AGENDA

- Summary
  - Regulatory bodies and product categories
  - Prohibited ingredients and fair labeling of cosmetics
  - Business Sweden
ALTHOUGH THE FDA REGULATES COSMETIC PRODUCTS, THEY ARE NOT REQUIRED TO BE FDA REGISTERED

PRODUCTS MAY EITHER BE CLASSIFIED AS A COSMETIC OR A DRUG, WHILE SOME CAN BE BOTH

**FDA and CBP regulate cosmetic products**
- The FDA’s FD&C (product categorization by intended use) and the FPLA (labeling) acts regulate cosmetic products
- Although the FDA regulates the industry, cosmetic products do not need to be registered with the FDA. Manufacturers are however recommended to register with the Voluntary Cosmetic Registration Program (VCRP)

**Soap is not a cosmetic product or a drug**
- Shampoo, makeup and nail polish are examples of products categorized as cosmetics
- Sunscreens and antiperspirants are products that are classified as drugs
- Products that are both cosmetics and drugs, such as antidandruff shampoo and toothpastes including fluoride, need to comply with regulations for both product categories
- Soaps are not cosmetics or drugs and therefore fall under CPSC* regulations

**Six factors for legible labeling**
- Cosmetics cannot contain ingredients that make the product harmful when used according to directions on the label
- Panel display and size, style and size of letters, background contrast, obscuring design and vignette and used language are the main factors to ensure legible cosmetic labeling
- Use of certain terminology, e.g. “Not tested on animals / Cruelty free” is not regulated

CORRECT PRODUCT CATEGORIZATION IS KEY TO UNDERSTAND WHICH REGULATIONS THE PRODUCT NEEDS TO COMPLY WITH

*U.S CONSUMER PRODUCT SAFETY COMMISSION
AGENDA

- Summary
- Regulatory bodies and product categories
  - Prohibited ingredients and fair labeling of cosmetics
  - Business Sweden
COSMETICS IMPORTERS SHOULD BE AWARE OF FDA* & CBP** REGULATIONS WHEN IMPORTING TO THE U.S.

THE FDA MONITORS THE COSMETICS INDUSTRY, WORKING CLOSELY WITH THE U.S. CBP

U.S. Cosmetics Regulatory Agencies

A  FDA monitors the cosmetics industry

- Solely cosmetics products are not required to register with FDA, and a registration number is not required
- FDA encourages domestic and foreign cosmetic firms to register and file Cosmetic Product Ingredient Statements with the Voluntary Cosmetic Registration Program (VCRP), but participation is not mandatory

B  U.S. CBP monitors cosmetics imports

- Cosmetics are subject to examination by CBP at the time of entry
- Foreign cosmetics that appear to be adulterated or misbranded may be refused entry into the United States—such products must be brought into compliance, destroyed, or re-exported

FDA Registration

If products are drugs, or both cosmetics and drugs, they are subject to requirements for drug registration. Cosmetic ingredients that are classified as food products are required to meet the registration requirements of the Bioterrorism Act of 2002

Example reasons for refusal of entry include: unsafe ingredients or contaminants, color additive violations, prohibited ingredients, microbial contamination, labeling violations or failure to include all labeling information in English, claims that cause violations to U.S. law

COSMETIC PRODUCTS DO NOT NEED TO BE REGISTERED WITH FDA

SOURCE: FDA

* U.S. FOOD AND DRUG ADMINISTRATION
** U.S. CUSTOMS AND BORDER PROTECTION
While cosmetics are FDA regulated, they do not require FDA approval.

The FD&C and FPLA Acts regulate cosmetics.

**Federal Food, Drug, and Cosmetic Act (FD&C Act)**
- The FD&C Act defines cosmetics by their intended use, and differentiates cosmetics versus drugs on the basis of this use (i.e. beautifying versus treating or diagnosing disease).

**Fair Packaging and Labeling Act (FPLA)**
- The FPLA requires all “consumer commodities” disclose net contents, identity of commodity, and name and place of business of the product’s manufacturer, packer, or distributor.

