

Wholesale Supplies Plus

Soap & Candle Making Materials

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October 16, 2008

The Honorable xxxx
Address
United States House of Representatives
Washington, DC 20515

Dear Representative xxxx

I am writing in regard to the draft bill entitled *The FDA Globalization Act of 2008*, being discussed by the Health Subcommittee of the House Energy and Commerce Committee.

Customers of Wholesale Supplies Plus purchase supplies to make scented soaps, lotions, bath salts and other personal care items, which would be regulated by this bill. The language in this bill will likely mean closure for Wholesale Supplies Plus, Inc. and end the employment for our 30 employees in the State of Ohio. Wholesale Supplies Plus is a company that would be forced to close its doors because thousands of our domestic customers, making small batches of products in their homes, will not have the ability to comply with the suggested requirements of this bill.

Some of our specific objections, rationale and proposed solutions are:

- **Draft Bill Language:** *The amount of the fee under this section shall be \$2,000 for the initial registration and each re-registration under section 415 of each facility operated by the registrant. The secretary shall assess and collect an annual fee for the registration of an importer of food, drugs, devices or cosmetics under section 801(s). The amount of the fee under this section shall be \$10,000. (Section 604: Page 62, Line 4-16. Page 64, Line 22-24. Page 65, Line 1-2.)*

Objection & Rationale: The annual registration fee of \$2,000 for domestic ingredients plus \$10,000 for imported ingredients would be an obstacle sufficient enough to render making of these products unreasonable for small businesses averaging a profit of less than \$25,000 per year. It hinders entrepreneurial growth in an industry that has historically benefited from innovation of small artisan businesses while not directly advancing current safety standards or practices.

Proposed Solution: Create an automatic fee waiver for small businesses. If the fee would present a significant barrier to innovation because of limited resources available to such persons or other circumstances, a waiver would be appropriate. Waivers such as these have already been added to the revised drug portion of the draft bill. It would be reasonable to have it applied to the cosmetic portion of the bill, as well. (Revised Drug Section 201: Page 4, Line10-22).

- **Draft Bill Language:** *The Secretary shall grant to a person a waiver or reduction of one or more fees under this section if the Secretary finds.... (Revised Drug Section 201: Page 4, Line 10-14).*

Objection & Rationale: The language of “reduction” is subjective and leaves the potential for unintended unfair application of fees.

Proposed Solution: Revise the language to read: The Secretary shall grant to a person a waiver of one or more fees under this section if the Secretary finds....

- **Draft Bill Language: Small Business Definition – In paragraph (1)(c), the term ‘small business’ means [to be supplied].**

Objection & Rationale: Small Business requires a definition so that the areas in the bill that refer to ‘small business’ can be fully evaluated.

Proposed Solution: Revise the language to read: ...the term ‘small business’ means an entity that is independently owned and operated and which is not dominant in its field of operation. Size requirements for a small business have 100 or less employees. This is the small business definition used by the US Small Business Administration, an independent federal government agency, for wholesale trade businesses.

- **Draft Bill Language:** *Each facility shall list in the registration the cosmetic product it manufactures, processes, packs, or holds and, in the case of a manufacturing facility, a list of the ingredients for each product so listed that it manufactures. (Section 604: Page 61 – Line 24. Page 62 – Line 3.)*

Objection & Rationale: The listing of individual ingredients for each product is currently required by the FDA through an effective cosmetic ingredient label program. Additional proposed registration paperwork would create hours of unnecessary, duplicative paperwork that micro businesses cannot afford to administer. This additional paperwork would not increase consumer safety.

Proposed Solution: Require facilities to submit a single list of all sources and ingredients used for manufacturing all products. This would minimize paperwork while allowing for public notifications and recalls.

- **Draft Bill Language: *Definition of facility.***

Objection & Rationale: This bill does not have an exemption for hobbyists that wish to make products in the privacy of their own home for personal use or to give to family and friends.

Proposed Solution: Expand the definition of facility to specifically state that a facility is not the private residence of an individual. There is precedence for this definition in the Food section of the Bioterrorism Act of 2002.

Wholesale Supplies Plus, Inc. has serviced the industry of small artisan cosmetic businesses for the past 10 years. It would be my pleasure to meet with you personally to discuss this market segment, the current discussion draft bill and proposed alternative language.

Sincerely,

Deborah L. May
President & CEO
Wholesale Supplies Plus.com, Inc.