U.S. Food and Drug Administration (FDA)

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The U.S. Food & Drug Administration (FDA) regulates the importation of food, drugs, medical and electronic devices, and cosmetics into the U.S. Many products that are approved for use in foreign countries may be prohibited or restricted in the United States.
Therefore, all foreign suppliers are expected to determine the FDA requirements prior to purchase order placement.
Because the FDA is so extensive, we can only provide guidance on the primary commodities for The Neiman Marcus Group, Inc. We urge our vendors to review the FDA laws and regulations as they pertain to the nature of goods they sell. Other requirements may apply.

Products of Concern

For The Neiman Marcus Group Inc., the key products of concern subject to FDA laws and regulations are:

- Sunglasses
- Tabletop items used for food & beverage consumption
- Cosmetics
- Foods

Requirements for Sunglasses

Nonprescription sunglasses are regulated as medical devices by the Center for Devices and Radiological Health (CDRH) in the Food and Drug Administration (FDA). Manufacturers, importers and distributors of sunglasses are ultimately responsible for assuring that the following regulatory requirements are met.

1. Impact Resistance
    - Sunglasses shall be fitted with impact-resistant lenses. Impact-resistant lenses must comply with FDA requirements set forth in 21 CFR 801.410, Use of Impact Resistant Lenses in Eyeglasses and Sunglasses.
    - A certificate illustrating the lens' compliance with the 21 CFR 801.410 must accompany each shipment of spectacle lenses/sunglasses seeking entry into the U.S.
    - The certificate must reflect that the eyewear have been "sampled" and are impact resistant, using a statistically significant method. Standard ANSI Z80.3-1996, Nonprescription Sunglasses and Fashion Eyewear - Requirements, Section 5.1- Impact Resistance Test.

2. Flammability
    - Sunglasses should be manufactured from finished materials that are nonflammable as defined in the

Federal Hazardous Substances Act [15 U.S.C. 1261 (f)].

- Meet the flammable solids requirements of 15 USC 1261~1, 1263 and 16 CFR 1500.44. Standard ANSI Z80.3-1996, Nonprescription Sunglasses and Fashion Eyewear - Requirements Section 5.3 - Flammability Test.

3. Biocompatibility
   - Sunglasses should be manufactured from finished materials that are non-toxic, non-irritating, nor capable of producing allergic reactions to a significant degree under normal conditions of use. Please review the Standard ISO 10993 of the Biological Evaluation of Medical Devices - Parts 1-12

4. Optical Properties
   - Sunglasses should be manufactured with plano spectacle lenses designed to attenuate sunlight and provide the optical characteristics or properties as stated in the labeling, advertising, or promotional materials for the device (e.g., polarizing, ultra violet (UV) blocking, tinted, reflecting. etc.) Please review the Standards ISO 14889, Ophthalmic Optics - Fundamental Requirements for Uncut Spectacle Lenses, Section 4.5., ISO 8980 - 3, Ophthalmic Optics -Uncut Finished Spectacle Lenses - Part 3, Transmittance Specifications and Test Methods, and ANSI Z80.3 - 1996, Nonprescription Sunglasses and Fashion Eyewear - Requirements, Sections 4.4 through 4.8.

Requirements for Ceramic and Glass Tabletop Products

Ceramic and glass tabletop with surfaces in contact with food and beverages, are subject to review by the FDA for lead and cadmium exposure levels.
The Ceramic and Food Contact Surface Lead Standards are:

- 3.0 ppm for Flatware
- 2.0 ppm for Small Hollowware
- 1.0 ppm for Large Hollowware
- 0.5 ppm for Cups and Mugs
- 0.5 ppm for Pitchers

The Ceramic and Food Contact Surface Cadmium Standards are:

- 0.5 ppm for Flatware
- 0.5 ppm for Small Hollowware
- 0.25 ppm for Large Hollowware

There are voluntary industry standards for Lip and Rim Areas. For lead and cadmium leaching there is a measurement from the top 20 mm of the outside of:

- Ceramic cups
- Mugs
- Drinking glasses

The limits are not to be more than:

- 4.0 ppm lead
- 0.4 ppm cadmium

This standard does not apply for any ceramic or glassware if:

- The product has less than 60 mm of decorating area below the rim
- Is not intended for use by children

Requirements for Decorative Products

Products used purely for decorative purposes require warning labels adhered to the item. The warning label must be clearly visible to the consumer informing them of the potential for poisoning. In addition, a permanent label must be marked on the bottom of the product.

Requirements for Cosmetics

The depth of the FDA requirements for cosmetics is very extensive. For that reason, NMG must defer all questions to the FDA website. We can guide you to general information in an effort to begin your search for guidance based on the commodity listing below:
For regulatory and compliance guidance in determining if your product is a cosmetic, drug, or true soap:
https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap
For regulatory and compliance guidance on products that claim to be moisturizing or deodorizing:
https://www.fda.gov/cosmetics/resources-consumers-cosmetics/cosmetics-safety-qa-personal-care-products
For regulatory and compliance guidance on products that claim to be antibacterial or deodorizing:
https://www.fda.gov/news-events/press-announcements/fda-issues-final-rule-safety-and-effectiveness-antibacterial-soaps

Requirements for Food Facilities

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) requires domestic and foreign facilities to register with the FDA if they:

- Manufacture
- Process
- Pack
- Hold food for human or animal consumption in the United States

Who must register?

- Owners, operators, or agents in charge of domestic or foreign facilities that manufacture/process, pack, or hold foods for human or animal consumption in the United States are required to register the facility with the FDA.

Examples of FDA-regulated Foods are:

- Food and food additives for man or animals
- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- Fish and seafood
- Dairy products and shell eggs
- Raw agricultural commodities for use as food or components of food
- Canned foods
- Live food animals
- Bakery goods, snack food, and candy