DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

COSMETIC PRODUCT LISTING

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

OMB Control No. 0910-XXXX
Expiration Date: Month XX, 20XX
See PRA Statement Page 4

FOR FDA USE ONLY ON INITIAL LISTINGS

LISTING DATE *(mm/dd/yyyy)*

PRODUCT NUMBER	PRODUCT LISTING NUMBER(S) *(if previously assigned)**
1	
2	
3	

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. For Section IV: List each ingredient on a separate row, in the order that they are listed on the label. If the Unique Ingredient Identifier (UNII) is not known, leave UNII blank. List additional ingredients on a separate page-2 of Form FDA 5067. 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
- ☐ UPDATE TO CONTENT *(annual)*
  - ☐ CHANGES TO LISTING
  - ☐ DISCONTINUATION OF LISTING
- ☐ ABBREVIATED RENEWAL (By checking this box, you are certifying that no changes have been made to your product listing since the previous listing was submitted)

SECTION II – PRODUCT LISTING

IS THIS A PRODUCT LISTING FOR A SMALL BUSINESS *(optional product listing)?* ☐ YES ☐ NO	RESPONSIBLE PERSON: TYPE OF BUSINESS *(As listed on label)* ☐ MANUFACTURER ☐ PACKER ☐ DISTRIBUTOR
RESPONSIBLE PERSON NAME* *(As listed on label)*	PARENT COMPANY NAME *(If applicable)*
RESPONSIBLE PERSON CONTACT PHONE NUMBER* *(Include* Area/Country Code)	RESPONSIBLE PERSON D&B D-U-N-S NUMBER FOR ADDRESS Listed On Product Label
PRODUCT CATEGORY CODE(S)* *(see references on page 4)*	IMAGE OF LABEL *(Attach images of the front and back product labels to this form)*

PRODUCT WEBPAGE LINK

PRODUCT NUMBER	PRODUCT NAME* *(As listed on label)*	DOES THIS PRODUCT CONTAIN FRAGRANCE OR FLAVOR?* *(select one or both, if applicable)*	IS THIS PRODUCT FOR PROFESSIONAL USE ONLY?
1		☐ FRAGRANCE ☐ FLAVOR	☐ YES ☐ NO
2		☐ FRAGRANCE ☐ FLAVOR	☐ YES ☐ NO
3		☐ FRAGRANCE ☐ FLAVOR	☐ YES ☐ NO

(continued on next page)

SECTION III – LIST OF FACILITIES WHERE THE COSMETIC IS MANUFACTURED OR PROCESSED
(See product number/product name provided in Section II)

PRODUCT NUMBER	FDA ESTABLISHMENT IDENTIFIER (FEI) OF EACH FACILITY(IES) WHERE THE PRODUCT IS MANUFACTURED OR PROCESSED *(if the facility is a small business and is not required to register, please enter the name and address of the facility)**
1	
2	
3	

SECTION IV – LIST OF INGREDIENTS IN THE COSMETIC PRODUCT
(Fragrances and flavors are included in Section II and do not need to be listed here)

INGREDIENT NUMBER	COMMON, USUAL, OR CHEMICAL NAME*	UNIQUE INGREDIENT IDENTIFIER (UNII)	PRODUCT NUMBER(S)
1			☐ 1; ☐ 2; ☐ 3; ☐ ALL
2			☐ 1; ☐ 2; ☐ 3; ☐ ALL
3			☐ 1; ☐ 2; ☐ 3; ☐ ALL
4			☐ 1; ☐ 2; ☐ 3; ☐ ALL
5			☐ 1; ☐ 2; ☐ 3; ☐ ALL
6			☐ 1; ☐ 2; ☐ 3; ☐ ALL
7			☐ 1; ☐ 2; ☐ 3; ☐ ALL
8			☐ 1; ☐ 2; ☐ 3; ☐ ALL
9			☐ 1; ☐ 2; ☐ 3; ☐ ALL
10			☐ 1; ☐ 2; ☐ 3; ☐ ALL
11			☐ 1; ☐ 2; ☐ 3; ☐ ALL
12			☐ 1; ☐ 2; ☐ 3; ☐ ALL
13			☐ 1; ☐ 2; ☐ 3; ☐ ALL
14			☐ 1; ☐ 2; ☐ 3; ☐ ALL
15			☐ 1; ☐ 2; ☐ 3; ☐ ALL
16			☐ 1; ☐ 2; ☐ 3; ☐ ALL
17			☐ 1; ☐ 2; ☐ 3; ☐ ALL
18			☐ 1; ☐ 2; ☐ 3; ☐ ALL
19			☐ 1; ☐ 2; ☐ 3; ☐ ALL
20			☐ 1; ☐ 2; ☐ 3; ☐ ALL
21			☐ 1; ☐ 2; ☐ 3; ☐ ALL

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SECTION V – 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 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 VI – 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)

Unique Ingredient Identifiers (UNIIs):
https://precision.fda.gov/uniisearch

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