**Voluntary Cosmetic Registration Program (VCRP)**
- Although not required, FDA encourages cosmetic firms to participate in FDA’s Voluntary Cosmetic Registration Program (VCRP) using the online registration system, where manufacturers, distributors, and packers can file information on products being marketed in the U.S.

### Complexity

**Drugs**
- Strict FDA process, requiring FDA premarket approval and registration.
- A New Drug Application (NDA) is required—FDA only approves an NDA after determining, for example, that the data is adequate to show the drug’s safety and effectiveness.

**OTC Drugs**
- Needs to comply with the FDA-regulations for OTC drugs.
- Needs to be registered and approved with FDA with a National Drug Code (NDC).
- FDA has published monographs, or rules, for a number of OTC drug categories, which describe what ingredients may be used and for what use.

**Cosmetics**
- Compliance with FD&C Act and FPLA Act.
- Does not need to be registered with the FDA.
- Can participate in FDA’s VCRP.

Source: FDA

Business Sweden
THE FD&C ACT FURTHER DEFINES ADULTERED AND MISBRANDED COSMETICS

Under the FD&C Act, cosmetics are regulated under Chapter IV, further defining “adulterated cosmetics”, “misbranded cosmetics”. FDA can take action against cosmetics on the market that are in violation of these laws.

### Adultered Cosmetics

- According to the FD&C Act, adulteration refers to violations involving product composition from ingredients, contaminants, processing, packaging, or shipping and handling. A cosmetic is adulterated if it:
  - Contains any poisonous or deleterious substance which may be injurious to users (except coal-tar hair dyes)
  - Consists of any filthy, putrid, or decomposed substance
  - Has been prepared under insanitary conditions whereby it may have become contaminated with filth, or it may have become injurious to health
  - Its container is composed of any poisonous substance
  - It contains, a color additive which is unsafe

### Misbranded Cosmetics

- “Misbranding” refers to violations involving improperly labeled or deceptively packaged products. Under the FD&C Act, a cosmetic is misbranded if its label:
  - Is false or misleading in any particular
  - Does not include all required information
  - Does not have information adequately prominent and conspicuous
  - Is on a container that is made, formed, or filled to be misleading
  - Also, if it contains a color additive, other than a hair dye, that does not conform to applicable regulations issued under section 721 of the FD&C Act
  - Is in violation of an applicable regulation in section 3 or 4 of the Poison Prevention Packaging Act of 1970 (FD&C Act, sec. 602)

ALL INFORMATION MUST BE COMPLETE, ACCURATE AND NOT MISLEADING TO CONSUMERS

SOURCE: FDA
WHETHER A PRODUCT IS A COSMETIC OR A DRUG IS DETERMINED BY A PRODUCT'S INTENDED USE

COSMETICS ARE NOT SUBJECT TO FDA APPROVAL WHILE DRUGS MUST BE APPROVED

<table>
<thead>
<tr>
<th>Intended Use</th>
<th>Cosmetics</th>
<th>Drugs</th>
<th>Both Cosmetic and Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>To be rubbed, poured, sprinkled, or sprayed on, introduced into the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance</td>
<td>The diagnosis, cure, mitigation, treatment, or prevention of disease</td>
<td>Products considered drug and cosmetic products must have at least two intended uses, fitting both the category of a drug and cosmetic</td>
<td></td>
</tr>
<tr>
<td>The diagnosis, cure, mitigation, treatment, or prevention of disease</td>
<td>To affect the structure or any function of the body of man</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulatory Body</th>
<th>Cosmetics</th>
<th>Drugs</th>
<th>Both Cosmetic and Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>No regulatory approval required with the exception of color additives</td>
<td>Drugs are regulated by FDA's Center for Drug Evaluation and Research (CDER)</td>
<td>FDA's Over-the-Counter (OTC) Drug Review</td>
<td></td>
</tr>
<tr>
<td></td>
<td>FDA's Over-the-Counter (OTC) Drug Review</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Regulatory Requirements</th>
<th>Cosmetics</th>
<th>Drugs</th>
<th>Both Cosmetic and Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Under the FD&amp;C Act, cosmetic products and ingredients do not require FDA approval before they go on the market</td>
<td>Drugs must generally receive premarket approval by FDA through the New Drug Application (NDA) process or conform to an OTC &quot;monograph&quot; for a particular drug category</td>
<td>Products characterized as both makeups and drugs must comply with the requirements for both cosmetics and drugs</td>
<td></td>
</tr>
</tbody>
</table>

