



July 24, 2008

**VIA FEDERAL EXPRESS**

Honorable John D. Dingel  
House Committee on Energy and Commerce  
2328 Rayburn House Office Building  
Washington, DC 20015

Honorable Edward J. Markey  
House Committee on Energy and Commerce  
2328 Rayburn House Office Building  
Washington, DC 20015

Honorable Fred Upton  
House Committee on Energy and Commerce  
2328 Rayburn House Office Building  
Washington, DC 20015

Honorable Joe Barton  
House Committee on Energy and Commerce  
2328 Rayburn House Office Building  
Washington, DC 20015

Re: **FDA Globalization Act of 2008**

Dear Chariman Dingel and Congressmen Markey, Upton and Barton:

On behalf of the member companies of the Indie Beauty Network,<sup>1</sup> I am pleased to offer our position on the Draft Discussion of the Food & Drug Administration Globalization Act of 2008. The Indie Beauty Network (IBN) is an organization of small and micro-businesses with nearly 700 members nationwide.

We support your efforts to stimulate discussion about how the US Food & Drug Administration (FDA) can be adequately funded to ensure the safety of the nation's food, drug,

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<sup>1</sup> [www.indiebeauty.com](http://www.indiebeauty.com). IBN Member Earth Mama Angel Baby is not a signatory to this letter.

medical device and cosmetics supply in an increasingly global marketplace, and we welcome the opportunity to work with you to address the issues involved. However, we are vigorously opposed to the draft legislation. As of the date of this letter, at our blog, the Indie Business Blog, we have collected well over 1,100 signatories to our Petition Opposing the FDA Globalization Act of 2008.<sup>2</sup> There will be more to come.

## **Introduction**

As you know, current cosmetics laws have been in effect for decades, and while many IBN members are fairly new entrants to the marketplace, they are nevertheless keenly concerned about the safety of the products they manufacture and sell to consumers. It is this concern, coupled with the numerous challenges facing small businesses when it comes to understanding and applying the various laws that apply to them, that prompted the formation of IBN in 2000 to address the business needs of companies that manufacture soap and cosmetics products on a small scale.

The main purpose of the draft legislation -- to protect consumers -- is important and we wholeheartedly support it. However, even well intentioned laws can go too far by imposing on small businesses so many financial and regulatory burdens that they serve only to sustain big businesses while devastating small ones. If enacted, this draft legislation, however well meaning, would destroy thousands of small businesses across the nation, and prevent many thousands more from entering the marketplace in years to come.

At a time when small businesses are struggling to survive in a weakened economy, and where issues like lack of access to affordable health insurance is forcing layoffs and closures nationwide, this draft legislation is a solution in search of a problem.

It is the wrong policy, the wrong law and the wrong time.

## **The Growth of "Micro-Cosmetics" Companies**

Prior to the mid-1990's almost all cosmetics manufacturers were nationally known brand names. Today, it is estimated by the Personal Care Products Council that, 11 billion personal care products are sold annually. Of that number, only a fraction is made by companies that are not world- or nationwide brands. The larger companies have thrived in the current marketplace in part because they have the manpower and financial resources to easily understand and embrace the many laws and regulations, both federal and state, which apply to them.

By contrast, small businesses invest proportionately far more resources than larger ones to comply with the exact same laws. Moreover, small companies typically do not have the

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<sup>2</sup> The text of the Petition and the signatories to it can be found here: [http://www.indiebusinessblog.com/indie\\_business/2008/06/stop-the-fda-gl.html](http://www.indiebusinessblog.com/indie_business/2008/06/stop-the-fda-gl.html). A copy of all of the signatories and their comments is attached to this letter.

resources to comply with new laws at the speed and efficiency of larger businesses. It is against this backdrop that IBN was formed with the goal of helping member companies understand, embrace and comply with cosmetics laws and regulations, and still have the time needed to run their businesses.

IBN provides a variety of regulatory educational opportunities. For example, earlier this year, IBN hosted a seminar with David Steinberg, a world-renowned cosmetics preservatives expert. Mr. Steinberg met with participating IBN members to discuss preservatives in cosmetics. He outlined the various types of preservative systems available and complemented IBN members' knowledge about how to choose the best preservative system for particular types of products. Mr. Steinberg's services were made available to members for one-on-one consultation after the meeting.

