The Global Regulatory Update

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United States

United States

- **Definition of a Drug**
  - **A. Articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and**
  - **B. Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals**

- **C. Articles (other than food) intended to affect the structure or any function of the body of man or other animals;**

- **D. Articles intended for use as a component of any articles in clause A, B or C; but does not include devices or their components, parts or accessories.**

United States

- **Definition of a Cosmetic**
  - **The term “cosmetic” means 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 articles intended for use as a component of any such articles;**
  - **except that such term shall not include soap.**

United States

- **Definition of Soap**
  - **Soap products consist primarily of an alkali salts of fatty acids**
  - **no label claim other than cleansing of the human body**
  - **Sold and labeled only as soap**

Cosmeceutical

- **Hybrid product**
- **First used by Raymond Reed when he was President of SCC in 1949**
- **Term popularized by Kligman**

Drugs Compared to Cosmetics

- **Actives**
- **Pre-market approval**

- **Registrations**
- **Good Manufacturing Practices**
- **Expiration Dating**
- **Label claims and warnings**

- **Safety and Efficacy**
- **Adverse Reactions**
- **Registration of Formulations**

Registrations of OTC Drugs

- The name on the label needs a Labeler code
- The manufacturer needs a Labeler code
- And a site registration
  - Renewed annually
- And the formulation registration
  - Renewed annually
- And the private label form if he is not the seller
- Most be done using the FDA's SPL electronic filing

Foreign Issues

- If the seller or the manufacturer is not in the US, they must have a US FDA liaison on record.

- Do not try to do SPL's yourself-outsource it!

OTC Drugs in the US

- **Simple way to enter market**
- **Simple way to change formulations**
- **Restricts claims**

Current Status

- **Final Monographs**
  - **Anti-Fungal**
  - **Acne**
  - **Antiperspirants**
  - **Skin Protectants**
  - **Sunscreens**

- **Tentative Final Monographs**
  - **Skin Bleaching**
  - **Health-care Antiseptic Drugs**
  - **Topical Analgesics**

Labeling

- Drug Facts now required on all OTC Drugs
- A way for consumers to report serious adverse reactions are now required Also for Dietary supplements)
  - Phone number must be 24/7
  - Address is preferred
  - Under Other information

The New Labeling Requirements for Sunscreens In the US

US Final Monograph

- May 21, 1999
- Proposed revisions issued 8/27/07
- New Changes published 6/17/2011
- Goes into effect **June 17,2012**
- **There is nothing Final about a Final Monograph**

Labeling & Effectiveness Testing

- Published 6/17/2011
- Effective 6/18/2012

- Effects Labeling both front and back; SPF and UVA testing and claims

Tests

- SPF-number of subjects required is reduced to 10. New SPF Standard. Maximum permitted claim is SPF 50+. Any number is permissible.
  - Issues with this new method

- Broad Spectrum-Critical Wavelength of 370 nm.
  - Issues with this new method

Front Label

- Required to identify the product as a sunscreen
- If you pass the new critical wavelength test you must say **Broad Spectrum SPF 30** (add the actual SPF)
  - Continuous text, no intervening text or graphics
  - Same font style, color, size on the same background

- If you do not pass the test you can only say **SPF 6** (add the actual SPF)

Water Resistant Products

Water resistant (40 minutes)

or

Water resistant (80 minutes)

NO WATERPROOF!!!

Drug Facts Labels

- Required for all sunscreens
- Exemption for products used only on specific small areas of the face (lips, nose, ears, etc.) is lifted.
  - Blister packs?
  - Ampersand labels?

- Only exemption is the 60% rule

Title

- ***Drug Facts*** is bold and italics

Actives/Purpose

- Header is bold italics: ***Active ingredients***
- List in alphabetical order using USAN names only, followed by %
  - This must be actual % in product
    - Using Titanium dioxide and Zinc oxide you must subtract the coatings and stabilizers, etc.
- ***Purpose*** is bold italics and the only permitted purpose is Sunscreen

Uses

- Helps prevent sunburn

For Broad Spectrum SPF 15 and higher (optional)

- If used as directed with other sun protection measures (see ***Directions***), decreases the risk of skin cancer and early skin aging caused by the sun.
  - Note: the comments-”Directions” must be bold italics

Warnings
Broad Spectrum Sunscreens

For external use only

Do not use on damaged or broken skin

Stop use and ask a doctor if rash occurs

When using this product keep out of eyes. Rinse with water to remove.