SOURCE: FDA
FDA PROVIDES EXAMPLES OF COSMETICS, DRUGS AS WELL AS BOTH COSMETIC AND DRUG PRODUCTS

COSMETICS ARE NOT SUBJECT TO FDA APPROVAL WHILE DRUGS MUST BE APPROVED

<table>
<thead>
<tr>
<th>FDA Provided Examples</th>
<th>Cosmetics</th>
<th>Drugs</th>
<th>Both Cosmetic and Drug</th>
</tr>
</thead>
<tbody>
<tr>
<td>Products included in the definition of cosmetics include, but are not limited to:</td>
<td></td>
<td></td>
<td>Products considered both a drug and a cosmetic products include:</td>
</tr>
<tr>
<td></td>
<td>‣ Skin moisturizers</td>
<td>‣ Sunscreen</td>
<td>‣ Antidandruff shampoo</td>
</tr>
<tr>
<td></td>
<td>‣ Perfumes</td>
<td>‣ Hair restoration</td>
<td>‣ Toothpastes that contain fluoride</td>
</tr>
<tr>
<td></td>
<td>‣ Lipsticks</td>
<td>‣ Skin protectant</td>
<td>‣ Deodorants that are also antiperspirants</td>
</tr>
<tr>
<td></td>
<td>‣ Fingernail polishes</td>
<td>‣ Pain relief</td>
<td>‣ Moisturizers marketed with sun protection claims</td>
</tr>
<tr>
<td></td>
<td>‣ Eye and facial makeup</td>
<td>‣ Anti-aging effects that involve the structure or function of the skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>‣ Cleansing shampoos</td>
<td>‣ Treatment of acne, dandruff, eczema, or irritated skin</td>
<td></td>
</tr>
<tr>
<td></td>
<td>‣ Permanent waves and hair colors</td>
<td>(also examples of both cosmetics and drugs)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>‣ Deodorants</td>
<td>‣ Antibacterial products (soap)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>‣ Any substance intended for use as a component of a cosmetic product</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td>‣ It does not include soap</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Other Considerations

- Soap is regulated by the Consumer Product Safety Commission (CPSC) and is not considered a cosmetic or a drug (unless it has antibacterial qualities making it an OTC drug)

SOURCE: FDA
AGENDA

- Summary
- Regulatory bodies and product categories
  - Product specific considerations
    - Prohibited ingredients and fair labeling of cosmetics
    - Business Sweden
SHAMPOO IS CONSIDERED A COSMETIC, UNLESS IT HAS SPECIFIC INTENDED USES

**SHAMPOO IS CONSIDERED A COSMETIC**

<table>
<thead>
<tr>
<th>Product: Shampoo</th>
<th>Product Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Classification</strong></td>
<td>Cleansing shampoos are considered cosmetics</td>
</tr>
<tr>
<td><strong>Registration</strong></td>
<td>Cleansing shampoos are not required to have FDA registration to be sold in the U.S.</td>
</tr>
<tr>
<td><strong>Special considerations</strong></td>
<td>Shampoos that have are intended for hair restoration are drugs</td>
</tr>
<tr>
<td></td>
<td>Shampoos that are intended for anti-dandruff are considered both a cosmetic and a drug</td>
</tr>
</tbody>
</table>