Additionally, IBN hosted a seminar with Kelley Reeves, Esq., a partner in the FDA/Healthcare practice group at the Washington, DC office of the law firm of King & Spaulding. Ms. Reeves and one of her associates delivered a dynamic and informative presentation on cosmetics laws and regulations. This presentation was made available to all of IBN's members in a live teleseminar format and as a recorded audio stream, with an accompanying Power Point presentation. While Ms. Reeves did not provide legal advice, the information she shared was helpful, and members were advised about how to contact her for one-on-one assistance after the meeting. Over the years, experts from several other disciplines have been made available to IBN members to help with all aspects of running a business, including compliance with cosmetics regulations.

Today, the cosmetics industry is vibrant and robust with many companies offering a variety of different products to a consumer base that is enjoying all of the options. The industry as a whole benefits greatly from the efforts of IBN and others to help these small manufacturers who have nowhere else to turn for assistance in interpreting and applying regulations to their particular situations. Many of these small businesses cannot afford costly attorneys and consultants, so organizations like IBN have stepped in, not to provide legal advice, but to share resources, information and ideas that make it as affordable and efficient as possible to own and manage a small cosmetics business.

Other organizations have stepped in to assist as well. For example, the Handcrafted Soapmakers Guild<sup>3</sup> with over 600 member companies was formed in 1998 to circulate information beneficial to small businesses that make and sell soap. The Soap Guild has an annual conference, which often includes speakers who also address issues associated with FDA regulations.

While no studies have been conducted to assess the growth of micro-cosmetics manufacturers, there is little doubt that this segment of the industry is growing by leaps and bounds. It is estimated that, between 2002 and 2007, the market for organic and natural personal

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<sup>3</sup> [www.soapguild.org/](http://www.soapguild.org/)

care products grew from \$3 billion to \$7.3 billion, and that the market for the larger companies' conventional products grew from \$48 billion to \$ 56 billion. Micro-cosmetics companies are a huge part of the reason for the growth of the organic and natural segments, and the accompanying increased consumer choices.

Even with this growth, statistics show that cosmetics are overwhelmingly safe in this country. According to the Personal Care Products Council, of the 11 billion personal care products sold annually, an average of less than 150 adverse reactions are reported, most of which are minor skin irritations. It is against this backdrop of a robust marketplace with remarkably few adverse events that the current draft legislation must be evaluated.

Stated simply, there is no evidence that the current laws are insufficient to protect consumers. The FDA can call on a panoply of enforcement options: banning or restricting ingredients, seizing and requiring the destruction of misbranded products and enjoining unlawful activities of all kinds. To the extent there are enforcement problems in terms of agency resources, small businesses should not bear a disproportionate share of the burden to correct those problems. Yet, that's exactly what this proposed legislation contemplates.

That's the wrong policy, the wrong law and the wrong time.

### **Small Businesses Are The Backbone of The American Economy**

Small businesses are critical to a robust national economy. They create most of the jobs in America and bring constant innovation to the marketplace. They are the engines that fuel the economy and keep it moving forward. The ability to start a small business is an integral part of the American free enterprise experience and makes real America's promise that anyone and everyone willing to work hard enough can enjoy their own slice of the American dream.

In the cosmetics industry, small businesses have thrived, but only in the face of regulations that are specifically tailored to protect consumers while maintaining a level playing field for all business participants. The current draft legislation would reverse all of that by imposing on cosmetics companies many of the same regulatory restrictions that apply to food and drug companies, when there is no need to do so.

Today, we express deep concern over what we fear is a remarkable example of over-regulation of a vulnerable segment of the market for the specific benefit of dominant market players. History has shown that unnecessary regulation serves only to discourage small business growth and investment, and poses barriers for new entrants, thereby limiting the potential for additional competition and new, innovative products for consumers. In particular, this draft legislation seems to indicate that Congress may be favoring big business over small business, pre-determining who will be the winners and who will be the losers in the competitive cosmetics market. This would be an abject policy failure and would effectively undo the success of the

current regulatory approach, which has benefited both consumers and businesses of all sizes by encouraging a fair and vibrant marketplace.

### **The Proposed Laws Would Force Small Business to Close**

The draft legislation goes far beyond what is necessary to protect consumers from unsafe cosmetics. In addition to mandating that all companies that manufacture, process, pack or hold cosmetics register with the federal government, the proposal also requires these companies to pay an annual registration fee of \$2,000. For small start-up businesses, this can be the profit margin for an entire year.

Small and micro-cosmetics companies, those with less than \$10M in annual gross sales, would be forced to leave the market immediately and in droves if this provision alone were to become law. Innovation would slow significantly. Thousands of jobs would be lost. Workers who cannot find work elsewhere would be forced into dire situations. Surely, this is the wrong policy, the wrong law and the wrong time.

