FDA Proposes Ban of OTC Skin Bleaching Products

In the Federal Register for August 29, 2006 (Click here for the Federal Register Notice: 71 Fed. Reg. 51146), FDA withdrew the September 3, 1982 Tentative Final Monograph (TFM) on OTC skin bleaching products (47 Fed. Reg. 39108), and proposed instead that all OTC skin bleaching active ingredients be deemed both not generally recognized as safe and effective and misbranded. FDA proposed to add to the list of ingredients that may not be used in OTC drug products a new listing comprising “§ 310.545(a)(17) Skin bleaching drug products—(ii) … Hydroquinone; Any other ingredient.” The effect of this new regulation would be (a) to make all skin bleaching products “new drugs,” and also (b) to limit these products to prescription status until an approved New Drug Application provided otherwise.

While FDA provided 120 days for the submission of comments (until December 27, 2006), it also proposed that any final regulation be effective 30 days after publication. After that date, the delivery for introduction or actual introduction of product into interstate commerce would be prohibited. FDA recognized that retail-level stocks would remain available longer and did not propose a market withdrawal of retail supplies. Any interstate restocking of retail outlets, however, would be prohibited.

The principal basis for the FDA action was its evaluation of the safety of hydroquinone, the only permitted active ingredient in the TFM, based on information developed after the publication of the TFM. The two main issues are the potential carcinogenicity of hydroquinone and FDA’s conclusion that it has been shown to cause exogenous ochronosis, a permanent thickening and discoloration of the skin, particularly affecting African-American women, significant users of skin bleaching products. With respect to carcinogenicity, FDA concurred in the conclusion of the National Toxicology Program that orally administered hydroquinone showed “some evidence” of carcinogenicity in male and female rats and female mice, and FDA concluded that it could not rule out a topical carcinogenicity risk due to studies showing a high degree of absorption from topical application. Given the essentially cosmetic purposes of skin bleaching, FDA concluded both with respect to carcinogenicity and exogenous ochronosis that, in a risk-benefit analysis, any demonstrable or potential significant risks would outweigh the lack of any health benefit from these products.

Although the focus of the FDA action was hydroquinone, it is significant that the listing of banned substances includes “Any other ingredient.” FDA described the skin bleaching category as articles “intended to affect the structure or function of the body (e.g., products intended to suppress melanin pigment formation within skin cells).” 71 Fed. Reg. at 51152. Hydroquinone itself is a “bleach,” i.e., it removes color from the site of application. There are, however, numerous cosmetic products promoted for “brightening” the skin, or helping to maintain “an even tone” that work by suppressing melanin production, even though that mechanism is not described. FDA is explicit in its proposal that it “now proposes that all skin bleaching drug products [as defined in the proposal] be considered new drugs … for which approved NDAs … are required for marketing.” Id. In its Analysis of Impacts, FDA does not consider any products other than those containing hydroquinone in evaluating the market impact of the proposed final action. FDA could still conclude, at some future point, that any melanin-
suppressing ingredient fell under the proposed ban, even if that mechanism of action was not promoted. Recent court decisions permit FDA to consider not only overt promotion, but also internal company documents in determining whether a company had the objective intent of having the product have an affect on the structure or function of the body.

It is unclear, despite the lengthy comment period, what meaningful comments could be submitted. FDA notes that, between 1996 and 1999, the Nonprescription Drug Manufacturers Association (now the Consumer Healthcare Products Association) (CHPA) met with FDA numerous times concerning the safety of hydroquinone and had concurred in the evaluation of the NTP study and other data by the Center for Food Safety and Applied Nutrition's Cancer Assessment Committee. CHPA had also proposed a timeline for further studies focusing on the topical carcinogenicity of hydroquinone, but “[s]ince April 13, 1999, CHPA has not provided any additional information.” Id. at 51149. If no significant comments are received, FDA could issue a final regulation relatively promptly, perhaps within 90-120 days, with a 30 day effective date. That would mean that by about the beginning of June 2007, the marketing of at least hydroquinone OTC skin bleaching products would have to end.

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This information is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

If you have any questions concerning the material discussed in this client alert, please contact the following members of our food & drug practice group:

- Eugene Lambert 202.662.5422 elambert@cov.com
- Jeannie Perron 202.662.5687 jperron@cov.com

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