Import Vendor Cosmetic/Drug Products Requirements

The federal Food, Drug & Cosmetics Act establishes requirements for the sale of cosmetics and drugs in the United States. Some cosmetics products are also considered drugs under the FD&C Act, and thus must comply with regulations for both. All cosmetics/drugs that you supply to Burlington Stores must comply with the FD&C Act and all applicable Food and Drug Administration requirements. This Certification outlines Burlington Stores’ requirements that are specific to cosmetics/drugs. This Certification is not a complete listing of all regulations that may apply to your products, and it remains your responsibility to ensure that your products comply with all applicable federal, state, and local statutes, rules, and regulations and any other Burlington Stores import requirements.

Determining If a Product Is a Cosmetic/Drug

Cosmetics/drugs include, but are not limited to, toothpaste, suntanning preparations that also protect against sunburn, antiperspirants that are also deodorants, and antidandruff shampoos. This may also include products like eye creams, anti-wrinkle, dark spot, and firming creams/serums. The key question is whether the intended use of the product is to clean, beautify and alter the appearance (cosmetics), or to affect the structure or function of the body (cosmetics/drugs). FDA’s guidance on determining whether a product is a cosmetic, a drug, or both, states that intended use may be determined by reviewing the product claims, considering consumer perception of what the product is expected to do, and examining product ingredients for therapeutic use (i.e., active ingredients). Products that are exclusively soaps as set forth in 21 C.F.R. § 701.20 are not cosmetics/drugs. See “Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?),” available at http://www.fda.gov/Cosmetics/GuidanceRegulation/LawsRegulations/ucm074201.htm.

FDA Cosmetic/Drugs Prohibitions

The FD&C Act prohibits introduction of any adulterated or misbranded cosmetics/drugs into interstate commerce, with violations subject to product seizure, recall, and fines. A cosmetic/drug is adulterated if it is:

- Contaminated rendering it injurious to health;
- Not manufactured in conformance with good manufacturing practices;
- Packed in a container containing poisonous or deleterious substances that render the drug injurious to health;
- Of a strength, quality, or purity that differs from official compendia (or misrepresents its strength).

A cosmetic/drug is misbranded if its label is false, misleading, or does not contain the information required by FDA’s labeling regulations.

FDA Requirements

Cosmetics/drugs require FDA approval prior to sale in the United States. This is done either through submission of a New Drug Application to FDA or by conforming to an FDA monograph for the applicable drug category. FDA establishes monographs through its “Over-the-Counter (OTC) Drug Review.” If a drug meets the conditions of an applicable monograph, it is generally recognized as safe and effective for its intended use.

Manufacturers of drugs imported into the US must register with FDA on an annual basis by providing the name and business address of the party “engaging in the manufacture, preparation, propagation, compounding, or processing of a drug” and the name and address of all facilities in which the manufacture, etc. is taking place. Registration also requires identification of the US agent for the establishment and the importer. Additional information may be required, including a listing of active ingredients and copies of labeling. Cosmetics/drugs must adhere to minimum Good Manufacturing Practices listed in 21 C.F.R §§ 210-211. Drugs manufactured without following the proscribed GMPs are considered adulterated.
Cosmetics/drugs must be labeled according to FDA requirements, including providing “Drug Facts” labeling. Drug Facts labeling requires the listing of each active ingredient and dosage, its purpose, its use, and any applicable warnings, such as external use, allergy, flammability, physician consultation warnings, and any warning required by an applicable OTC monograph. Labels must also list all inactive ingredients according to the cosmetics labeling requirements.


Reporting
Manufacturers of OTC cosmetics/drugs must report adverse events that are serious and unexpected within 15 days of initial receipt of the information. Manufacturers of OTC drugs approved through an NDA must submit quarterly reports on adverse drug experiences for three years following approval, and then annually thereafter. Information on reporting is available at http://www.fda.gov/Safety/MedWatch/HowToReport/ucm085680.htm.

Cosmetics/Drugs and the Toxic Substances Control Act
The Toxic Substances Control Act establishes certain requirements on the importation of chemical substances, but cosmetics/drugs are expressly excluded from these requirements. However, regulations under TSCA require that cosmetics/drugs imported into the United States be certified as not subject to TSCA. You must complete the Import Vendor TSCA Cosmetics Certification included here. More information on TSCA and cosmetics/drugs is available at http://www.epa.gov/oppt/import-export/pubs/sec13.html.

Compliance Documentation
You must provide Burlington Stores at imports.test@coat.com with the following documentation demonstrating compliance with the FD&C Act and related regulations at least 45 days prior to the ship date for your cosmetics/drugs:

- Import Vendor Cosmetic Products Certification
- Approval Data: Documentation showing that the product is approved by FDA, either through an NDA or OTC monograph.
- Registration Confirmation: Documentation showing that you are registered with FDA.
- Packaging Photos: Enlarged photos of all sides of outer packaging and item itself showing the ingredients, warning language, and country of origin labeling.
- Import Vendor TSCA Cosmetics/Drugs Certification
Import Vendor Cosmetic/Drug Products Certification

1. **PRODUCT IDENTIFICATION:**

   PO#: ___________________________  STYLE#: ___________________________

   DESCRIPTION: ________________________________ (“Product”)

   SHIPPING WINDOW: __________________________

2. **VENDOR INFORMATION:**

   VENDOR NAME: ____________________________ (“Vendor”)

   VENDOR ADDRESS: ___________________________

   CONTACT INFORMATION: ______________________

3. **FACTORY INFORMATION:**

   FACTORY NAME: ____________________________

   FACTORY ADDRESS: __________________________

   CONTACT INFORMATION: ______________________

4. **LIST INGREDIENTS IN DESCENDING ORDER FROM LARGEST QUANTITY TO SMALLEST**

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<th>INGREDIENT</th>
<th>CAS NUMBER</th>
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<th>INTENDED USE</th>
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Vendor certifies that Product and all ingredients therein conform to all United States federal, state and local laws and requirements, including but not limited to the Food, Drug, and Cosmetic Act and related regulations. Vendor certifies that Product is not adulterated and labeled in accordance with 21 C.F.R. Parts 201 and the Fair Packaging and Labeling Act. Vendor certifies that all chemicals in this product are not subject to TSCA.

By: ____________________________  Date: __________

Name & Title: ____________________________
Import Vendor TSCA Cosmetics Certification

1. PRODUCT IDENTIFICATION:

PO#: ___________________________ STYLE#: ___________________________

DESCRIPTION: ______________________________________________________ (“Product”)

SHIPPING WINDOW: ________________________________________________

2. VENDOR INFORMATION:

VENDOR NAME: ________________________________________________ (“Vendor”)

VENDOR ADDRESS: ________________________________________________

CONTACT INFORMATION: __________________________________________

Vendor certifies that all chemicals in Product are not subject to TSCA.

By: ______________________________________ Date: __________

Name & Title: ______________________________________________________