

### Initial Information about Market Access Reuqirements for Exporting Cosmetics into the United States (non-exhaustive)

**Preliminary Overview** 

December, 2019

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### Introduction



- The primary objectives of this compilation are:
  - To provide preliminary information about issues to be considered when thinking about exporting cosmetics from Jordan to the U.S.
  - To provide websites and links, which include more detailed information for the possibility of deeper understanding and elaboration for interested targetgroups/companies
  - It is further recommended to consult additional sources, e.g. AmCham in Jordan

#### Main Overview of Cosmetics Regulations



source: https://www.fda.gov/cosmetics/cosmetics-laws-regulations/fdaauthority-over-cosmetics-how-cosmetics-are-not-fda-approved-are-fdaregulated

- The law does not require cosmetic products and ingredients, other than color additives, to have FDA approval before they go on the market, but there are laws and regulations that apply to cosmetics on the market in interstate commerce.
- In the following, important Cosmetics Regulations (according to FDA elaborations) are addressed, related to:

»ingredients
»color additives
»labeling



source: https://www.exportusa.eu/cosmetics\_import.html

- The United States FDA encourages manufacturers, packers and distributors to take part in the Voluntary Cosmetic Registration Programs. Just as the name suggests, this is a voluntary initiative. Moreover, firms may only join it once they have already entered the market. As a consequence, this is not a main concern for importers.
- Firms interested in exporting to the United States should make sure that their product is in compliance with requirements regarding:
  - Ingredients (prohibited/restricted)
  - color additives
  - Iabeling

# **Prohibited Ingredients**



sources: https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics and https://www.exportusa.eu/cosmetics\_prohibited-ingredients.html

- The usage of the following substances are prohibited in cosmetics sold in the United States:
  - Bithionol
  - Chlorofluorocarbon propellants
  - Chloroform
  - Halogenated salicylanilides (di-, tri-, metabromsalan and tetrachlorosalicylanilide)
  - Methylene chloride
  - Vinyl chloride
  - Zirconium-containing complexes
  - Prohibited cattle materials

#### Ingredients restricted by FDA regulations



sources: https://www.fda.gov/cosmetics/cosmetics-laws-regulations/prohibited-restricted-ingredients-cosmetics and https://www.exportusa.eu/cosmetics\_prohibited-ingredients.html

- The following are substances that may only be used in cosmetics under the restrictions set by the FDA regulations:
- Hexachlorophene (HCP)
- Due to its toxicity, this substance may only be used when other preservatives are not proven to be as effective. The concentration of HCP in a cosmetic may not exceed 0.1%. Its use is also prohibited in cosmetics meant for use on mucous membranes such as the lips, nose and eyelids.

#### Mercury compounds

 Mercury compounds may only be used in eye area cosmetics. Their concentration may not exceed 0.0065% of mercury calculated as a metal. It is only allowed when alternative preservatives are not available.

#### Sunscreens in cosmetics

 Sunscreens are classified as drugs by the FDA. Sunscreen ingredients are only allowed in cosmetics if they have nontherapeutic and non-physiologic ends (for example, if they are used as preservatives). Otherwise, the product will be subject to the rules regulating the importing and sale of drugs in America.

# Color Additives in Cosmetics -- I



sources: https://www.fda.gov/industry/color-additives-specific-products/color-additives-and-cosmetics-fact-sheet and https://www.exportusa.eu/cosmetic\_color-additives.html

- The FDA may refuse entry of a cosmetic product into the United States if it contains unauthorized color additives.
- Ensuring that all color additives are approved by the FDA is a crucial step to exporting a cosmetic to the United States.
- The use of all color additives in cosmetics, with the exception of carbon-tar hair dye, requires FDA approval.

# Color Additives in Cosmetics -- II



sources: https://www.fda.gov/industry/color-additives-specific-products/color-additivesand-cosmetics-fact-sheet and https://www.exportusa.eu/cosmetic\_color-additives.html

 If the beauty product to be exported contains color additives, the following rules should be followed:

#### Approval

All color additives must have FDA approval. Manufacturers must also follow specifications and rules on use and restrictions of the additive.

#### Certification

In the case of specific additives, batch certification is required in addition to approval.

#### Identity and Specification

All color additives must fulfill requirements regarding identity and specification found in the Code of Federal Regulations.

#### Use and Restrictions

Color additives may only be used in accordance with the restrictions set by the regulations.