**SUNSCREEN IS CONSIDERED A DRUG**

<table>
<thead>
<tr>
<th>Product: Sunscreen</th>
<th>Product Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Classification</strong></td>
<td>The majority of sunscreens in the United States are marketed under the OTC Monograph System as an OTC drug</td>
</tr>
<tr>
<td><strong>Registration</strong></td>
<td>The OTC Monograph Process or the New Drug Application (NDA) Process</td>
</tr>
<tr>
<td><strong>Special considerations</strong></td>
<td>Review of OTC drugs is handled by the Center for Drug Evaluation's Office of Drug Evaluation IV</td>
</tr>
<tr>
<td></td>
<td>The Sunscreen Innovation Act (SIA) established an alternative process for the review of safety and effectiveness of additional active ingredients for use in sunscreens</td>
</tr>
</tbody>
</table>

UNLIKE MANY OTHER COUNTRIES, SUNSCREEN IS CONSIDERED A DRUG IN THE U.S.

SOURCE: FDA
**LIPSTICK, BLUSH, FOUNDATION, AND MASCARA DO NOT REQUIRE FDA APPROVAL**

**MAKEUP WITH SUN PROTECTION IS ALSO A DRUG**

<table>
<thead>
<tr>
<th>Product: Makeup</th>
<th>Product Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Classification</strong></td>
<td>▶ FDA regulates “makeup” (i.e. lipstick, blush, foundation, face powder, eye shadow, eye liner, and mascara)—as cosmetics</td>
</tr>
<tr>
<td><strong>Registration</strong></td>
<td>▶ The law <strong>does not require</strong> cosmetic products/ingredients to have FDA approval (except color additives not intended as hair dyes)</td>
</tr>
</tbody>
</table>
| **Special considerations** | ▶ Any color additives used in cosmetics must be approved by FDA  
▶ In addition to approval, a number of color additives must be batch certified by FDA  
▶ Products intended both as makeup and sun protection are both cosmetics and drugs |

<table>
<thead>
<tr>
<th>Product: Nail polish</th>
<th>Product Details</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Classification</strong></td>
<td>▶ Nail products for home and salon use are generally regulated as <strong>cosmetics</strong></td>
</tr>
</tbody>
</table>
| **Registration** | ▶ Nail products **do not need FDA approval**, with the exception of most color additives  
▶ The requirement for an ingredient declaration does not apply to products used only at salons and free samples |
| **Special considerations** | ▶ Nail products intended to treat medical problems, such as nail fungus, are drugs  
▶ The labels of all cosmetics must include a warning statement whenever necessary to prevent a health hazard that may occur with use of the product |

**MOST COLOR ADDITIVES USED IN MAKEUP AND NAIL POLISH MUST BE FDA APPROVED**

**SOURCE:** FDA
# ANTIPERSPIRANTS ARE CONSIDERED OTC DRUGS, WHILE LOTIONS ARE COSMETICS

## ANTIPERSPIRANTS ARE TYPICALLY DEODORANTS

<table>
<thead>
<tr>
<th>Product: Antiperspirant</th>
<th>Product Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification</td>
<td>▶ Antiperspirants inhibit perspiration—a biological function—thus are classified as an <strong>OTC drug</strong></td>
</tr>
<tr>
<td>Registration</td>
<td>▶ Antiperspirant-deodorants must meet requirements for cosmetics and drugs</td>
</tr>
<tr>
<td>Special considerations</td>
<td>▶ Deodorants are personal care products applied topically to minimize the odor—they are classified as cosmetics by the FDA, as they do not change a biological function of the body</td>
</tr>
<tr>
<td></td>
<td>▶ Antiperspirants are typically also deodorants</td>
</tr>
</tbody>
</table>

