

Dockets Management
Division of Dockets Management
Food and Drug Administration
5630 Fishers Lane
Room 1061, HRA-305
Rockville, MD 20852



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CITIZEN PETITION

The Handcrafted Soap and Cosmetic Guild, on behalf of its membership and the handcrafted soap and cosmetic industry as a whole, submits this petition pursuant to 21 CFR § 10.30 to request the Commissioner of Food and Drugs to amend certain regulations concerning the labeling of cosmetic products and the placement of the manufacturer's street address thereon.

A. ACTION REQUESTED

With this petition, we request the Commissioner to:

1) Revise the text of paragraph (d) of 21 CFR § 701.12, "Name and place of business of manufacturer, packer, or distributor," adopted on June 28, 1968¹ and still in effect today, which **currently** reads as follows (emphasis added):

(d) The statement of the place of business shall include the street address, city, State, and ZIP Code; however, the **street address may be omitted if it is shown in a current city directory or telephone directory**. The requirement for inclusion of the ZIP Code shall apply only to consumer commodity labels developed or revised after the effective date of this section. In the case of nonconsumer packages, the ZIP Code shall appear either on the label or the labeling (including the invoice).

by **updating the text to the following**²:

(d) The statement of the place of business shall include the street address, city, state, and zip code; however, the street address may be omitted if it is listed in a readily accessible, widely published, and publicly available resource, including but not limited to a printed directory, electronic database, or Web site.

2) Affirm that during the rulemaking process, no action will be taken against a cosmetic manufacturer whose label omits the street address and where the actual physical address is listed in a readily accessible, widely published and publicly available resource, but where such resource would not qualify under a strict definition of a "telephone directory."

1 FR 33:9845. When the regulation was approved in 1968 it was numbered differently. The numbers were subsequently changed to the organization that is in place today. For ease of reference, only the current numbering is being used to refer to the regulations.

2 The updated text is identical to the comparable regulation implementing the Fair Packaging and Labeling Act by the FTC addressing the business name and place (16 CFR § 500.5), discussion of which is covered in Section B of this document.

B. STATEMENT OF GROUNDS

INTRODUCTION

The Handcrafted Soap and Cosmetic Guild is a IRS exempt 501(c)(6) non-profit trade association representing the industry of handcrafted soap and cosmetic makers. These soap and cosmetic makers, both members and non-members of the association, make cosmetics as defined by the Food, Drug and Cosmetic Act³ which are subject to cosmetic labeling regulations.

Many handcrafted soap and cosmetic handcrafters also make soap which is exempt from the definition of a cosmetic in accordance with 21 CFR § 701.20(a), which reads:

(a) In its definition of the term cosmetic, the Federal Food, Drug, and Cosmetic Act specifically excludes soap. The term *soap* is nowhere defined in the act. In administering the act, the Food and Drug Administration interprets the term “soap” to apply only to articles that meet the following conditions:

- (1) The bulk of the nonvolatile matter in the product consists of an alkali salt of fatty acids and the detergent properties of the article are due to the alkali-fatty acid compounds; and
- (2) The product is labeled, sold, and represented only as soap.

Where the soap is exempt from the definition of a cosmetic, the federal labeling requirements are dictated by the FTC under 16 CFR § 500.

SAFETY AND SECURITY CONSIDERATIONS

The current regulation for the labeling of cosmetics includes a requirement (21 CFR § 701.12, quoted on page 1) that the street address be included on the label unless the street address is shown in a current city directory or telephone directory.

Members of the handcrafted soap and cosmetic industry typically have small businesses, a large percentage of which are home-based. Those with home-based businesses often have legitimate concerns about widely publishing their home address on product labels.

While a very small percentage of these home-based businesses may have designated a small portion of their home as a tiny retail store and welcome walk-in customers, most reach their customers by going to the places the customers frequent, rather than opening their homes to the customers. The most common business model for such home-based businesses is to use online e-commerce websites and social media outlets along with local farmers markets and craft fairs to market and sell their products.