As if the \$2,000 annual fee were not enough, an annual \$10,000 fee is proposed for companies that import cosmetics. Since many of the ingredients used in cosmetics are processed abroad, this provision would leave small companies with two choices: either purchase ingredients domestically in small quantities (from suppliers who presumably have paid the \$10,000 fee), thereby cutting deeply into profit margins, or continue buying directly from international suppliers, and then cease operations on the day the law goes into effect because they can't pay a \$10,000 annual fee.

The draft legislation subjects all IBN members to an annual fee of between \$2,000 and \$12,000 each year. Of course for ingredient suppliers, this exorbitant fee would have to be absorbed by their customers, the manufacturers who cannot afford it. Once again, the result is the same: massive exits from a currently healthy industry with a remarkable safety record.

Had laws like these been in effect 10 years ago, the marketplace would look like it did 10 years ago: larger companies providing the same basic products as other larger companies at prices that could hardly be called competitive. There would be no companies like Bella Luccè in Columbia, South Carolina. Bella Luccè makes bath and body care products such as sugar scrubs, bath oils and body wash. The company was founded in 2003 by Lela Barker, a single mother of daughters aged 2 and 5 at the time. Recently divorced, Lela and her children moved into Lela's mother's home, and Lela pondered how she was going to support her daughters with no job prospects and no child support.

When Lela's sister encountered some health problems, Lela created a lotion to help lift her spirits. As time passed, Lela perfected a small number of recipes using basic ingredients. A friend took some of Lela's products into a local spa and emerged with a \$3,000 order. Lela sold a valuable antique rug and poured all of her money into buying the ingredients she needed to fill

that order and launching a website. Lela's aunt took professional product photos in exchange for Lela's house cleaning services for a weekend. Lela filled the order on time and Bella Luccè was born.

Only 5 years later, Lela employs 8 full-time people in her manufacturing facility in suburban Columbia, South Carolina. She complies with all cosmetics laws, and even educates consumers on cosmetics labeling requirements at her website. Lela has customers all over the world, including boutiques and 5-star hotels for which she formulates and manufactures for their private label. Today, Bella Luccè is supporting Lela and her daughters, and while Lela has since remarried, it is the income earned from Bella Luccè that is going to put Lela's daughters through college. Additionally, Lela regularly donates her time and her employee's time to volunteer at non-profit organizations that help needy people in her community.

Lela embodies the strength and tenacity of small business owners throughout this industry. The same combination of entrepreneurial excellence and civic concern that Lela displays is repeated many times over in IBN members across this nation. Nicole Perkins of Brooklyn, New York, is another example.

Nicole is a 33-year old Black American woman currently working in the pharmaceutical industry as she also launches Nidasii, a bodycare products company. Nicole has been diligently working on weekends and after work hours for three years to launch Nidasii. She has made considerable headway, including spreading the word about her products through national vending events and traditional media outreach.

Due to the state of the economy, Nicole's monthly business expenses have increased 10% over the last year. While it would be easy to fold up shop, Nicole is pressing onward through this difficult economic period. She is determined to be successful. If this law is passed, Nidasii will cease to exist, and along with it, Nicole's dream of growing a business that will one day provide jobs for women in her community.

If the provisions in this proposed legislation had been in effect when Lela needed to find a way to support her family, Bella Luccè would not exist today. If this law passes, Nidasii and thousands of companies like it *will vanish*, leaving consumers with a few global cosmetics brands and only the occasional specialty and boutique brand, which would often be owned by a global cosmetics company.

Another troublesome aspect of the law is the requirement that companies be required to comply with a one-size-fits-all set of good manufacturing practices (GMP). While this sounds good, the fact is that the current practices only contemplate large businesses and, in many instances, make it impossible for small businesses to comply with GMP.

For example, one GMP section provides for the weighing and measuring of raw materials by a second person at the company. Many IBN member companies are composed of one person. While they are perfectly capable of double-checking weights and measures, therefore complying

with the spirit of GMP, the method they employ may be different from what is specified in GMP. Should they be forced out of business or barred from starting because one person instead of two is double-checking weights and measures? We think not.

Small companies can and do comply with GMP, but they don't necessarily have the resources to do it in the exact same way that multi-million dollar companies with several dozen or even hundreds of employees do. Codifying current one-size-fits-all GMP would force small companies from the marketplace for no good reason.

### **Adverse Consumer Impact**

Small and micro-businesses will be adversely impacted by this legislation, yes. But even more importantly, consumers will be adversely impacted by this legislation. At a time when they are just beginning to truly enjoy a wide array of choices when it comes to their cosmetics and personal care products, this law would return them back to the days of limited options and higher prices.

