View Single Post **Thread**: What exactly are the regulations re: ingredients

Today, 01:45 PM #37

new12soap
registry_dropdown_7170_459051

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From: "Wright, Shontell" <Shontell.Wright@fda.hhs.gov>
Date: October 9, 2014, 11:14:43 AM EDT
To: (me)
Subject: RE: VCRP Question

Dear (me),

Shaving soaps are regulated as cosmetics.

The intended use of a shaving soap is aid the process of shaving similar to a shaving cream or foam. Shaving products are intended to smooth the face by lubricating the skin which allows a gentler shave.

For your information in the United States, products are regulated according to their intended use. FDA determines intended use by the way in which a product is marketed as a whole, not on a word or phrase taken out of context. Intended use may be established in a number of ways. Among them are--

• Claims stated on the product labeling, in advertising, on the Internet, or in other promotional materials. As noted above, certain claims may cause a product to be considered a drug even if the product is marketed as if it were a cosmetic.

• Consumer perception, which may be established through the product's reputation. This means asking why the consumer is buying it and what the consumer expects it to do.

• Ingredients that may cause a product to be considered a drug because they have a well-known (to the public and industry) therapeutic use.

Consider the following definitions to determine the regulatory status of a product according to the intended use:

• The term "cosmetic" means articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and articles intended for use as a component of any such articles; except that such term shall not include soap.

• The term "drug" means 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 or other animals.

Drugs and cosmetics are regulated differently. For example, drugs are subject to premarket approval by FDA and drug manufacturers are required to register their manufacturing facilities with FDA. Please direct questions about drugs to FDA's Center for Drug Evaluation and Research (CDER). You can contact CDER's Division of Drug Information, Small Business Assistance, directly at CDERSmallBusiness@fda.hhs.gov. Or, you may contact CDER's Division of Drug Information with general drug-related inquiries at druginfo@fda.hhs.gov. For more information on drug registration, see "Drug Registration and Listing System (DRLS & eDRLS)" at http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/DrugRegistrationandListing/default.htm and "Electronic Drug Registration and Listing Instructions" at http://www.fda.gov/ForIndustry/ElectronicSubmissionsGateway/ucm177328.htm.

If, after reviewing this information, you still have questions, please let me know. I will be glad to help.

Best regards,

Shontell Wright
VCRP Staff
<image001.png>

So there it is, spelled out directly from the FDA (Bolding added).

Quote

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