For those who have home-based businesses which are not set up for direct sales in the home, placing their home address on a product label poses significant safety and security issues for themselves and their families.

- a) Customers, seeing a street address on the label, may assume that it is a business keeping “normal business hours” and show up unexpectedly. While the most likely reason for a customer to come to the “business address” is to purchase product, the other reason for a customer to search out the business is if they are upset or disgruntled for some reason. In the latter case the safety of the home or the occupants may be threatened.

3 21 USC §321(i)

- b) A criminal, determining that it is a home-based business, may realize that there is likely to be valuable computer or other equipment located at the address and view it as a potential target.
- c) Illegal drug producers need sodium hydroxide (lye) in order to make methamphetamine. Soapmakers legitimately use sodium hydroxide in the production of soap and frequently have 2 - 50 pounds in stock. The street address of a soapmaker is a veritable open invitation to a methamphetamine producer seeking an untraceable source of lye.

In all these cases, the potentiality of threat or harm tends to be one of opportunity. A customer is disgruntled with the product, looks at the label, sees the address and drives over there to give the company a piece of his mind. Or a criminal, buying a soap from a handcrafter at a craft show, gets the address and burglarizes the home with the confidence of knowing that no one will be home because they are at the craft show.

Notwithstanding, we recognize that a customer, attorney, or government agency with a valid reason for contacting a business at their physical address must have a way to locate and contact the business. Such entities should be able to find the company street address and other contact information with currently available technology, without requiring that the owner of a small, home-based business make their home address broadly and immediately available to all if they believe doing so would put them at risk.

Obviously, having the business street address publicly available online instead of on the package does not eliminate all potential threat to a home-based business, but it does eliminate the most likely threats by removing immediate access to the information which could spur on a crime of opportunity.

CHANGES IN DATA ACCESS

As noted above, the current regulation for the labeling of cosmetics includes a requirement that the street address be included on the label unless the street address is shown in a **current city directory or telephone directory**.

Meeting the existing options for omitting the street address can be limited and difficult.

- a) Printed phone directories have devolved since the regulation was first approved in 1968. They are now optional, only include land-lines (which may not even be used by a small, home-based businesses), have limited distribution, and are no longer free. City directories don't even exist any more (except possibly in very large cities).
- b) Online telephone directories⁴ have changed in their function and structure in the last 5 years. For example, the number of new pages indexed for www.yellowpages.com by the Wayback Machine⁵ dropped 72% from 2015 to 2018, indicating a lack of use by consumers it now appears to be focused on paid advertisements. Other online phone directories have had similar reductions in traffic. None of them are any longer the "go to" place for finding information about a business. In addition, the "free" version of most of these listings come

4 Docket FDA-2012-P-0872 In their final response, dated November 14, 2014, the FDA stated that a listing in an online telephone directory would be an acceptable alternative and even provided contact information for several online services providing such services.

5 <https://web.archive.org/details/www.yellowpages.com> viewed April 20, 2019. New pages indexed in 2018 was 125K; in 2015 it was 1,503K

with aggressive telephone marketing to upgrade to a “paid” listing. Several of our members reported received multiple calls per day, even when they requested the marketers to stop.

- c) As of 2019, the main methods people use to people find information on a business on the internet are:
- i. Directly typing in the website address, if known.
 - ii. Doing a web search of the whole internet using a search engine—primarily Google, but there are still a few other broad search engines still extant.
 - iii. Browsing through a website which is likely to provide the necessary information (such as a State business database, local Chamber of Commerce listings, or a trade association directory).

Just as the technology and the way it is used has changed over the last 50 years, in all likelihood the available technologies and the way they are used will continue to evolve over time. Any change in the existing regulations must be sufficiently flexible to encompass new technologies as they emerge.

FTC MODERNIZATION OF THE PLACE-OF-BUSINESS LISTING REQUIREMENT

In March 2014, the FTC recognized a need for updating some other their regulations, including modernization the place-of-business listing requirement. In the Notice of Proposed Rulemaking⁶ the FTC cited a comment received from the NCWM⁷ regarding modernizing the place-of-business listing requirement:

The NCWM comment suggested that this exception be extended to Internet directories, explaining that they serve the same purpose as printed telephone directories.

