



Mr. Virgil Miller
Professional Staff Member

Re: **FDA Globalization Act of 2009 – HR-759**

Dear Virgil,

On behalf of the members of the Indie Beauty Network and the Handcrafted Soap Makers Guild, thank you again for taking the time to learn about how small cosmetics manufacturers operate and to understand the nuances that make us unique participants in the cosmetics industry.

We see many positive aspects in HR-759. As a result of the most onerous provisions of the earlier draft being omitted from this bill, we know many very small soap and cosmetics businesses will remain in business. We are in agreement with most sections of the bill as written.

Still of concern to us is Section 605, requiring that “**every** establishment .. submit .. for **each** cosmetic ..a cosmetic ingredient statement...”. It is not uncommon for very small cosmetic manufacturers to keep a small inventory of ingredients on hand and make very small batches, perhaps for custom orders, on a one-time basis using those ingredients. At this level of manufacture, her entire inventory of cosmetic ingredients are those that are already generally regarded as safe, so interchanging ingredients or making new formulations does not pose a safety issue. For example, she might run out of almond oil for a batch of lip balm and replace it with a different but similar cosmetic oil for that batch. Alternatively, she might develop sugar scrub formulation and make a single batch of 10 or 20 jars to test market at a craft show, and if they don’t sell well, she never makes that particular formulation again. Since her labels are printed in-house, she can easily create a new label for the product with a correct ingredient label as the law currently requires.

This scenario is commonplace among small cosmetic companies. To require companies in this position, where such a tiny number of products are affected, to submit a statement every time this situation occurs, would create unnecessary paperwork both for the company and the Secretary. In order to minimize this, we request that language be added to HR-759 empowering the Secretary to waive filing of the cosmetic and ingredient statement in certain circumstances for small businesses as defined by the Secretary. Language to this effect can be found in other portions of the bill, for other regulated industries, specifically in sections 741, 418A and elsewhere.

Also of concern is Section 304 concerning Good Manufacturing Practices of Cosmetics. As we have discussed before, the manufacturing practices used by very small cosmetic

manufacturers to produce safe cosmetics are vastly different from the manufacturing practices and controls that are necessary to make safe cosmetics in large scale production. In consideration of these differences, we request that language be added to HR-759 that empowers the Secretary to take into account the workable and safety-driven practices in use by very small cosmetic companies, if cosmetic Good Manufacturing Practice rules are promulgated pursuant to the Act.

Empowering the Secretary, using federal rulemaking procedures, to define small cosmetic businesses and treat them appropriately when it comes to submitting ingredient statements and determining good manufacturing practices allows for consideration of industry nuances that are best addressed at the agency level, with the input of industry participants through public rulemaking.

We therefore propose that the following language be inserted into HR-759:

SEC. 605 COSMETIC AND INGREDIENT STATEMENTS.

(b) WAIVERS.— The Secretary shall waive the filing requirement under this section with respect to any facility that is a small business, as defined by the Secretary.

SEC. 304 GOOD MANUFACTURING PRACTICES FOR COSMETICS.

(insert as last sentence of part (f))

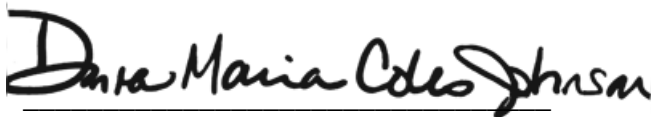
In issuing guidance or promulgating regulations under this section, the Secretary shall consider the differences of small businesses.

We are very interested in knowing your thoughts on these two important matters, as we consider whether or not to publicly support this legislation.

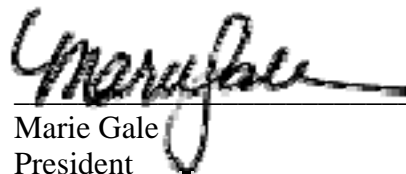
We are available at your convenience, by phone or in person, to discuss and answer any questions you or your colleagues may have.

We look forward to hearing back from you.

Sincerely,



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