#### If the imported cosmetic contains a non-authorized color additive, it may be be rejected by the FDA.

# Labeling Cosmetics in the US -- I



source: https://www.exportusa.eu/labeling-cosmetics-fda.php and for more details see https://www.fda.gov/cosmetics/cosmetics-labeling-regulations/cosmetics-labeling-guide

- The last step before exporting your cosmetic products to the United States is checking your product's labels.
- The product's labels all must be FDA compliant.
- All cosmetics sold in America must have labels that meet the FDA requirements. Because of this, exporters must ensure that their product labels are up to standard.
- Getting your label "right" is very important. Even the FDA recommends consulting an expert due to the level of technical knowledge required.

# Labeling Cosmetics in the US -- II



source: https://www.exportusa.eu/labeling-cosmetics-fda.php and for more details see https://www.fda.gov/cosmetics/cosmetics-labeling-regulations/cosmetics-labeling-guide

 The rules regarding labeling are very specific and often quite technical. Requirements generally include the following:

#### On the Principal Display Panel:

- Statement of Identity: must identify the nature and the use of the product through its name, description or an image
- ✓ Accurate description of the net quantity of the product

#### On the label's Information Panel:

- ✓ Name and address of the company (producer or distributor)
- ✓ Producer declaration (ex. Produced for...)
- ✓ Objectively relevant facts
- ✓ Warnings and precautions
- ✓ Ingredients

# Labeling Cosmetics in the US -- III



https://cosmereg.com/how-to-import-cosmetics-into-us/ and for more details see https://www.fda.gov/cosmetics/cosmetics-labeling-regulations/cosmetics-labeling-guide

 FDA labeling regulations require a display label and a declaration of ingredients label. Labels must be both on the inside and outside of the wrapper/container. For example, for a bottle that packaged in a box, the label must be affixed to both on the bottle and the box.

#### • What items required on the display label?

- The name of the product
- Identification of the type of product
- Name of the manufacturer and distributor of the product
- An accurate description of the amount of product contained. This should be in pounds, gallons, pints, ounces, etc.

#### • What is the declaration of ingredients rule?

- Be easy to find on the container
- Have lettering that is not less than 1/16 of an inch high. If the total space available for the label is less than 12 inches, the lettering must not be less than 1/32 of an inch high.
- List ingredients in descending order, starting with ingredients with the highest concentration first. Ingredients that are added for color or that make up less than one percent of the product can be listed in any order.





source: https://www.exportusa.eu/cosmetics-drugs-fda.php

- If your cosmetic does not comply with FDA regulations, it can be easily rejected.
- To provide you with an idea of what some of the most common violations leading to a product being rejected and blocked from being imported into the United States, here is a list of some cosmetics that were rejected in January 2011:
- FACE POWDER IN BLUK produced by the Italian company Tecnocosmesi S.p.A. was rejected on January 25, 2011 because it was classified as a drug and lacked the necessary documents.
- EYELINER produced by the German company Schwan Cosmetics Gmbh & Co. KG was rejected on January 4, 2011 because it contained dyes which were considered dangerous and its label did not include a complete list of the ingredients.
- SKIN CARE produced by the Italian company Med Care Srl was rejected on January 3, 2011 because its label was not appropriate.
- DAILY SCRUB produced by the Canadian company Apollo Health And Beauty Care was rejected on January 24, 2011 because it contained substances deemed to be health hazards.
- DETTOL CONC. DISINFECTANT produced by the British company Reckitt Benkiser Ltd was rejected on January 31, 2011 as it did not meet the directives of section 510 (j).

### FDA Sanctions -- II



source: https://cosmereg.com/how-to-import-cosmetics-into-us/

#### Why cosmetics are refused entry to the U.S.?

A cosmetic can be refused entry into the United States if it appears not to comply with U.S. laws and FDA regulations. Here are some of the most common reasons:

- Ingredients or contaminants considered unsafe
- Color additive violations
- Labeling violations
- Microbial contamination
- To avoid import detention by the FDA, it is important to understand import requirements for cosmetics and make sure that product is in compliance with all the regulations.

