



"The Rose Sheet"

TOILETRIES, FRAGRANCES, AND SKIN CARE

March 30, 2009

Volume 30 | Number 013 | page 3

2009 FDA Globalization Act Scratches Fees For Cosmetics, "Unanticipated" AEs

02300130002

Printed by Christopher Walker Firm: Fdc+Reports [Mar 31 2009]

The latest version of the FDA Globalization Act includes a number of changes beneficial to small cosmetic firms; however, the draft legislation still presents some overly burdensome requirements, according to Indie Beauty Network founder and CEO Donna Maria Coles Johnson, Esq.

Speaking with "The Rose Sheet" March 20, Coles Johnson said the Globalization Act of 2009 "has come a long way" since the 2008 version was introduced last May, and shows that the "voices of small businesses have been heard."

FDA's Globalization Act aims to strengthen food, drug and cosmetic safety with requirements for registering products and reporting adverse events.

Last summer, Coles Johnson and other small business reps met with the House Committee on Energy and Commerce's Subcommittee on Health, asking for changes to the bill. The legislation was spearheaded by Committee member John Dingell D-Mich (¹["The Rose Sheet" Aug. 25, 2008](#), p. 3).

The group was most concerned about the impact of a registration fee of \$2,000 per facility per registration and an additional fee of \$10,000 per year for companies importing cosmetics from abroad.

The latest version exempts cosmetic companies from the registration fees, and the new language also mandates less stringent reporting requirements for adverse event reporting of cosmetics.

Rather than having to report "all anticipated and unanticipated serious adverse events" related to the use of cosmetics, the new version requires only that firms report "serious and unexpected" adverse events.

Ingredient Registration Too Onerous For Some?

While applauding those changes, Coles Johnson said the new version needs some work. Specifically, it contains registration requirements that "seem to leave a lot of room for very small businesses simply not being able to comply."

Under the terms of the bill, companies that manufacture or package cosmetics for use in the U.S. are required to register their facilities with the Secretary of Health and Human Services.

Additionally, within 60 days of manufacturing a new product, companies are required to submit a cosmetic and ingredient statement that lists all the ingredients in the formulation.

Coles Johnson holds that the time commitment needed in submitting data for each product could be detrimental to small companies, which - unlike larger manufacturers - often customize products for consumers.

"For example, if you manufacture soaps for weddings, you may have any number of fragrances you offer" customers, Coles Johnson said. "To have to go through the registration process with every single product every single time - well, that is going to be an issue."

In a Feb. 4 letter to the Committee on Energy and Commerce, the Indie Beauty Network and the Handcrafted Soap Makers Guild urged Congress to allow FDA the power to provide a waiver for small businesses.

"In the public interest and for companies whose reach is so small their proportionate risk is so small, we think it would be fair for Congress to allow FDA to make that determination," the CEO said.

Coles Johnson also recommends establishing a database of ingredients already recognized by the agency so that products made entirely of substances on that list can register via a streamlined or expedited process.

GMP Exemption For Small Biz Also Requested

In their letter to the Committee, the organizations recommended that special considerations be given to small cosmetic manufacturers with regard to good manufacturing practices, which would be required 18 months after the date of Act's enactment.

According to the signatories, cosmetic manufacturers that produce safe cosmetics are "vastly different from the manufacturing practices and controls that are necessary to make safe cosmetics in large scale production."

Thus, the groups request that language be added to the bill that "empowers the secretary to take into account the workable and safety-driven practices in use by very small cosmetic companies, if cosmetic [GMPs] are promulgated pursuant to the Act."

A Blow To "Self-Regulation?"

There is growing concern among industry that proposed regulatory action such as FDA's Globalization Act of 2009 is pushing the cosmetics industry toward a model of regulatory oversight closer to that in place for food and drugs.

Currently, cosmetics are not required to undergo pre-market review, though consumer advocacy groups such as the Environmental Working Group aim to change that.

During a recent interview with "The Rose Sheet," EWG President Ken Cook said the organization sees opportunity in the new administration to step up its efforts with allies in Congress to end the practice of personal-care self-regulation (²["The Rose Sheet" Nov. 17, 2008](#), p. 9).

However, not all industry execs following the news see the Globalization Act as a threat to the current regulatory regime for cosmetics.

During a March 18 interview with "The Rose Sheet," Hyman, Phelps & McNamara Lawyer Ricardo Carvajal said the Act stays true to post-market regulation, especially given that companies have 60 days from the start of product manufacture to submit ingredient statements.

The Act simply helps FDA maintain its oversight of the industry within the existing framework, according to Carvajal.

"Cosmetics are still going to be subject to a post-market regulatory scheme, it's just that there will be more information flowing to FDA," he said.

Though no timeline has been given for passing the legislation, the agency likely will offer a comment period to solicit feedback on the draft.

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