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NAVIGATE FDA REQUIREMENTS

CHECKLIST GUIDE FOR SWEDISH MEDICAL DEVICE, DRUG, AND COSMETIC COMPANIES

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The Food and Drug Administration (FDA) is responsible for protecting public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices; and by ensuring the safety of our nation's food supply, cosmetics, and products that emit radiation. As a Swedish manufacturer of medical devices, drugs, or cosmetics, it is important to comply with all applicable FDA requirements and recommendations before selling to the U.S. market.

This guide outlines many of the FDA requirements placed on medical devices, drugs, and cosmetics when imported and sold in the U.S. Please note that this is not an exclusive list and each importer is required to confirm and meet all requirements applicable to the given product.

As defined by the FDA:

- **A medical device** includes an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar article, which is intended for use in the diagnosis of disease or in the cure, mitigation, treatment or prevention of disease, or intended to affect the structure or function of the body of man, which does not achieve its primary intended purpose through chemical action or is dependent upon being metabolized for the achievement of its primary intended purpose
- **Drugs** are defined as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, and articles (other than food) intended to affect the structure or any function of the body of man
- **Cosmetics** include articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body...for cleansing, beautifying, promoting attractiveness, or altering the appearance

Navigate U.S. FDA Requirements:

Medical Devices

IDENTIFY YOUR PRODUCT CLASS

- Class 1
- Class 2
  - Submit Premarket Notification (510(k))
- Class 3
  - Obtain Premarket Approval (PMA)

IS YOUR ESTABLISHMENT LOCATED IN THE UNITED STATES?

- Yes
  - Designate an Official Correspondent
- No
  - Designate a U.S. Agent

Then:

1. Register Establishment
2. List Products
3. Prepare Label, Including UDI
4. Annually Renew Registration

EXPORT WITH CONFIDENCE.
EXPORT WITH EXPERTS.
EXPORT WITH REGISTRAR CORP.

Contact Business Sweden by phone at **+1 312-781-6222** or email **ask.usa@business-sweden.se** to get started.

MEDICAL DEVICES

The FDA regulates and sets requirements for all medical devices sold in the U.S., which are verified and enforced at the time of importation. Certain medical devices will need to comply with additional Premarket Submission (Premarket Notification or Approval) requirements based on use and classification. As the FDA conducts field examinations and analyzes medical device samples to ensure compliance with applicable standards and label requirements, it is important that all Swedish medical device manufacturers comply before selling to the U.S. market.

Determine Medical Device Classification and List Device

- Medical devices are categorized by the FDA in three regulatory classes based on the intended use and level of risk. The class to which a device is assigned determines, among other things, the type of premarketing submission/application required for FDA clearance to market.
- Each medical device must also be categorized and registered with the FDA under the correct product classification. The name and product code identify the generic category of a device for FDA.

Register the Establishment Annually

- The FDA requires all companies that manufacture, prepare, propagate, compound, assemble, process, or import medical devices to register their establishments or facilities with the FDA annually. Medical device manufacturers may be required to register their supplier locations as well if finished devices are assembled in a supplier's facility.

Pay the Annual Establishment Registration Fee

- Medical device companies are required to pay the Annual Establishment Registration Fee when registering their establishment and listing their devices with the FDA. This fee is separate from other FDA fees such as the 510(k) or 513(g) application fees.

Establish a U.S. Agent

- Any foreign establishment engaged in the manufacture, preparation, propagation, compounding or processing of a device imported into the U.S. must identify a U.S. agent. The agent must reside or maintain a place of business in the U.S. and is responsible for assisting with FDA correspondence.

Receive a Unique Device Identifier (UDI)

- Medical devices distributed in the U.S. are required to include a numeric or alphanumeric code as a unqiue device identifier (UDI) on device labels, device package and, in some instances, directly on the device. UDI's are assigned by FDA-accredited issuing agencies and must be submitted to the Global Unique Device Identifier Database (GUDID).

Ensure Labeling Compliance

- Labeling errors are one of the leading causes of FDA detentions. Medical devices must comply with labeing requirments including, but not limited to, the company name, brand name, description, size, expiration date, handling instructions, physical address, contact infromation, applicable warnings and the UDI code.

Meet the Current Good Manufacturing Practices (CGMP)

- Medical device manufacturers must establish and follow quality systems to help ensure that products consistently meet applicable requirements and specifications.
- FDA has determined that certain types of medical devices are exempt from GMP requirements. Those exempt devices are published in the Federal Register and codified in 21 CFR 862 to 892.

