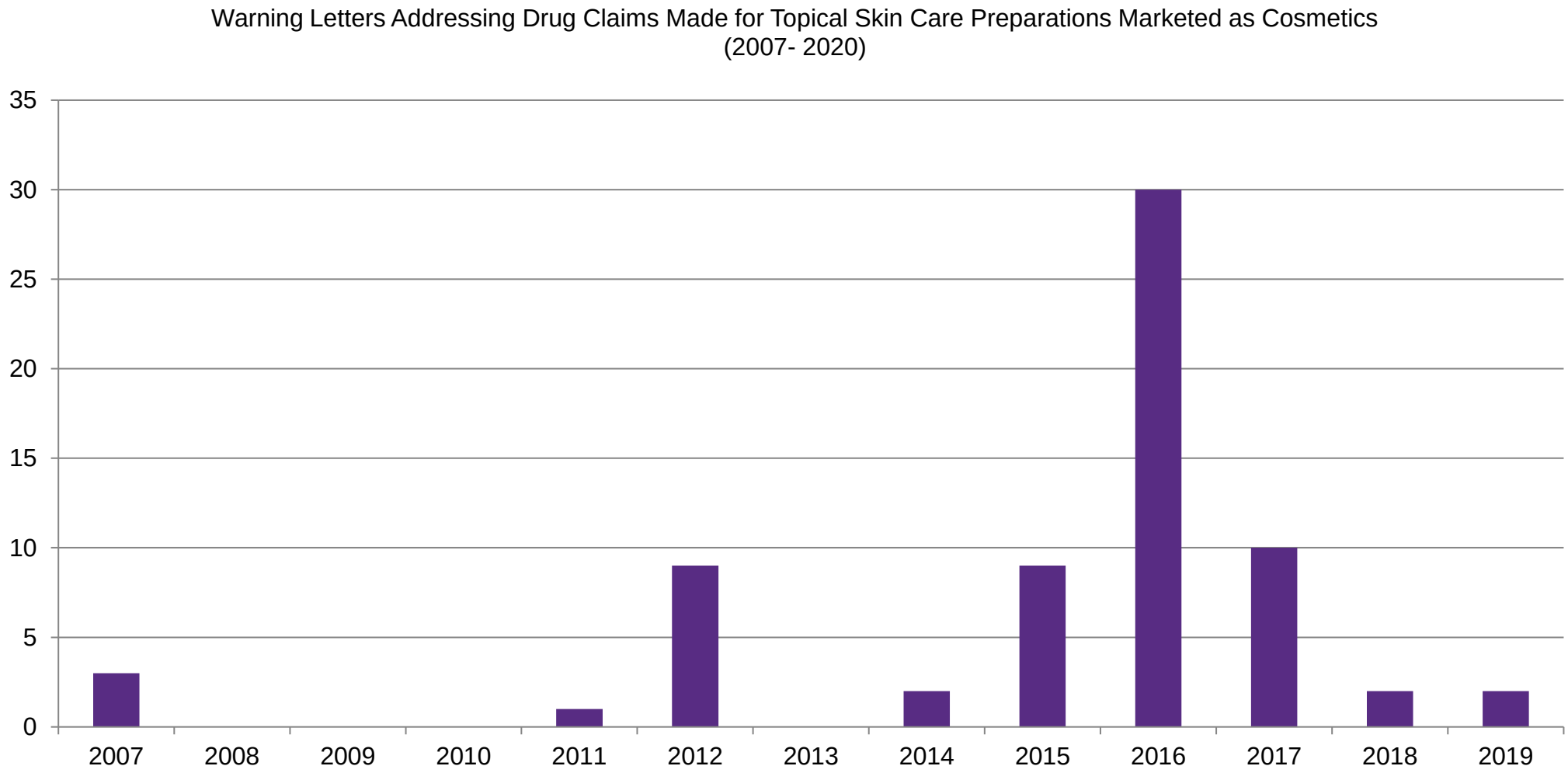
Self-Regulatory Programs

FDA voluntary registration (VCRP)

- FDA uses product ingredient information in safety analyses
- FDA shares this information as allowable – e.g., with CIR, Congress
- Benefit to participants?