# CBP – Customs and Border Protection



source: https://cosmereg.com/how-to-import-cosmetics-into-us/

- Cosmetics are regulated by the U.S. CBP (Customs and Border Protection) and are defined as anything used to color and beautify the face or other parts of the body.
- As Imported cosmetics are subject to examination by CBP at the time of U.S entry, Foreign cosmetics that appear to be adulterated or misbranded will be refused entry to the U.S. Not all cosmetics are inspected or sampled upon entry into the U.S.
- Examples of beauty products that fall under CBP definition:
  - Lipstick / Eyeshadow
  - Nail polish / Non-medicinal skin lotions
  - Sunscreen and tanning lotions
- Items that the CBP does not inspect:
  - Products meant to treat medical conditions
  - Colored contact lenses / Makeup application tools (brushes)

#### See also link:

https://www.cbp.gov/sites/default/files/documents/Importing%20into%20the%20U.S.pdf

### Cosmetics Importers -- I



- FDA often receives questions from cosmetics firms about requirements for importing cosmetics into the United States. Here are some commonly asked questions and our responses.
- How does FDA monitor imports? FDA works closely with U.S. Customs and Border Protection (CBP) to monitor imports. Imported 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. They must be brought into compliance, destroyed, or re-exported. Import refusals are listed on FDA's website and are updated monthly.

### Cosmetics Importers -- II



- Are all imported cosmetics sampled and examined?
- Not all cosmetics are inspected or sampled upon entry into this country. In order to focus inspection efforts most efficiently, FDA issues Import Alerts to advise inspectors of trends in violations. Among the products addressed in Import Alerts are cosmetic-type products marketed with therapeutic claims that cause them to be considered unapproved new drugs under the law, cosmetics that are adulterated because of microbial contamination, failure to meet U.S. requirements for color additives, and bulk shipments of high-risk bovine tissue from BSE (bovine spongiform encephalopathy) countries.
- However, examination of imported cosmetics is not limited to the types of products specified in Import Alerts. Also, the fact that a product has not been detained previously does not protect it from being detained in the future, if it appears to be in violation of U.S. law.
- While not all imported products are examined at the time of entry, those not examined are still subject to all the legal requirements of the laws we enforce.

# International Differences in the Definition of Cosmetics and Drugs



- Many countries define drugs and cosmetics differently from the United States. For example, in some countries, sunscreens are regulated as cosmetics. In the United States, they are regulated as drugs. Hair restoration, skin protectant, pain relief, anti-aging effects that involve the structure or function of the skin, and treatment of acne, dandruff, eczema, or irritated skin are other examples of claims that would cause products to be regulated as drugs (or in some cases, both cosmetics and drugs) in the United States. Cosmetics and drugs are subject to different requirements.
- Drugs are regulated by FDA's Center for Drug Evaluation and Research (CDER). Questions about drugs can be directed to CDER at CDERSmallBusiness@fda.hhs.gov or druginfo@fda.hhs.gov

# Are "natural" or "organic" cosmetics required to receive certification?



- FDA does not define or regulate terms such as "organic" and "natural." However, the U.S. Department of Agriculture (USDA) does regulate the use of the term "organic" when used in terms of agricultural ingredient marketing. Questions about the use of organic agricultural ingredients should be directed to USDA. There are also private organizations that certify "natural" and other claims; however, these organizations are in no way affiliated with FDA.
- Also, remember that all cosmetics are required to be safe, regardless of the sources of their ingredients. An ingredient's source does not determine its safety.

# Good Manufacturing Practice (GMP) Guidelines/Inspection Checklist for Cosmetics (according to FDA)

### Good Manufacturing Practices (GMP) for Cosmetics



source: https://www.intertek.com/cosmetics/good-manufacturing-practice/

- Good Manufacturing Practices (GMP) of cosmetic products are mandatory in the EU, and are highly recommended by many other countries, such as the United States.
- However, rigorous adherence to Good Manufacturing Practice (GMP) minimizes the risk of adulteration or misbranding of cosmetic products. A useful reference "Guidelines for Good Manufacturing Practice of Cosmetic Products (GMPC)" was published by the Council of Europe in 1995. Similar references are also available from United States Food and Drug Administration (FDA) and European Cosmetic Toiletry and Perfumery Association (Colipa).

### Good Manufacturing Practice (GMP) -- I



source: https://www.fda.gov/cosmetics/cosmetics-guidance-documents/goodmanufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics

- The Federal Food, Drug and Cosmetic Act (/federal-food-drug-and-cosmetic-actfdc-act) prohibits the introduction or delivery for introduction into interstate commerce of cosmetics that are adulterated or misbranded (Sec. 301).
- A cosmetic may be deemed adulterated (Sec. 601) for essentially four reasons, namely:
  - 1. It may be injurious to users under conditions of customary use because it contains, or its container is composed of, a potentially harmful substance.
  - 2. It contains filth.
  - 3. It contains a non-permitted, or in some instances non-certified, color additive.
  - 4. It is manufactured or held under insanitary conditions whereby it may have
  - 5. become injurious to users or contaminated with filth.

