DIAZ
TRADE LAW

Is Your Cosmetic Product Really a Drug?

In June alone, the U.S. Food and Drug Administration (FDA) refused the importation of over 200 different shipments of Cosmetics from 22 different countries.

The two main reasons the FDA cited in refusing entry of cosmetic products were:

The products were "misbranded" (lack of adequate directions for use, nutrient content and/or health claims, anti-ageing labeling claims rendering the product a drug; or
The products were "adulterated" (unsafe addition of a color additive).

Definition of a Cosmetic vs. Drug

Misbranding may come down to whether the FDA believes the product is a drug (which is often based on the products intended use, and labeling claims). It is therefore important to know the difference in the way FDA defines cosmetics and drug products, to ensure you label your products correctly.

A product designed for “cleansing beautifying, promoting attractiveness, or altering the appearance,” is generally defined as a cosmetic by the FDA.

A drug on the other hand, is as a product “intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease," or “intended to affect the structure or any function of the body.”

Why Cosmetic Products will be Refused by the FDA

One prevalent reason the FDA refuses cosmetic products is because of the claims cosmetic products makes rendering the product a "drug". A health claim is one example of a type of claim, specifically it is a claim that the product affects the structure and or function of the human body. If your product makes a health claim it may be rendered and regulated as a drug by the FDA.

In response to the increase use of “health claims” on cosmetic products, the FDA re-published an import alert for skin care products labeled as anti-aging. These products claimed to reverse the effects of aging by controlling or preventing the aging process, which is a claim that the product affects the structure and functions of the human body, and were thus regulated a drug product by the FDA.

The FDA issued a consumer update this March highlighting the difference between a drug and a cosmetic product. The purpose of this publication was to inform consumers about cosmetic products that promise too much. In order to protect consumers from this type of cosmetic misbranding, the FDA has told companies to remove drugs claims or seek FDA approval to market these products as drugs (this is a timely and very expensive process). However, the FDA further admits that there is "no one-size-fits all answer" to whether a claim is a drug claim or cosmetic claim.

Form 766

If your product is on hold by the FDA because it is misbranded, there are affirmative actions you can take. Section 801(b) of the Federal Food, Drug, and Cosmetic Act states that an importer of record may submit to the FDA a written application (using FDA's Form 766) requesting permission to "recondition" your product. This post-compliance action, if approved by the FDA, will allow your product to be released. As approval is discretionary by the FDA, it is important you take the right steps and hire the right expert to assist you in this process.

FTC

In addition to regulation by the FDA, cosmetic companies are also subject to regulation by the Federal Trade Commission (FTC). The FTC issues administrative complaints when companies engage in unfair methods of competition or unfair and deceptive acts, such as deceptive advertising. The FTC has issued complaints following FDA warning letters to cosmetic companies.

You may recall cosmetics company L'Oréal USA, Inc. receiving a FTC complaint alleging deceptive advertising of its products Lancôme Génifique and L'Oréal Paris Youth Code. The FTC has accepted, subject to final approval, an agreement containing a consent order (proposed order) from L'Oréal. According to the complaint, L'Oréal violated Sections 5(a) and 12 of the Federal Trade Commission Act because they claimed that its Génifique products were "clinically proven" to "boost genes' activity and stimulate the production of youth proteins that would cause "visibly younger skin in just 7 days," and would make you look as if you "slept 2 extra hours." Similarly, L'Oréal claimed that its Youth Code products were the "new era of skincare: gene science," and that consumers could "crack the code to younger acting skin." L'Oréal made these claims via print, radio, television, internet, and social media outlets. (It is important to note, both FDA and FTC regulate not only the product, but, also all ancillary advertisements, including websites).
The FTC's complaint followed the U.S. Food and Drug Administration's (FDA) warning to L'Oreal about language used in their advertisements that made the products sound more like drugs than cosmetics.

How Diaz Trade Law Can Help

Although the FDA has issued import alerts, consumer updates, and labeling guides for cosmetics, there is still no bright line between cosmetic type claims and drug claims. Unfortunately, if the FDA finds your cosmetic product on the wrong side of that line, your product may be detained and later potentially refused by the FDA. The solution is to ensure you use "pre-compliance", by having all products, ingredients, claims and ancillary marketing reviewed by an expert PRIOR to importation.