Current Enforcement Trends

FDA: Cosmetic v. Drug Enforcement Trends



FDA: Cosmetic v. Drug Enforcement Trends

- Recent FDA Warning Letters
  - Disease treatment or mitigation – eczema; psoriasis; rosacea; dermatitis; acne; antibacterial properties; anti-inflammatory effects; sun damage repair

  - Structure/function effect –
    - Skin lightening effects, dark spot reduction, and redness reduction
    - Collagen claims (e.g., “help activate collagen,” “boost collagen production,” and “promote collagen synthesis”)
    - Cell regeneration or renewal (e.g., “stimulates cellular regeneration,” “accelerates cell renewal,” “increases cell turnover,” “boost[s] natural cell metabolism,” and “encourages healthier skin replication”)
    - Anti-aging effects, including wrinkle reduction and fine line reduction

Other Enforcement Considerations

State Authorities

- Many states active under authorities parallel to FDCA
- California
  - Safe Cosmetics Act and Registry
  - Prop 65 (doesn’t carve out OTC drugs)
  - Slack Fill
  - Animal Testing

Consumers

- Class actions - consumer protection state laws
  - “Natural”
  - “Organic”
  - Safety
  - Products don’t work as advertised
  - Claims

Enforcement Trends

FTC actions

- rare for traditional cosmetics
- more active with clear health benefit claims
- 2014: consent order with L'Oreal
  - parallel to FDA warning letter
  - "clinically proven" to "boost genes' activity and stimulate the production of youth proteins that would cause visibly younger skin in just 7 days"

FTC: "All Natural" Cosmetic Claims

- April 2016, FTC settled with four cosmetic companies and filed a complaint against a fifth company after concluding that "all natural" or "100% natural" claims were not substantiated because are not "all natural" because the products contain "at least one synthetic ingredient"
  - ShiKai
  - Rocky Mountain Sunscreen
  - EDEN Body Works
  - Beyond Coastal
  - California Naturel

Prop 65

- Business must warn a person before "*knowingly and intentionally*" exposing that person to a listed chemical
- Business must be aware that it is causing an exposure (but no requirement that business be aware of Prop 65 obligations)
- Exposure must result from a deliberate act, like the sale of a product
- Warning must be "*clear and reasonable*":
  - clearly communicate that the chemical is known to cause cancer, and/or birth defects or other reproductive harm;
  - effectively reach the person before exposure

- Exposure? Consumer product; environmental; occupational

CA Safe Cosmetics Act

- For all cosmetic products sold in CA, the manufacturer, packer, and/or distributor named on the product label must provide to CDPH a list of all cosmetic products that contain any ingredients known or suspected to cause cancer or developmental or other reproductive harm
- Requirement does *not* depend on concentration or method of application
- CA maintains list of chemicals (similar to Prop 65)
- Reports are publicly available – both substances and companies
- Little public enforcement since enactment (2005)
- Ingredient disclosure addition - 2019

Other State Activity

- Animal testing
- Sunscreen ingredient bans
- Fragrance ingredient disclosure
- PFAS-related restrictions

Class Actions: Marketing Claims

- Recent trend to challenge claims that plaintiffs assert are unapproved drug claims:
  - The plaintiff (and the proposed class members) purchased product X
  - Product X was marketed as a cosmetic but in fact, because of claims, was an unapproved new drug
  - Plaintiffs would not have purchased the product had they known that it was an unapproved new drug and/or product could not do what it purports to do and be a cosmetic, and plaintiffs were therefore harmed in the amount they spent
  - Plaintiffs also often seek injunctive relief, arguing that the company must stop selling the product until it obtains an approved NDA

Class Actions: Marketing Claims

- *Reid v. GMC Skin Care USA Inc.* (N.D.N.Y filed Mar. 11, 2015)
  - consumer fraud class action, challenging the "Phyto Stem Cell+" line of anti-aging products
  - argued that the products are not only ineffective, but are in fact unapproved new drugs
  - court dismissed most of claims after motion to dismiss; case settled

Marketing Trends

Clean

Cruelty Free

Vegan

Green Claims

Free of "XX"

Natural

Organic

What to Expect?

Federal Cosmetics Reform

- Periodically discussed over past 15-20 years
- Bills introduced 2016-2019:
  - May 2017, Senators Dianne Feinstein (D-CA) and Susan Collins (R-MA) introduced the Personal Care Products Safety Act
  - October 2017, Senator Orrin Hatch (R-UT) introduced the FDA Cosmetic Safety and Modernization Act
  - September 2016, Representatives Frank Pallone, Jr. (D-NJ) and Leonard Lance (R-NJ) released discussion draft
  - Early 2017, Representative Pete Sessions (R-TX) introduced the Cosmetic Modernization Amendments of 2017
- These all followed industry/FDA negotiations in 2013-2014 that ended abruptly

Federal Cosmetics Reform

- Key Concepts:
  - serious adverse event reporting requirements;
  - facility registration requirements;
  - ingredient listing requirements
  - current good manufacturing practice requirements;
  - tools related to ingredient safety;
  - preemption;
  - mandatory recall authority

Federal Cosmetics Reform

- Status:
  - In 2018, Feinstein and Hatch bills referred to Senate HELP Committee
  - HELP Discussion Draft early 2018
  - 2019: House E&C – Pallone bill
  - 2022: Potential path as part of user fee negotiations