Noting that “The [FPL]Act itself requires the label to include the place of business, but does not specify to what level of detail,”⁸ the Commission agreed with the NCWM, stating:

The Commission agrees. It, therefore, proposes to revise this exception to permit a business to omit the street address if it is listed in any readily accessible, well-known, widely published, and publicly available resource, including but not limited to a printed directory, electronic database, or Web site. The inclusion of “any readily accessible, widely published, and publicly available resource” in the exception is flexible and intended to encompass new technologies that meet these requirements.

Notice of the final rule was published in the Federal Register on November 17, 2015⁹, and amended 16 CFR § 500.5 Name and place of business of manufacturer, packer or distributor, to read:

(c) The statement of the place of business shall include the street address, city, state, and zip code; however, the street address may be omitted if it is listed in a readily accessible, widely published, and publicly available resource, including but not limited to a printed directory, electronic database, or Web site.

6 Docket ID FTC-2015-0017-0001, Federal Register Number 2015-01629

7 National Conference on Weights and Measures

8 Docket ID FTC-2015-0017-0001, Federal Register Number 2015-01629, Footnote #28

9 80 FR 221 (Nov 17, 2015) page 71686

HARMONIZATION OF FDA AND FTC REGULATIONS IMPLEMENTING THE FPLA

The FPLA authorized both the FDA and the FTC to promulgate regulations to implement the labeling requirements specified in the FPLA. In 1968, both agencies implemented regulations using identical wording for the exemption to omit the street address from the business name and place. With the 2015 final rule by the FTC, the regulations are currently slightly different.

As noted above, handcrafted soap and cosmetic makers make not only cosmetics which are always subject to FDA governance, but also soap. A soap that meets the criteria outlined in 21 CFR § 701.20(a)¹⁰ would be exempt from the definition of a cosmetic and therefore could be regulated by FTC. However, based on statements made on the label or in the labeling, the exact same soap bar could fall within the definition of a cosmetic and therefore be regulated by the FDA. While the HSCG works diligently to educate and inform our membership and the industry-at-large about the labeling regulations, the difference in labeling requirements for a soap that is a cosmetic and one that is exempt from the definition of a cosmetic continues to be a point of considerable confusion, especially for those just starting their handcrafted soap and cosmetic business.

Also as noted above, many people operating home-based businesses have legitimate concerns over placing their physical business street address (which is also their home address) on their product labels. For cosmetic products (including soap as a cosmetic) they have limited options for omitting the business street address on cosmetic products under the FDA regulations. However, for soap that is exempt from the definition of a cosmetic they have different and considerably better options under the FTC labeling regulations.

Harmonization between the FDA and FTC regulations implementing the FPLA as concerns the business name and place would:

- ◆ Modernize the FDA regulations covering cosmetic label requirements for the business name and place while still meeting the requirements of the Fair Packaging and Labeling Act;
- ◆ Provide flexibility and the ability to encompass new technologies in the future without the necessity to update the regulation;
- ◆ Make it easier for small business to comply with the regulation;
- ◆ Reduce confusion for emerging small businesses; and
- ◆ Help protect the safety of handcrafted soap and cosmetic makers with home-based businesses;

C. ENVIRONMENTAL IMPACT

Under 21 CFR § 25.31, this petition qualifies for a categorical exemption from the requirement to submit an environmental assessment.

¹⁰ Full text of 21 CFR § 701.20(a) is quoted on page 2

D. ECONOMIC IMPACT

According to 21 CFR § 10.30, economic impact information will be provided if requested by the Commissioner following review of this petition.

E. CERTIFICATION

The undersigned certifies, that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "L. O'Donnell". The signature is cursive and somewhat stylized, with the first letters of the first and last names being capitalized and prominent.

Leigh O'Donnell
Executive Director
Handcrafted Soap and Cosmetic Guild
184 Edie Rd., Suite A
Saratoga Springs, NY 12866