DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

REGISTRATION OF COSMETIC PRODUCT FACILITY

(In accordance with section 607(a) and (b) of the Federal Food, Drug, and Cosmetic Act (FD&C Act))

OMB No. 0910-XXXX
Expiration Date: Month XX, 20XX
See PRA Statement on Page 3

FOR FDA USE ONLY ON INITIAL REGISTRATIONS

REGISTRATION DATE *(mm/dd/yyyy)*

INSTRUCTIONS

For faster processing please use the electronic submission portal at: https://direct.fda.gov. Type all entries in CAPITAL LETTERS. An item followed by an asterisk (*) denotes a required field. Use standard abbreviations wherever possible. Omit all punctuation. Complete a separate Form FDA 5066 for each facility location. Mail completed form to: DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION, Office of Cosmetics and Colors, Registration and Listing of Cosmetic Product Facilities and Products Program (HFS-125), 5001 Campus Drive, College Park, MD 20740-3835 or email it to RLC-PaperSubmissions@fda.hhs.gov.

SECTION I – DOCUMENT TYPE

DOCUMENT TYPE*

- ☐ INITIAL
- ☐ AMENDED
  - ☐ CHANGES TO REGISTRATION
  - ☐ CANCELLATION OF REGISTRATION
- ☐ BIENNIAL REGISTRATION RENEWAL
- ☐ ABBREVIATED REGISTRATION RENEWAL (By checking this box, you are certifying that no changes have been made to your registration since the previous registration was submitted)

SECTION II – REGISTRATION

IS THIS A FACILITY REGISTRATION FOR A SMALL BUSINESS *(optional registration)*?

☐ YES ☐ NO

FACILITY NAME*	PARENT COMPANY NAME (If applicable)
FACILITY FEI (FDA Establishment Identifier) NUMBER*	FACILITY D&B D-U-N-S NUMBER

STREET ADDRESS*

CITY*	STATE OR PROVINCE*	ZIP/POSTAL CODE*	COUNTRY* (If other than USA)

FACILITY EMAIL*	FACILITY PHONE NUMBER* (Include Area/Country Code)

NAME OF THE OWNER AND/OR OPERATOR OF THE FACILITY*

BRAND NAMES OF COSMETIC PRODUCTS MANUFACTURED OR PROCESSED IN THIS FACILITY*	**RESPONSIBLE PERSON NAME*** (As listed on label)	**PRODUCT CATEGORY CODE(S)*** (See references on page 3)
1.		
2.		
3.		

(continued on next page)

SECTION III – U.S. AGENT CONTACT INFORMATION	
U.S. AGENT NAME* (for foreign facilities)	EMAIL* (If not available, enter "N/A")
PHONE NUMBER* (Include Area Code)	PHONE EXTENSION

SECTION IV – CONFIRMATION STATEMENT		
The data and information in this submission have been reviewed and, to the best of my knowledge, are certified to be true and accurate. I agree to report changes to this information and renew as required under section 607 of the FD&C Act. **WARNING:** A willfully false statement is a criminal offense, U.S. Code, Title 18, Section 1001.		AGREE ☐
SIGNATURE OF SUBMITTER	PRINTED NAME OF SUBMITTER	DATE *(mm/dd/yyyy)*

SECTION V – ADDITIONAL CONTACT INFORMATION FOR AUTHORIZED AGENT	
ADDITIONAL CONTACT NAME	EMAIL
PHONE NUMBER (Include Area/Country Code)	PHONE EXTENSION

(continued on next page)

REFERENCES

Registration and Listing of Cosmetic Product Facilities and Products:
https://www.fda.gov/cosmetics

Registration and Listing of Cosmetic Product Facilities and Products: Guidance for Industry:
http://www.fda.gov/

How to request an FEI number or determine if an entity already has an FEI number:
https://www.accessdata.fda.gov/scripts/feiportal/index.cfm?action=portal.login

Cosmetic product category codes:
https://www.fda.gov/cosmetics

Product category code examples:
02B (Bubble baths)
06A2 (Hair conditioners; Rinse-off)
10E (Nail polishes and enamels)
15B3 (Indoor tanning preparations; Spray applications)

DEFINITIONS

MANUFACTURING OR PROCESSING OF A COSMETIC PRODUCT — means engaging in one or more steps in the making of any cosmetic product by chemical, physical, biological, or other procedures, including manipulation, sampling, testing, or control procedures applied to the product.

OPERATOR — means a person, as defined in section 201(e) of the FD&C Act (21 U.S.C 321(e)), who has management authority over an establishment.

OWNER — means a person, as defined in section 201(e) of the FD&C Act (21 U.S.C. 321(e)), who has an ownership interest in an establishment.

RESPONSIBLE PERSON — as defined in section 604(4) of the FD&C Act, means the manufacturer, packer, or distributor of a cosmetic product whose name appears on the label of such cosmetic product in accordance with section 609(a) of the FD&C Act or section 4(a) of the Fair Packaging and Labeling Act.

SMALL BUSINESSES — as defined in section 612 of the FD&C Act, means responsible persons, and owners and operators of facilities, whose average gross annual sales in the U.S. of cosmetic products for the previous 3-year period is less than $1,000,000, adjusted for inflation, and who do not engage in the manufacturing or processing of certain cosmetic products described in section 612(b) of the FD&C Act. A small business is exempt from the registration and listing requirements.

THE INFORMATION BELOW APPLIES ONLY TO REQUIREMENTS OF THE PAPERWORK REDUCTION ACT OF 1995.

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DRAFT- for commenting purposes only