## LOTIONS WITH MEDICAL QUALITIES ARE DRUGS

<table>
<thead>
<tr>
<th>Product: Lotion</th>
<th>Product Details</th>
</tr>
</thead>
<tbody>
<tr>
<td>Classification</td>
<td>▶ Lotions intended to make people more attractive are <strong>cosmetics</strong></td>
</tr>
<tr>
<td>Registration</td>
<td>▶ Lotions are <strong>not required</strong> to have FDA registration to be sold in the U.S.</td>
</tr>
<tr>
<td>Special considerations</td>
<td>▶ If used for therapeutic, treatment or preventative purposes they may be cosmetics and drugs (i.e. a lotion that moisturizes and provides sun protection is classified as a drug)</td>
</tr>
</tbody>
</table>

## DEODORANTS WITHOUT ANTIPERSPIRANT QUALITIES ARE CONSIDERED PERSONAL CARE PRODUCTS

**SOURCE:** FDA
AGENDA

- Summary
- Regulatory bodies and product categories
- Prohibited ingredients and fair labeling of cosmetics
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GENERALLY, SIX FACTORS SHOULD BE CONSIDERED WHEN LABELING COSMETICS

IN ADDITION TO THE BELOW, MANUFACTURERS SHOULD RESEARCH THE MINIMUM FONT SIZE REQUIRED

1. **Panel display**: required information must be on a panel presented under customary conditions. Required information cannot be on the bottom of a cosmetic, unless the consumer would typically inspect as such.

2. **Panel size**: the label must be large enough to provide sufficient space for prominent display of the required information.

3. **Size and style of letters**: the font must be in at least the required minimum size and in a style so that the required label statements are easily readable for the consumer.

4. **Background contrast**: the contrast must be sufficient to make the required label statements conspicuous and easily readable.

5. **Obscuring designs and vignettes**: the required statements must not be obscured by vignettes or other designs or by crowding with other printed or graphic material.

6. **Language**: all labeling must be in English. Products distributed solely in Puerto Rico or a Territory where the predominant language is one other than English, may state required information in the predominant language.

ALL PRODUCT LABELING MUST BE IN ENGLISH AND EASILY LEGIBLE

SOURCE: FDA
COSMETICS INGREDIENTS CANNOT BE HARMFUL WHEN USED AS INTENDED

SPECIFIC INGREDIENTS ARE PROHIBITED BY FDA

- Cosmetics cannot contain ingredients that make the product harmful when used according to directions on the label, or in customary or expected ways.
- Color additives are permitted only FDA-approved for the intended use—some may be used only if they are from batches that FDA has tested and certified.

FDA has regulations that prohibit or restrict the following ingredients in cosmetics:

- Bithionol, Chlorofluorocarbon propellants, Chloroform
- Halogenated salicylanilides (di-, tri-, metabromsalan and tetrachlorosalicylanilide)
- Hexachlorophene
- Mercury compounds
- Methylene chloride
- Prohibited cattle materials
- Sunscreens in cosmetics
- Vinyl chloride
- Zirconium-containing complexes

CERTAIN CLAIMS ARE NOT OVERSEEN BY FDA

- FDA does not substantiate or approve efficacy of cosmetic safety claims. Examples of such claims that are not regulated or overseen by FDA include:
  - Hypoallergenic
  - Non-comedogenic (i.e. won’t clog pores)
  - Natural
  - Fragrance-free

Examples of acceptable, but unsubstantiated claims used on product labelling include “Alcohol Free” and “Cruelty Free”:

- Alcohol Free - In cosmetic labeling, “alcohol,” typically refers to ethyl alcohol. Cosmetic products, including those labeled "alcohol free," may contain other alcohols, such as cetyl, stearyl, cetearyl, or lanolin alcohol.
- Cruelty Free / Not Tested on Animals - companies promote products with such claims in labeling or advertising. The use of these terms is unrestricted by FDA as there are no legal definitions for these terms.

CLAIMS SUCH AS “CRUELTY FREE” ARE UNRESTRICTED BY FDA, AS THERE IS NO LEGAL DEFINITION

SOURCE: FDA
THE FD&C AND FP&L ACT REGULATE COSMETICS LABELING

LOCATIONS OF LABELING VARY BY ACT

Cosmetics distributed in the U.S. must comply with labeling regulations published by FDA under the FD&C Act and FP&L Act.