CHECKLIST | Medical Devices

The FDA regulates and sets requirements for all medical devices sold in the U.S., which are verified and enforced at the time of importation. Certain medical devices will need to comply with additional Premarket Submission (Premarket Notification or Approval) requirements based on use and classification. Below is a simple checklist for Swedish companies to keep in mind when applying their Medical Devices.

- ☐ Determine Medical Device Classification and List Device
- ☐ Register the Establishment Annually
- ☐ Pay the Annual Establishment Registration Fee
- ☐ Establish a U.S. Agent
- ☐ Receive a Unique Device Identifier (UDI)
- ☐ Ensure Labeling Compliance
- ☐ Meet the Current Good Manufacturing Practices (CGMP)

** As the FDA conducts field examinations and analyzes medical device samples to ensure compliance with applicable standards and label requirements, it is important that all Swedish medical device manufacturers comply before selling to the U.S. market.*

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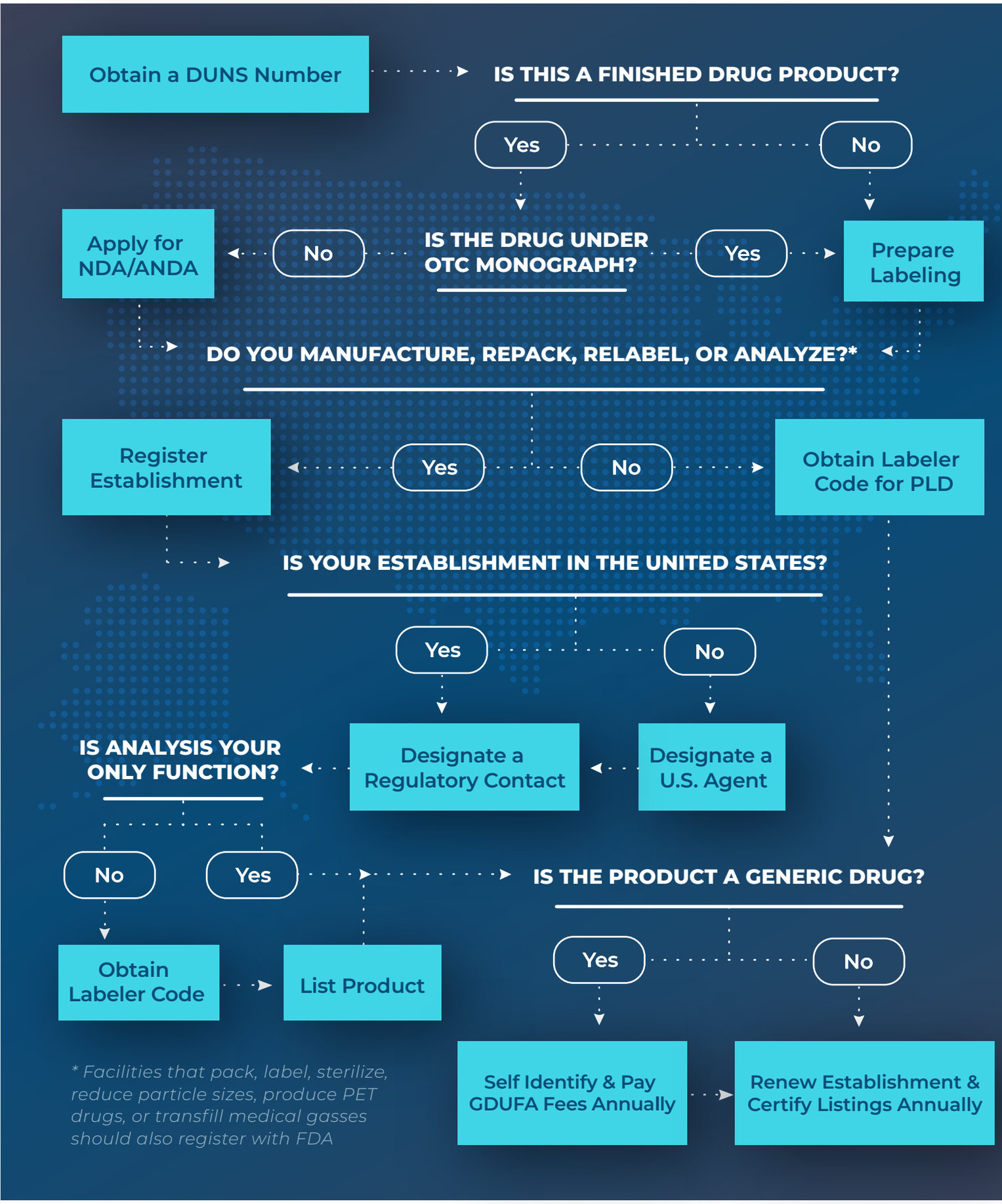
Navigate U.S. FDA Requirements:

Human Drug Products



** Facilities that pack, label, sterilize, reduce particle sizes, produce PET drugs, or transfill medical gasses should also register with FDA*

QUESTIONS? REGISTRAR CORP CAN HELP!