### Good Manufacturing Practice (GMP) -- II



source: https://www.fda.gov/cosmetics/cosmetics-guidance-documents/goodmanufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics

- A cosmetic may be deemed misbranded (Sec. 602) for reasons of:
  - 1. False or misleading labeling.
  - 2. Failure to state prominently and conspicuously any information required by or under authority of this act.
  - 3. Misleading container presentation or fill.
- To determine whether cosmetic firms manufacture, hold or deliver for introduction into interstate commerce cosmetics that are adulterated or misbranded, and to prevent these and other practices violating Sec. 301 of the FD&C Act, the law gives the agency the authority to enter the establishments of such firms and inspect their facilities as well as all pertinent equipment, finished and unfinished materials, containers and labeling therein. See Sec. 704(a) of the FD&C Act.
- Rigorous adherence to good manufacturing practice minimizes the risk of adulteration or misbranding of cosmetics. The following cosmetic establishment instructions, excerpted from FDA's Inspection Operations Manual, may serve as guidelines for effective selfinspection. A good inspection score means that an establishment follows good manufacturing practice.

### GMP Guidelines – Buildings & Facilities



source: https://www.fda.gov/cosmetics/cosmetics-guidance-documents/goodmanufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics

- Buildings used in the manufacture or storage of cosmetics are of suitable size, design and construction to permit unobstructed placement of equipment, orderly storage of materials, sanitary operation, and proper cleaning and maintenance.
- A. Floors, walls and ceilings are constructed of smooth, easily cleanable surfaces and are kept clean and in good repair.
- B. Fixtures, ducts and pipes are installed in such a manner that drip or condensate does not contaminate cosmetic materials, utensils, cosmetic contact surfaces of equipment, or finished products in bulk.
- C. Lighting and ventilation are sufficient for the intended operation and comfort of personnel.
- D. Water supply, washing and toilet facilities, floor drainage and sewage system are adequate for sanitary operation and cleaning of facilities, equipment and utensils, as well as to satisfy employee needs and facilitate personal cleanliness.

# GMP Guidelines – Equipment



source: https://www.fda.gov/cosmetics/cosmetics-guidance-documents/goodmanufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics

- A. Equipment and utensils used in processing, holding, transferring and filling are of appropriate design, material and workmanship to prevent corrosion, buildup of material, or adulteration with lubricants, dirt or sanitizing agent.
- B. Utensils, transfer piping and cosmetic contact surfaces of equipment are wellmaintained and clean and are sanitized at appropriate intervals.
- C. Cleaned and sanitized portable equipment and utensils are stored and located, and cosmetic contact surfaces of equipment are covered, in a manner that protects them from splash, dust or other contamination.

### GMP Guidelines – Personnel



source: https://www.fda.gov/cosmetics/cosmetics-guidance-documents/goodmanufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics

- A. The personnel supervising or performing the manufacture or control of cosmetics has the education, training and/or experience to perform the assigned functions.
- B. Persons coming into direct contact with cosmetic materials, finished products in bulk or cosmetic contact surfaces, to the extent necessary to prevent adulteration of cosmetic products, wear appropriate outer garments, gloves, hair restraints etc., and maintain adequate personal cleanliness.
- C. Consumption of food or drink, or use of tobacco is restricted to appropriately designated areas.

# GMP Guidelines – Raw Materials



source: https://www.fda.gov/cosmetics/cosmetics-guidance-documents/goodmanufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics

- A. Raw materials and primary packaging materials are stored and handled in a manner which prevents their mix-up, contamination with microorganisms or other chemicals, or decomposition from exposure to excessive heat, cold, sunlight or moisture.
- B. Containers of materials are closed, and bagged or boxed materials are stored off the floor.
- C. Containers of materials are labeled with respect to identity, lot identification and control status.
- D. Materials are sampled and tested or examined in conformance with procedures assuring the absence of contamination with filth, microorganisms or other extraneous substances to the extent necessary to prevent adulteration of finished products. Pay particular attention to materials of animal or vegetable origin and those used in the manufacture of cosmetics by cold processing methods with respect to contamination with filth or microorganisms.
- E. Materials not meeting acceptance specifications are properly identified and controlled to prevent their use in cosmetics.

