

## **FDA to Take Up Major Enforcement Action Against Cosmetics Manufacturers With Illegal “Anti-Aging” Labeling Claims**

*U.S. Food & Drug Administration’s Center for Drug Evaluation and Research (CDER) will soon initiate a major enforcement initiative against cosmetics product labels bearing illegal drug claims, including “SPF,” “anti-aging,” or “anti-wrinkle,” according to Benjamin L. England, former 17-year FDA veteran and FDAImports.com, LLC Founder.*

The U.S. Food and Drug Administration issued [Import Alert](#) #66-38, “Skin Care Products Labeled As Anti-Aging Creams” (IA 66-38) in 1988, subjecting cosmetic manufacturers—including several large, non-U.S. cosmetics importers Estee Lauder, L’Oreal, Avon, Almay and Fleur de Sante—to “intensive surveillance” for importing cosmetics with drug claims on cosmetic product labeling. FDA appears to be cracking down on importers whose cosmetic product labels bear illegal drug claims. As recently as April 2010, FDA added 93 cosmetics products and four firms to the IA 66-38 “Yellow List,” which subjects those companies’ imported cosmetics to “intensive FDA surveillance” including increased import field examinations. “These additions to the alert show that FDA is getting serious,” said England. With a major enforcement initiative coming soon, Mr. England noted, “cosmetics manufacturers and importers of all sizes will likely see increased enforcement on labeling compliance generally, and drug claims, in particular.”

However, some have questioned whether the import alert is enough to curb importation of cosmetics products containing these and other illegal drug claims (e.g., “SPF,” “anti-aging,” or “anti-wrinkle”). Recently, FDA has been increasing its reviews of imported cosmetics. As a result, it has also been detaining more shipments of cosmetic products bearing impermissible drug claims and cosmetics with more technical labeling violations. “The more FDA looks, the more FDA finds,” noted England. All of this is about to increase in intensity and focus, apparently. According to some FDA officials, the agency is preparing a notification to the industry reminding companies about the importance of complying with all labeling requirements for topical cosmetics and over the counter drugs. This probably will come in the form of a group of FDA Warning Letters to a number of cosmetics manufacturers and distributors alleging that because of the claims on the labels, the articles they are selling are actually misbranded or unapproved new drugs. This new initiative seems reminiscent to the recent “Front of Package” food labeling enforcement initiative (announced in March 2010 by FDA Commissioner Margaret Hamburg).

The new FDA cosmetics labeling initiative “will likely bring a measure of parity to FDA’s enforcement practices, since it appears FDA has mainly targeted small cosmetics importers in the past,” said England. “It’s as if, compared to smaller importers, FDA has given multinational companies a ‘get out of jail free’ card on importing cosmetics bearing these kinds of claims.”

Some large firms have received [Warning Letters](#) from FDA concerning illegal claims on their product labels. “Then what?” asks Mr. England, “It’s apparent FDA believes the labeling claims are illegal, so it issued Warning Letters. And yet, these products, with these same labeling claims, continue to make it to the U.S. market. In the meantime, FDA detains products from smaller manufacturers imported by smaller importers.” It is expected that FDA’s upcoming enforcement action plans will decrease the inequality of current enforcement at the border and ‘little importers’ will no longer be singled out.

Cosmetics are used for promoting attractiveness or altering the appearance of the consumer. So, all labeling claims must be “cosmetic” claims. Claims that a product can be used to counteract, retard or control the aging process or its effects are drug claims and are illegal on cosmetic labeling. “Anti-wrinkle claims are a big ‘no-no’ to FDA,” says [England](#), “yet look around you the next time you walk through the beauty section of a major department store in the US. Apparently FDA believes it is time to do more than ‘just say no.’”

If you are a cosmetics manufacturer or importer potentially subject to IA 66-38, or are concerned about your product labeling compliance, let [FDAImports.com, LLC](#) show you ‘the way through.’ [FDAImports.com, LLC](#) is a consulting firm that helps importers avoid the financial hardship of FDA enforcement by solving problems before they arise, and by quickly resolving existing enforcement matters. Don’t let a Warning Letter or other FDA enforcement action subject your firm to being placed on the Yellow List of Import Alert #66-38. Contact [FDAImports.com](#) today to help your firm succeed in the U.S. cosmetics marketplace without FDA enforcement.