

Seizure Of Cosmetic Signals New Enforcement Trend

Friday, Feb 22, 2008 --- The Jan. 7, 2008, issue of Health Law360 contained an article, entitled Jan Marini Discontinues Second Eyelash Product, that noted the Food and Drug Administration's November 2007 seizure of a cosmetic, "Age Intervention Eyelash."

This seizure is one in a series of recent FDA enforcement actions against cosmetic and dietary supplement companies that classify products as unlawfully marketed "drugs" based on their use of ingredients that are also used in prescription drugs.

This trend is important and interesting because it marks a tactical change from FDA that industry should watch closely.

The press release (available on the agency's website) announcing FDA's seizure of Jan Marini's product – which had been discontinued by the company over a year earlier – cited several grounds for the action.

FDA alleged that the product was an "unapproved and misbranded drug" because it had been promoted to increase eyelash growth. It also alleged that the product was an "adulterated cosmetic" because it contained bimatoprost, the active ingredient in a prescription drug used for elevated intraocular pressure.

FDA described the dangers of patients taking too much bimatoprost and noted other risks associated with use of the prescription drug.

Putting aside the questions whether Jan Marini's product was, in fact, promoted to increase eyelash growth or whether it presented any real risk to patients, FDA's press release leaves the distinct impression the seizure was necessary because the product contained a prescription drug ingredient.

Indeed, the press release was subtitled, "Product contains drug ingredient, makes unapproved drug claims, could damage eye" (emphasis added). If this consideration triggered the seizure, it represents a change in FDA's traditional enforcement strategy.

Under the Food, Drug, and Cosmetic Act, products are regulated as "cosmetics," "dietary supplements," or "drugs" based on manufacturers' intended uses for the products.

Cosmetics, for example, are defined as products intended to be used for cleansing, beautifying, or promoting attractiveness.

Dietary supplements are products intended for ingestion to “supplement the diet” and that contain one or more ingredients such as vitamins, minerals, or herbs.

And drugs are defined as articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease, or intended to affect the structure or function of the body. See 21 U.S.C. §§ 321(i), (ff), and (g)(1).

The distinctions between these categories are critical primarily because cosmetic and dietary supplement manufacturers are not required to seek pre-market approval or clearance from FDA. The manufacturers of most drugs, of course, must do so.

In the course of drug regulation, FDA looks to things such as labeling, advertising, or oral or written statements by the company or its representatives to determine “intended use” and FDA closely regulates drug labeling and advertising.

But, intended uses are not generally determined based on the “mere inclusion” of any particular ingredient in a product. For example, coffee is not regulated as a drug due to its inclusion of caffeine. Nor are cigarettes regulated as drugs due to the inclusion of nicotine.

Indeed, when this last question was put to the courts, one remarked that “no court has ever found that a product is ‘intended for use’ ... absent manufacturer claims as to that product’s use.” *Brown & Williamson Tobacco Corp. v. FDA*, 153 F.3d 155, 163 (4th Cir. 1998) (emphasis added and quotation omitted), *aff’d on other grounds*, 529 U.S. 120 (2000).

The agency has in a few cases asserted that the inclusion of a certain ingredient could cause a product to be a drug, but only where the drug effect of that ingredient would be recognized by consumers.

In effect, the name of the ingredient makes the drug claim. FDA has used this rationale in regulating as drugs products containing “sunscreen” and “fluoride.” This could only be the case, however, where the effect of the ingredient is well known, and where its presence is communicated to consumers.

Nevertheless, in the *Jan Marini* case and others, FDA has initiated enforcement actions against companies due to the inclusion of certain drug ingredients – even where those ingredients are not declared. And, several times, FDA appears to have alleged that the mere inclusion of these ingredients causes the products to be “drugs.”

If they are drugs, the products are unlawful, because they have not undergone clinical testing and have not been reviewed and approved by FDA. For example:

On May 10, 2007, FDA issued a “Health Risk Alert” advising consumers not

to use “True Man” or “Energy Max” dietary supplements. FDA asserted that they contain “substances called analogs that have similar structures to active ingredients in approved prescription drugs.” FDA cited the risks associated with use of the prescription drugs, sildenafil and vardenafil, used to treat erectile dysfunction.

On Nov. 2, 2007, FDA announced that it had requested a recall of the products, calling them “illegal drug products” that, “[a]s formulated,” are “classified as unapproved new drugs.”

On Aug. 9, 2007, FDA warned consumers not to use three red yeast rice products because they were “found to contain unauthorized drug.” Again, the agency’s press release focused on the fact that they contained lovastatin, the active ingredient in a prescription drug used to treat high cholesterol. FDA cited risks known to be associated with use of prescription lovastatin.

On Dec. 29, 2007, FDA advised consumers not to use several products being sold over the Internet because they “are illegal drugs and contain undeclared active ingredients in prescription erectile dysfunction drugs.”

The agency’s press release noted that the products – known as “Super Shanghai” and “Shanghai Ultra,” among others – are labeled as dietary supplements, but “do not qualify as dietary supplements because they contain undeclared active ingredients of FDA-approved prescription drugs for erectile dysfunction.” FDA concluded that the products are “thus drugs that are illegal because they lack FDA approval.”

These and several similar actions in 2007 are complex. In some cases, FDA may have also believed that the companies’ intended uses of their products – evidenced by marketing or labeling claims – qualified the products as “drugs.”

Other cases implicated a provision in the Dietary Supplement Health and Education Act of 1994 that excludes from the definition of a dietary supplement ingredients that are also approved as drugs, unless the ingredients were marketed as supplements first. See 21 U.S.C. § 321(ff)(3)(B).

And in other cases, including the Jan Marini seizure, FDA alleged that the products were “adulterated” and unsafe because of the drug ingredients. But FDA presented no evidence that any consumers had actually been harmed by the products. Instead, the agency merely listed certain known side effects of the prescription drugs.

Despite these complexities, the flurry of cases throughout 2007 leaves the impression that FDA is aggressively acting against companies that use ingredients present in prescription drugs.

If such enforcement actions are based on companies’ intended uses for their products, or on real evidence that the products are injurious to consumers,

the actions may be justified. If, on the other hand, the actions are based on the “mere inclusion” of drug ingredients, the agency has radically changed its enforcement strategy and may have exceeded the bounds of its authority under the law.

--By Brian R. McCormick, Hogan & Hartson LLP

Brian R. McCormick is an associate in Hogan & Hartson's pharmaceutical and biotechnology products practice. The author would like to acknowledge Meredith Manning, a partner in the pharmaceutical and biotechnology products practice, for her assistance in the preparation of this article. Hogan & Hartson represents Jan Marini Skin Research; however the views expressed herein are solely those of the author and not of the firm or any of its clients.