Independent Cosmetic
Manufacturers And Distributors

October 14, 2016

Congressman Frank Pallone, Jr.
237 Cannon HOB
Washington, DC 20515

Congressman Leonard Lance
2352 Rayburn HOB
Washington, DC 20515

Dear Congressman Pallone and Congressman Lance:

We want to thank you for providing ICMAD with the opportunity to review and comment on the draft legislation you propose to introduce, which amends the cosmetic provisions of the Federal Food and Drug Act.

As you know from the many meetings we had in your offices, and from the tour we arranged for you at one of our member companies facilities, ICMAD represents the small and emerging growth companies in the cosmetics industry. ICMAD currently represents over 700 member companies located both in New Jersey and around the country.

ICMAD supports modernization of the FDA laws governing cosmetics and we believe that as part of the strengthening of FDA's oversight of cosmetics, modernization must create one National Standard that applies to regulation of Cosmetics throughout the U.S. Our members cannot remain in business if they are forced to comply with potentially, 50 different state requirements for cosmetics. Our members have already been challenged by existing state requirements; we need to relieve this burden and not add to it. To provide for a strong FDA with enhanced authority and to then permit state statutes to undermine the FDA's authority seems incongruous, and will lead to state courts inevitably making decisions on Federal Enforcement authority. The EU has developed one standard; our members do not understand why this cannot be achieved in the U.S.

Beyond the issue of National Uniformity, we would like to comment on the proposed registration requirements for facilities. Because the registration requirements in the discussion draft are tied to the definition of a Brand Owner, not all manufacturers will be required to register their facilities. Not only does this put unregistered facilities beyond the risks of having their facility registrations cancelled, but it also makes these manufacturers harder for the FDA to locate, with regard to inspection and compliance purposes. If this stands, these foreign manufactures will have an unfair advantage over their U.S. counterparts and may well force more manufacturing outside of the U.S. as a result, which we do not support. Many of our members prefer to use U.S. manufacturing facilities and we want to make sure that there is a level playing field for these U.S. based manufacturers.

As with the Bill proposed by Senators Feinstein and Collins, the financial test for a small business is far too low. $500,000 annual revenue for three years running is not a realistic test for what constitutes a small business from a revenue perspective. Based upon our knowledge of the industry this number is significantly off the mark. A products business in the competitive arena of the cosmetic industry could not survive with revenues at that level. By setting the revenue test so low and with the percentage contribution required by the lower level revenue companies the smaller companies will pay a disproportionate share of the user fees and a greater percentage of fees on a per dollar of revenue basis than the multinationals.

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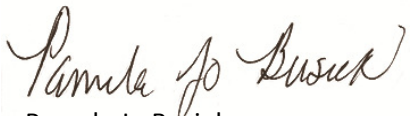
ICMAD has proudly represented our small business members for over forty years and has been a strong advocate for FDA compliance and safe cosmetics. We note with pride that the FDA's low number or experiences reported by the FDA with regard to cosmetic products is quote low in comparison to that of dietary supplements or over the counter drugs marketed under the OTC Monograph proceedings. These of course are consistent with the insurance ratings on cosmetic products. Our cosmetic products enjoy far lower premiums than any of these other categories as there are very few incidents of injury, even minor injuries, with regard to cosmetics, than with other regulated classes of products. Despite this record we note that cosmetics under your discussion draft will be held to far higher standards for serious adverse event reporting requirements and will be held to adverse event reporting, which is not required in these other two programs. Additionally, the discussion draft, would if enacted provide enforcement actions and lower standards for enforcement actions than those provided for dietary supplements and over the counter drugs, which have significantly great experience reporting and present far greater risk than Cosmetics.

During our meetings you expressed on several occasions your interest in supporting the industry and your concern regarding burdening the agency without providing adequate financial support to the agency. We too are concerned on this point, and we believe that the program being proposed by your discussion draft will go far beyond what is called for in the way of fees. We believe there are ways to create a strong FDA in order to protect and educate the public without the burdens that are being proposed, and which represent a significant deviation from the regulatory procedures that exist within the FDA's other regulatory programs; most importantly the program that regulates OTC drugs. This alone will create significant burdens and uncertainty for both the regulated community and the regulators as many cosmetics such as sunscreens and many other personal care products fall into both regulatory categories.

We are, as we have always been, ready to assist in working with you and your staff on this very important piece of legislation. Our members have been the driver of innovation and growth in this industry by creating not just new products but new categories of products which enhance not just our consumer's appearance but contribute to great healthy skin. Our members create jobs and good jobs here in the U.S., and despite the rise in the dollar that have burdened so many industries, our American made products are sought after all around the world and many of them as you know are made in New Jersey. Despite all of our innovation, the costs of our member's products have helped maintain a healthy level of competition in the industry which ensures that these cosmetic products are not beyond the reach of the average consumer. The price of excessive regulation, regulation that exceeds that which is required to ensure safe products that perform well, could well put many of our members out of business, leaving the market dominated by the larger multinationals, who would then be in control of the product pricing.

I sincerely thank you for your consideration.

Warmest regards,



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