At our blog, we have collected the signatures of well over 1,000 Americans, many of them consumers, in opposition to this legislation. Some of their comments at the blog are illustrative of their outrage about this draft legislation:

“Please stop the FDA Globalization Act of 2008. I want the right and opportunity to purchase from small personal companies that hand make their products.”  
Heather-Dawn Filipiak, Gibsonia, PA

“Please stop FDA Globalization Act of 2008 - as a dedicated customer of a number of [small] retailers I despair the loss of innovative, customer-focused beauty businesses.” Tamara Lee

“I oppose the FDA Globalization Act of 2008. As a customer of small independently run cosmetic businesses I appreciate the variety, options, quality, personal attention, low prices, and lack of chemical toxins that are available through these businesses.” Jodi Sabin

“Please Stop the FDA Globalization Act of 2008. I am a customer of several independent natural skin care/perfume companies. They provide superior, safer, purer products than I can find in drug stores and most of the products in natural foods stores. This act would be prohibitively expensive for independent businesses and their customers. Please stop the FDA Globalization Act of 2008 and keep freedom of choice alive for consumers and independent business!” Lisa Catella

“As a customer of several small businesses who would be forced to close as a result if this proposal became law, I completely oppose the FDA Globalization Act of 2008 and will be contacting my representatives to say so.” Shannon Sudderth

“Please protect entrepreneurship in the USA. Putting undue hardship on small cosmetics companies will effectively eliminate choice for the consumer and opportunity for anyone willing to take a risk in this marketplace. I oppose the FDA Globalization Act of 2008.” Maggie Mahboubian, Los Angeles, CA

“Please stop the FDA Globalization Act of 2008! I am a regular customer of small cosmetics businesses that would be forced to close if this were to pass.” Alissa Mooney

Clearly, consumers are delighted with the vast array of choices they have when it comes to their personal care and bath and body products. These choices are made possible in large part because of the tenacity and innovative spirit of small and micro-business owners. Limiting their options at a time when they are just beginning to enjoy them is simply unnecessary.

### **Possible Alternatives**

We believe that the current laws, which give broad rulemaking and enforcement authority to the FDA, need not be overhauled in order to protect consumers and ensure that the FDA has adequate funding.

Having said that, if Congress is determined to move forward with new laws, we suggest that there are far less burdensome ways to protect consumers, ways that are less threatening to small businesses and far more solution-oriented. We strongly urge you to adopt the least restrictive means to accomplish legitimate legislative goals.

For example, if the law requires compliance with GMP, those practices should be proportionate to the risk small businesses present. Without disturbing the intent of GMP and without endangering consumers, the law could require that the FDA promulgate one set of GMP for large companies and another set of GMP for smaller ones grossing under a certain amount of sales each year and/or producing under a certain number of products each year.

Additionally, federal laws and regulations are often extremely difficult for experienced attorneys to understand and apply, let alone a small business owner who is wearing all the hats in a particular organization. The law could require that the FDA use low cost technological tools, such as teleconferences and webinars, to create educational working sessions to make it easier for small companies to comply with good manufacturing practices, considering their peculiar needs and challenges.

The law could also require the FDA to establish an “ombudsman” or other type of small business liaison so small businesses can get the help they need to understand and apply the law.

Another possible option would be to require that small business representatives be more proactively consulted during FDA rulemaking proceedings so that decisions affecting them are not made without taking into consideration their unique contribution to the marketplace. This would enhance the small business community voice by allowing them to play a more vigorous role in determining future regulations.

## **Conclusion**

As you consider legislation to update the nation's cosmetics laws, we respectfully request that you also acknowledge the pre-existing legal framework that created the vibrant marketplace that exists today. These fundamental elements of a level playing field must be preserved.

Congress should not consider abandoning the current approach to the cosmetics market place. Rather, we urge Congress to look comprehensively at the robust nature of today's cosmetics market and consider the growing competition that has come about as a result of Congress and the FDA's current policies.

We stand prepared to work with Congress, the FDA and the industry as a whole to achieve our shared goal of protecting consumers from unsafe cosmetics. However, we believe that the one-size-fits-all approach that is currently before us falls miserably short of what Congress needs to do to achieve this goal.

We look forward to working with you on this and other important matters affecting our members.

Sincerely,

Donna Maria Coles Johnson  
Founder & President  
The Indie Beauty Network

Enclosures (signatures to Petition to Stop the FDA Globalization Act of 2008)

cc: Honorable John F. Kerry, Chair (w/o enclosures)  
US Senate Committee on Small Business & Entrepreneurship  
United States Senate  
Honorable Nydia Velázquez, Chair (w/o enclosures)  
US House of Representatives Small Business Committee