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DRUGS

The United States Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. section 331) prohibits the interstate shipment (which includes importation) of unapproved new drugs. Unapproved new drugs are any drugs, including foreign-made versions of U.S. approved drugs, that have not been manufactured in accordance with and pursuant to an FDA approval. It is of utmost importance to ensure Swedish drug manufacturers are compliant with FDA regulations before importing commences.

Confirm Drug Classification

- Determine if the product is classified as a drug or if it is classified as a cosmetic product. Drugs are intended to diagnose, cure, treat, or prevent disease whereas products intended for beautifying and alternating appearance are considered cosmetics. See the following section for more information on cosmetics.
- If the product is determined to be a drug, the next step is to determine whether the drug would be considered an over-the-counter (OTC) drug or if it will require a prescription.

Obtain a Data Universal Numbering System (DUNS) Number

- The FDA requires a DUNS number to meet the requirements of the Foreign Supplier Verification Programs (FSVP) rule. The DUNS number is a unique facility identifier (UFI) and issued free of charge to importers by Dun & Bradstreet.

Determine Over-The-Counter (OTC) Monograph

- If the drugs are classified as over-the-counter (OTC), an OTC monograph must be determined. OTC drug monographs include an overview of acceptable ingredients, doses, formulations, and labeling. Many of these monographs are found in section 300 of the Code of Federal Regulations. Drugs that conform to an existing monograph may be marketed without further FDA review.
- If the product does not conform to an existing monograph, a New Drug Application is required.

Complete the Center for Drug Evaluation and Research (CDER) Testing and Validation

- Before the FDA can approve a drug, data on the drug's effects must be reviewed by the CDER to determine if the drug provides benefits that outweigh its known and potential risks for the intended population. Even though a drug and its intended use may be approved abroad, the FDA may refuse entry of the drug into the U.S.

Ensure Proper Drug Labeling and Ingredient Review

- The Fair Packaging and Labeling Act (FPLA) requires all consumer commodities to disclose net contents, identity, and name and place of the product's manufacturer. Labeling errors are one of the leading causes of FDA detentions.

Register the Establishment and List Drugs

- The FDA requires companies that manufacture, prepare, propagate, compound or process drugs to register their establishments with FDA and list all drugs manufactured. This enables the FDA to perform inspections. In general, the type of inspections performed in both domestic and foreign facilities include pre-approval, surveillance, and for-cause inspections.

Designate a Registrant Contact

- FDA registered drug establishments are required to designate a registrant contact. Non-U.S. drug establishments must designate a U.S. agent for FDA communications.

Pay Generic Drug User Fees

- Is your product a generic drug? Generic drugs must self-identify and pay the Generic Drug User Fee Amendments (GDUFA) annually

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Participate in Voluntary Drug Master File (DMF) Submissions

- DMFs are used to provide confidential information about establishment processes, or articles used in the manufacturing, processing, packaging, and storing of human drugs. DMFs allow a party other than the holder of the DMF to reference material without disclosing to that party the contents of the file. Companies wishing to submit a DMF must designate an agent for FDA communications.

CHECKLIST | Drugs

The United States Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. section 331) prohibits the interstate shipment (which includes importation) of unapproved new drugs. It is of utmost importance to ensure Swedish drug manufacturers are compliant with FDA regulations before importing commences. Below is a simple checklist for Swedish companies to keep in mind when classifying their drugs in the U.S.*

- [ ] Confirm Drug Classification
- [ ] Obtain a Data Universal Numbering System (DUNS) Number
- [ ] Determine Over-The-Counter (OTC) Monograph
- [ ] Complete the Center for Drug Evaluation and Research (CDER) Testing and Validation
- [ ] Ensure Proper Drug Labeling and Ingredient Review
- [ ] Register the Establishment and List Drugs
- [ ] Designate a Registrant Contact
- [ ] Pay Generic Drug User Fees
- [ ] Participate in voluntary Drug Master File (DMF) Submissions

** Unapproved new drugs are any drugs, including foreign-made versions of U.S. approved drugs, that have not been manufactured in accordance with and pursuant to an FDA approval.*

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COSMETICS

Cosmetics do not need to be FDA-approved to be on the U.S. market, however, they are regulated by the FDA under The Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA). The FD&C Act allows the FDA to take action against cosmetics that are adultered or misbranded, and the FPLA allows the FDA to enforce labeling requirements. Products intended for beautifying and alternating appearance are considered cosmetics. Soap is not a cosmetic product and is instead regulated by the Consumer Product Safety Commission (CPSC). Examples of cosmetics include skin moisturizers, perfumes, lipsticks, fingernail polishes, makeup, shampoos, and deodorants.

