DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
College Park, MD 20740-3835

COSMETIC PRODUCT INGREDIENT STATEMENT

(In accordance with 21 CFR 720)

Form: OMB No. 0910-0027. Expiration Date: 09/30/2020
See Burden Statement on Reverse of Part I.

TYPE OF SUBMISSION
☐ ORIGINAL ☐ AMENDED ☐ DISCONTINUED

FOR FDA USE ONLY ON ORIGINAL SUBMISSIONS

FDA CPIS NO.	FILING DATE (MM/DD/YY)
F _ _ _ _ _ _ _	_ _ – _ _ – _ _

NOTE: This report is authorized by Public Law 21 U.S.C. 371(A); 21 CFR 720. While you are not required to respond, your cooperation is needed to make the results of this voluntary program comprehensive, accurate, and timely.

INSTRUCTIONS:
For faster processing please submit this form electronically at: http://www.fda.gov/Cosmetics/RegistrationProgram/OnlineRegistration/default.htm.
Type all entries in CAPITAL LETTERS. Use standard abbreviations wherever possible. Omit all punctuation. Complete a separate Form FDA 2512 for each formulation. Mail completed form to: DEPARTMENT OF HEALTH AND HUMAN SERVICES, FOOD AND DRUG ADMINISTRATION, Office of Cosmetics and Colors, Voluntary Cosmetic Registration Program (HFS-125), 5001 Campus Drive, College Park, MD 20740-3835.

LABELER TYPE OF BUSINESS (As listed on label)
☐ MANUFACTURER ☐ PACKER ☐ DISTRIBUTOR

IS THIS PRODUCT CURRENTLY COMMERCIALLY DISTRIBUTED (ANNUAL SALES EXCEED $1000) IN THE UNITED STATES?
☐ YES ☐ NO

LABELER NAME (As listed on label)

LABELER ADDRESS (As listed on label)

PRODUCT WEBSITE

Attach images of the front and back product labels to this form

PRODUCT CATEGORY CODE
___ ___ ___

TYPE OF MANUFACTURER
☐ MANUFACTURER ☐ CONTRACT MANUFACTURER

Manufacturer/Contract Manufacturer Name (If different than labeler)

Manufacturer/Contract Manufacturer Registration No. (If registered)
E _ _ _ _ _ _ _
If not registered, complete FORM FDA 2511 and attach to this form

PACKER NAME (If different than labeler)

PACKER ESTABLISHMENT REGISTRATION NO. (If registered)
E _ _ _ _ _ _ _
If not registered, complete FORM FDA 2511 and attach to this form

	BRAND / SPECIFIC PRODUCT NAME (ex. Cosmetico Moisturizing Skin Cream) (List additional on separate form)	ADD	DLT
1		☐	☐
2		☐	☐
3		☐	☐

WHO IS FILING THIS STATEMENT
☐ MANUFACTURER ☐ PACKER ☐ DISTRIBUTOR ☐ RETAILER

AUTHORIZED INDIVIDUAL NAME (Required)		ALTERNATIVE AUTHORIZED INDIVIDUAL NAME	
TITLE (Owner, president, or manager)	PHONE NUMBER	TITLE (Consultant or attorney)	PHONE NUMBER
EMAIL		EMAIL	
SIGNATURE	DATE (MM/DD/YY) _ _ – _ _ – _ _	SIGNATURE	DATE (MM/DD/YY) _ _ – _ _ – _ _

CONTINUE COSMETIC PRODUCT INGREDIENT STATEMENT ON FORM FDA 2512a

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 20 minutes per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."