Keep out of reach of children. If swallowed, get medical help or contact a Poison Control Center right away.

Note the parts that are bold must be bold on your label

Warnings are separated by fine lines that do not touch.

Warnings

Other Sunscreens Including Broad Spectrum with SPF below 15 and Sunscreens which fail the Critical Wavelength test or products not tested

- **Skin Cancer/Skin Aging Alert:** Spending time in the sun increases your risk of skin cancer and early skin aging. This product has been shown only to help prevent sunburn, **not** skin cancer or early skin aging
- **For external use only**
- **Do not use** on damaged or broken skin
- **Stop use and ask a doctor if** rash occurs
- **When using this product** keep out of eyes. Rinse with water to remove.
- **Keep out of reach of children**. If swallowed, get medical help or contact a Poison Control Center right away.

Directions
Water Resistant Products

- Apply liberally 15 minutes before sun exposure
- Reapply:
  - After 40 [or 80] minutes of swimming or sweating
  - Immediately after towel drying
  - at least every 2 hours
- Children under 6 months: Ask a doctor
- Optional: apply to all skin exposed to the sun

Directions
Non-water resistant Products

- Apply liberally 15 minutes before sun exposure
- Use a water resistant sunscreen if swimming or sweating
- Reapply at least every 2 hours
- Children under 6 months: Ask a doctor
- Optional: apply to all skin exposed to the sun

Additional *Directions* for Broad Spectrum Products

- **Sun Protection Measures.** Spending time in the sun increases your risk of skin cancer and early skin aging. To decrease this risk, regularly use a sunscreen with a Broad Spectrum SPF value of 15 or higher and other sun protection measures including:
  - Limit time in the sun, especially from 10 a.m.-2 p.m.
  - Wear long-sleeved shirts, pants, hats and sunglasses

Other information

- Protect the product in this container from excessive heat and direct sunlight

This is also the preferred location of this:

You may report a serious adverse reaction event from using this product to ……

More on this later

Prohibited Claims

- Sunblock
- Sweatproof
- Waterproof
- All day protection or citing a specific number of hours of protection

Type

- Outer box-bold 2.5 point
- Font-any allowed but not more then 39 characters to the inch. Letters cannot touch
- Type is left justified unless noted
- Leading must be 0.5
- Title (Drug Facts) bold italics min. 9 point
- Headings bold italics min. 8 point (1 point smaller than Drug Facts
- Text-min. 6 point-2 point smaller then headers.

Bullets

- Must be solid square or circle, 5 point and same color as the text
- Bullets are separated by bullet-no run ons

It doesn't fit

- If Drug Facts take up more then 60% of the FDA required information; you can use a modified format:
  - Box not required
  - May use less then 0.5 point leading
  - Drug Facts must be a minimum of 7 point
  - Headings 1 point smaller
  - Text 1 point smaller then headers
  - Bullets can run on but must be separated by 2 EM spaces

Enforcement

- **Adulteration**
- **Misbranding**

Cosmetic Labeling

- Carmine is no longer allowed in the “may contains” section
- Only approved colors are allowed here
- Possible FDA action this year

State of California

The California Safe Cosmetic Act of 2005

You are Required To Register Your Product if it Contains As an Ingredient

- Titanium dioxide
- Black 2
- Retinol or its esters
- BHA
- Cocamide DEA
- Methanol

Other Ingredients

- There are 700+ chemicals but few other than those listed are used.
- No distinction between cosmetics or drugs that also make cosmetic claims
- Name of company on the label is who must register
- No minimum levels, only detection is needed
- No money to enforce!

Proposition 65

- New additions
  - Methanol
  - Benzophenone
  - Cocamide DEA
- Current headaches
  - Acrylamide for reproductive toxicity

Lawyers

- The California lawyers who thrive on Prop. 65 lawsuits are now filing false advertising suits.

- As with Prop 65 letters, the goal is to force settlements as quickly as they can by threatening major litigation

Other Countries

- Korea issued new regulations
- Israel adopted the new EU regulations
- Mexico changed some medical devices to other categories