Confirm Cosmetics Classification

- Do your cosmetics contain ingredients intended to diagnose, cure, treat, or prevent disease? Cosmetics with ingredients classified as drugs are regulated as drugs by the FDA, even if they are also a cosmetic. See previous section to follow requirements for drugs. Some products which are typically used as cosmetics, but also are regulated as drugs, include sunscreens, antiperspirants, and toothpastes with fluoride.

Receive FDA approval for color additives

- If your color additive is not already on the FDA's list of color additives approved for use within the U.S., you must receive approval and a batch certification from the FDA. Color additive violations are a common reason for FDA detention of imported cosmetics.

Confirm Cosmetics Do Not Include Prohibited Ingredients

- The FDA prohibits bithionol, chlorofluorocarbon propellants, chloroform, halogenated salicylanilides, hexachlorophene, mercury compounds, methlylene chloride, prohibited cattle materials, vinyl chloride, and zirconium-containing complexes.

Ensure Compliance with Labeling Requirements

- The FPLA and FD&C regulate labeling requirements. Generally, six factors should be considered when labeling cosmetics: panel display, panel size, size/style of letters, background contrast, obscuring designs and vignettes, and language. All labeling must be in English. Products may contain multiple labels, including a principal display panel, side panels, and a back panel. Cosmetics manufacturers are not required to print expiration dates on labels; however, the cosmetics company is ultimately responsible for product safety. The FDA does not regulate cosmetic safety claims on labels. These claims may be unsubstantiated but are acceptable. For example, "alcohol free," "cruelty free," "natural," "non-comedogenic," "hypoallergenic," and "fragrance free" may be used as there is no legal definition for these terms.

Comply with the California Safe Cosmetics Program if Selling in California

- The California Safe Cosmetics Act requires the manufacturer, packer, or distributor on the product label to send a list of products containing ingredients that may cause cancer or reproductive harm to the California Department of Public Health (CDPH). The list of harmful chemical agents is available to the public.

Participate in the Voluntary Cosmetic Registration Program (VCRP)

- For cosmetics sold directly to consumers, many manufacturers and distributors of cosmetics participate in the Voluntary Cosmetic Registration Program (VCRP) filing. The VCRP provides transparency and information about the cosmetics products and ingredients in the market. The Cosmetic Product Ingredient Statement (CPIS) is the form to file a cosmetic formulation with the FDA in the VCRP system.

CHECKLIST | Cosmetics

Cosmetics do not need to be FDA-approved to be on the U.S. market, however, they are regulated by the FDA under The Federal Food, Drug, and Cosmetic Act (FD&C Act) and the Fair Packaging and Labeling Act (FPLA). Products intended for beautifying and alternating appearance are considered cosmetics. Below is a simple checklist for Swedish companies to keep in mind when applying their Cosmetics.

- ☐ Confirm Cosmetics Classification
- ☐ Receive FDA approval for color additives
- ☐ Confirm Cosmetics Do Not Include Prohibited Ingredients
- ☐ Ensure Compliance with Labeling Requirements
- ☐ Comply with the California Safe Cosmetics Program if Selling in California

** The FD&C Act allows the FDA to take action against cosmetics that are adultered or misbranded, and the FPLA allows the FDA to enforce labeling requirements*
*** Soap is not a cosmetic product and is instead regulated by the Consumer Product Safety Commission (CPSC)*
**** Examples of cosmetics include skin moisturizers, perfumes, lipsticks, fingernail polishes, makeup, shampoos, and deodorants.*

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Business Sweden is happy to offer turnkey FDA compliance support for Swedish healthcare companies exporting to the U.S. market. Business Sweden can help support you in every aspect of your FDA journey. Whether you are starting from scratch, trying to identify the regulatory steps required for your organization, or if you simply need help reviewing your current labels, we are here to help.

As part of this process, we are excited to offer the services of our FDA partner, Registrar Corp, a leading provider of FDA compliance assistance. Their expert handling of all your local FDA needs will ensure you can focus on your local operations.

Reach out to our team today to set up an advisory meeting. Together we can pinpoint the next steps you need to take on your U.S. expansion journey.

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Business Sweden helps Swedish companies grow global sales by providing strategic advice, sales execution and operational support. Business Sweden is owned by the Swedish government and the industry with a unique mandate to help Swedish companies grow abroad and international companies invest and expand in Sweden.

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We help Swedish companies grow global sales and international companies invest and expand in Sweden.