



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug
Administration Rockville,
MD 20857

May 2, 2019

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

Sent via email to: admin@soapguild.org

Dear Petitioner:

Your petition to the Commissioner of Food and Drug Administration requesting that the FDA 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, 1968, and still in effect today and affirm that during the rulemaking process, no action will be taken against a cosmetic manufacturer whose label omits the street address was received by this office on 05/01/2019.

It was assigned docket number FDA-2019-P-2122. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Dynna Bigby
Supervisory Administrative Proceedings Specialist
Division of Dockets Management
FDA/Office of the Executive Secretariat (OES)