Label Location Considerations

- Under the FD&C Act label statements must appear on the inside as well as any outside container or wrapper.
- Under the FP&L Act requirements labeling applies only to the label of the outer container.

The principal display panel (i.e., the part of the label most likely displayed under conditions of display for sale) must state:

- The name of the product (i.e. shampoo, lipstick, eyeshadow)
- Identify by descriptive name or illustration the nature or use of the product
- Bear an accurate statement of the net quantity of contents of the cosmetic (i.e. pound or ounce, or gallons, quart, pint, fluid ounces)

PRODUCTS SHOULD CONTAIN MULTIPLE LABELS

- A label may consist of a front panel (the principal display panel), as well as side panels and a back panel. Back and side panels are generally called information panels.

Information panels must include (in English):

- The name and place of business of the firm marketing the product
- A listing of ingredients, at least 1/6 inches in height
- The address, which must state the street address, city, state, and zip code
  - If a firm is listed in a current city or telephone directory, the street address may be omitted
- Directions for safe use
- If the distributor is not the manufacturer or packer, this fact must be stated on the label by the qualifying phrase "Manufactured for ..." or "Distributed by ..." or similar wording
- Labels must bear a warning statement whenever necessary or appropriate to prevent health hazards associated with the product (i.e. flammable cosmetics, such as aerosols)

IN ADDITION TO BASIC INFORMATION, LABELS MUST HAVE A WARNING STATEMENT WHENEVER NECESSARY

SOURCE: FDA
OTC DRUGS MUST LIST SEVERAL SPECIFIC PRODUCT SPECIFICATIONS ON LABELING

OTC DRUGS DEFINITION AND LABELING REQUIREMENTS MUST BE ADHERED TO

- The FDA defines over-the-counter (OTC) drugs as intended to affect the structure or any function of the body of man or other animals.
- Unlike products that are classified as cosmetics, OTC drugs need to be registered with the FDA, which is done by applying for a National Drug Code (NDC) and registering the company.

OTC drugs must be registered with the FDA

In order to register these products, they need to comply with certain labelling requirements, including:

- Active Ingredients
- Product purpose
- Uses for the product
- Specific warnings, including when the product should not be used and when it is appropriate to consult with a doctor. Also description of side effects and substances or activities to avoid
- When, how, and how often to take the product
- The product’s inactive ingredients and important information to help consumers avoid ingredients that may cause an allergic reaction

Full list of labeling requirements for products classified as drugs can be found [here](http://www.fda.gov/Drugs/ResourcesForYou/Consumers/UCM143551.htm)

OTC LABELING MUST INCLUDE A DESCRIPTION OF SIDE EFFECTS AND SUBSTANCE OR ACTIVITIES TO AVOID
AGENDA

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BUSINESS SWEDEN MAKES IT EASIER FOR SWEDISH COMPANIES TO GROW INTERNATIONALLY

BUSINESS SWEDEN INTERNATIONALISATION SERVICES

**EVALUATE OPPORTUNITIES**
Examine opportunities and choose market
- Export Information
- Steps to Export
- Trade Facilitation
- Market Selection Analysis

**CHOOSE STRATEGY**
Understand market and define entry strategy
- Market Analysis
- Visiting Program
- Market Entry Strategy
- Partner Search

**ESTABLISH PRESENCE**
Establish presence in foreign markets
- Incorporation
- Business Support Office
- Acquisition Support
- Recruitment Services
- Sourcing Services

**GROW BUSINESS**
Develop and grow your international business
- Sales and Marketing Support
- Operational Support
- Business Development

**PROMOTIONAL ACTIVITIES**
Swedish companies can use the official brand of Sweden to open doors and acquire new contacts. Business Sweden arranges seminars, site visits, trade fairs, delegations, conferences and many other activities to strengthen brands and to increase the visibility for Swedish companies.