# GMP Guidelines – Production -- I



source: https://www.fda.gov/cosmetics/cosmetics-guidance-documents/good-manufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics

Check whether manufacturing and control have been established and written instructions, i.e., formulations, processing, transfer and filling instructions, in-process control methods etc., are being maintained. Determine whether such procedures require that:

- A. The equipment for processing, transfer and filling the utensils, and the containers for holding raw and bulk materials are clean, in good repair and in sanitary condition.
- B. Only approved materials are used.
- C. Samples are taken, as appropriate, during and/or after processing, transfer or filling for testing for adequacy of mixing or other forms of processing, absence of hazardous microorganisms or chemical contaminants, and compliance with any other acceptance specification.
- D. Weighing and measuring of raw materials is checked by a second person, and containers holding the materials are properly identified.

# GMP Guidelines – Production -- II



source: https://www.fda.gov/cosmetics/cosmetics-guidance-documents/goodmanufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics

- E. Major equipment, transfer lines, containers and tanks are used for processing, filling or holding cosmetics are identified to indicate contents, batch designation, control status and other pertinent information.
- F. Labels are examined for identity before labeling operations f. to avoid mix-up.
- G. The equipment for processing, holding, transferring and filling of batch is labeled regarding identity, batch identification and control status.
- H. Packages of finished products bear permanent code marks.
- I. Returned cosmetics are examined for deterioration or contamination.

#### GMP Guidelines – Laboratory Controls



source: https://www.fda.gov/cosmetics/cosmetics-guidance-documents/goodmanufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics

- A. Raw materials, in-process samples and finished products are tested or examined to verify their identity and determine their compliance with specifications for physical and chemical properties, microbial contamination, and hazardous or other unwanted chemical contaminants.
- B. Reserve samples of approved lots or batches of raw materials and finished products are retained for the specified time period, are stored under conditions that protect them from contamination or deterioration, and are retested for continued compliance with established acceptance specifications.
- C. The water supply, particularly the water used as a cosmetic ingredient, is tested regularly for conformance with chemical-analytical and microbiological specifications.
- D. Fresh as well as retained samples of finished products are tested for adequacy of preservation against microbial contamination which may occur user reasonably foreseeable condition of storage and consumer use.

### GMP Guidelines – Records



source: https://www.fda.gov/cosmetics/cosmetics-guidance-documents/goodmanufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics

Check whether control records are maintained of:

- A. Raw materials and primary packaging materials, documenting disposition of rejected materials.
- B. Manufacturing of batches, documenting the:
  - i. Kinds, lots and quantities of material used.
  - ii. Processing, handling, transferring, holding and filling.
  - iii. Sampling, controlling, adjusting and reworking.
  - iv. Code marks of batches and finished products.
- C. Finished products, documenting sampling, individual laboratory controls, test results and control status.
- D. Distribution, documenting initial interstate shipment, code marks and consignees.

### GMP Guidelines – Labeling I



source: https://www.fda.gov/cosmetics/cosmetics-guidance-documents/goodmanufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics

Check whether the labels of the immediate and outer container bear:

- On the principal display panel:
  - In addition to the name of the product, the statements of identity and net contents,
  - The statement "Warning--The safety of this product has not been determined" if the safety of the respective product has not adequately been substantiated. Determine whether and what toxicological and/or other testing the firm has conducted to substantiate the safety of its products. See 21 CFR 740.10.

# GMP Guidelines – Labeling II



source: https://www.fda.gov/cosmetics/cosmetics-guidance-documents/goodmanufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics

On the information panel:

- The name and address of the firm manufacturing the product or introducing it into interstate commerce.
- The list of ingredients (only on outer container) if intended for sale or customarily sold to consumers for consumption at home.
- The warning statement(s) required at 21 CFR 740.11, iii. 740.12 and 740.17.
- Any other warning statement necessary or appropriate to prevent a health hazard.
   Determine the health hazard or their basis for a warning statement.
- Any direction for safe use of product.
- In case of a hair dye product, the caution statement of Sec. 601(a) of the Act and appropriate directions for preliminary patch testing. This warning only applies to coal-tar hair dyes which, if so labeled, are then exempted from the adulteration provision of the Act.

# GMP Guidelines – Complaints



source: https://www.fda.gov/cosmetics/cosmetics-guidance-documents/goodmanufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics

Check whether the firm maintains a consumer complaint file and determine:

- The kind and severity of each reported injury and the body part involved.
- The product associated with each injury, including the manufacturer and
- code number.
- The medical treatment involved, if any, including the name of the attending physician.
- The name(s) and location(s) of any poison control center, government agency, physician's group etc., to whom formula information and/or toxicity data are provided.

### GMP Guidelines – Other



source: https://www.fda.gov/cosmetics/cosmetics-guidance-documents/goodmanufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics

Check whether the firm is:

- Participating in the program of voluntary registration of:
  - Cosmetic manufacturing establishments i. (21 CFR 710).
  - Cosmetic product ingredient and cosmetic raw material composition statements (21 CFR 720).
- Using a color additive which is not listed for use in cosmetics (21 CFR 73, 74, and 82) or which is not certified (21 CFR 80).
- Using a prohibited cosmetic ingredient (21 CFR 700).

# GMP Guidelines – Further Resources



source: https://www.fda.gov/cosmetics/cosmetics-guidance-documents/good-manufacturing-practice-gmp-guidelinesinspection-checklist-cosmetics

- Draft Guidance for Industry: Cosmetic Good Manufacturing Practices (/regulatoryinformation/search-fda-guidance-documents/draft-guidance-industrycosmeticgood-manufacturing-practices)
- Inspection of Cosmetics: An Overview (/cosmetics/complianceenforcement/inspection-cosmetics)
- FDA Authority Over Cosmetics (/cosmetics/laws-regulations/fda-authorityovercosmetics-how-cosmetics-are-not-fda-approved-are-fda-regulated)
- Key Legal Concepts: "Interstate Commerce," "Adulterated," and "Misbranded" (/cosmetics/laws-regulations/key-legal-concepts-interstate-commerceadulteratedand-misbranded)
- Is It a Cosmetic, a Drug, or Both? (/cosmetics/laws-regulations/it-cosmetic-drugorboth-or-it-soap)
- Title 21 Code of Federal Regulations, Cosmetic Products (/cosmetics/lawsregulations/regulations-related-cosmetics)

# Facilitating Company ExportUSA -- I



 Contact for further information on how to sell beauty products and cosmetics in the United States:

#### ExportUSA Corp.

- 18 Bridge Street 2A Brooklyn
- NY 11201 New York; USA
- Tel: (+1) 718-5225575
- Website: https://www.exportusa.eu/cosmetics\_import.html

# Facilitating Company ExportUSA -- II



source: https://www.exportusa.eu/cosmetics\_import.html

- It is required to follow FDA rules when importing cosmetics into the United States.
- While a pre-marketing approval is not required, all ingredients, color additives and labels must be FDA approved.
- ExportUSA offers consulting services to companies interested in exporting cosmetics to the United States.
- Our experienced staff can help verify that all ingredients in the product are FDA approved and that labeling requirements are met. This can speed up necessary procedures at the border which can prevent goods from being detained or refused.
- The standards for foreign exported cosmetics are the same as American standards. Thus, there is no need to obtain FDA pre-marketing approval to export cosmetics to the United States. Nonetheless, the FDA does monitor products on the market and can request that products be refused entry to the American market.

#### ExportUSA – Export Services Overview - I



source: https://www.exportusa.eu/export\_services\_exportusa.html

- Exporting and Selling Cosmetics in the US;
- FDA Best Importing Practices for food in the US
- Establishing a Corporation in the US
- Search for Importers, Agents, Sales, Representatives, Distributors
- Consulting for Exporting to the US
- Marketing and Advertising Campaigns in the US
- Sales and representative office in the US
- Market research in the US
- Online selling through Ecommerce in the US
- Legal Advice in the US
- Procedures for US B1 E2 visas

#### ExportUSA – Export Services Overview - II



source: https://www.exportusa.eu/export\_services\_exportusa.html

- Logistics Services for the US
- Opening Renting an Office in the US
- Search for sales managers in the US
- Tax and accounting advice in the US
- Organization trade shows and events in the US
- FDA Medical Devices US
- Professional and Personal Fashion and Merchandising Consulting Services

# Other Facilitator Company "cosmereg"

source: https://cosmereg.com/about-us/

- Cosmereg is a regulatory firm founded in 2013 with offices in London, Florida,
   Dubai and Quito. At Cosmereg, we have a driving force that is simple: Being a reputed regulatory affairs consulting firm we are committed to assisting Cosmetic, OTC, Food and Medical Devices producers, distributors, and manufacturers by allowing quality products to reach the market.
- With our expert team of safety consultants, we dedicate to ensuring the safety of consumers around the world. As we always strive to provide a wide variety of quality resources and tailored solutions to each of our clients, we still consider your unique needs. Confidentiality and quality are our top priorities.
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# COSMETICS