

Request for Comments on New Electronic and Paper Forms for FDA's Voluntary Cosmetic Registration Program

FDA has developed draft revised versions of Forms FDA 2511, 2512, and 2512a for use by cosmetics firms to participate in FDA's Voluntary Cosmetic Registration Program (VCRP). Form FDA 2511 is used to register a cosmetic establishment. Form FDA 2512 is used for filing a cosmetic product formulation. Form FDA 2512a is a continuation of Form FDA 2512. FDA is seeking comments on both the draft online forms and the draft paper forms. Draft paper and online Forms FDA 2511, 2512, and 2512a are available below for review and comments.

Commenting starts May 31, 2017. Submit comments electronically in docket folder FDA-2010-N-0623 on <https://www.regulations.gov>.

For more information on how to comment, see the [Federal Register Notice](#).

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VCRP Paper

Registration of Cosmetic Product Establishment (Form FDA 2511)

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION College Park, MD 20740-3835		Form Approved: OMB NO. 0910-0027. Expiration Date: August 31, 2017. See Burden Statement on Reverse of Part I.	
REGISTRATION OF COSMETIC PRODUCT ESTABLISHMENT (In accordance with 21 CFR 710)		TYPE OF SUBMISSION <input type="checkbox"/> ORIGINAL <input type="checkbox"/> AMENDED <input type="checkbox"/> CANCELLATION	
FOR FDA USE ONLY ON ORIGINAL SUBMISSIONS			
FDA REGISTRATION NO. E _____		REGISTRATION DATE (MM/DD/YY) _ _ - _ _ - _ _	
NOTE: This report is authorized by Public Law 21 U.S.C. 371(A); 21 CFR 710. 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 2511 for each establishment location. 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.			
TYPE OF ESTABLISHMENT <input type="checkbox"/> MANUFACTURER <input type="checkbox"/> PACKER OTHER <input type="checkbox"/> DISTRIBUTOR <input type="checkbox"/> RETAILER <input type="checkbox"/> BUSINESS OFFICE			
ESTABLISHMENT NAME		PARENT COMPANY NAME (if any)	
STREET ADDRESS			
CITY	STATE (USA only)	ZIP/POSTAL CODE	COUNTRY (if other than USA)
Is the address on this form the location of a cosmetic manufacturing and/or packing facility? <input type="checkbox"/> YES <input type="checkbox"/> NO			
OTHER BUSINESS TRADING NAMES (List additional on a separate form)			ADD
			DELETE
1			
2			
3			
ESTABLISHMENT 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) _ _ - _ _ - _ _

Cosmetic Product Ingredient Statement (Form FDA 2512)

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 Approved: OMB NO. 0910-0027. Expiration Date: August 31, 2017. See Burden Statement on Reverse of Part I.			
		TYPE OF SUBMISSION <input type="checkbox"/> ORIGINAL <input type="checkbox"/> AMENDED <input type="checkbox"/> DISCONTINUED			
		FOR FDA USE ONLY ON ORIGINAL SUBMISSIONS			
		FDA CPIS NO. F _____		FILING DATE (MM/DD/YY) ____ - ____ - ____	
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) <input type="checkbox"/> MANUFACTURER <input type="checkbox"/> PACKER <input type="checkbox"/> DISTRIBUTOR			IS THIS PRODUCT CURRENTLY COMMERCIALY DISTRIBUTED (ANNUAL SALES EXCEED \$1000) IN THE UNITED STATES? <input type="checkbox"/> YES <input type="checkbox"/> NO		
LABELER NAME (As listed on label)			PRODUCT WEBSITE		
LABELER ADDRESS (As listed on label)			Attach images of the front and back product labels to this form		PRODUCT CATEGORY CODE ____
TYPE OF MANUFACTURER <input type="checkbox"/> MANUFACTURER <input type="checkbox"/> CONTRACT MANUFACTURER		BRAND / SPECIFIC PRODUCT NAME (ex. Cosmetico Moisturizing Skin Cream) (List additional on separate form)		ADD	DLT
Manufacturer/Contract Manufacturer Name (If different than labeler)		1			
Manufacturer/Contract Manufacturer Registration No. (If registered) E _____		If not registered, complete FORM FDA 2511 and attach to this form		2	
PACKER NAME (If different than labeler)		3			
PACKER ESTABLISHMENT REGISTRATION NO. (If registered) E _____		If not registered, complete FORM FDA 2511 and attach to this form		3	
WHO IS FILING THIS STATEMENT <input type="checkbox"/> MANUFACTURER <input type="checkbox"/> PACKER <input type="checkbox"/> DISTRIBUTOR <input type="checkbox"/> 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) ____ - ____ - ____

Cosmetic Product Ingredient Statement Continued (Form FDA 2512a)

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 Approved: OMB NO. 0910-0027. Expiration Date: August 31, 2017. See Burden Statement on Reverse of Part I.	
		TYPE OF SUBMISSION <input type="checkbox"/> ORIGINAL <input type="checkbox"/> AMENDED	
		FOR FDA USE ONLY ON ORIGINAL SUBMISSIONS	
		FDA CPIS NO. F _____	FILING DATE (MM/DD/YY) _ _ - _ _ - _ _
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. List ingredients in the order that they are listed on the label. If CAS number is not known, leave CAS NO. blank. List additional ingredients on a separate Form FDA 2512a. Attach completed form to FORM FDA 2512. If submitting a trade secret petition, enter "confidential" next to the ingredient in your petition.			
INGRED NO.	COMMON, USUAL, OR CHEMICAL NAME	CAS NO.	
01			
02			
03			
04			
05			
06			
07			
08			
09			
10			
11			
12			
13			
14			
15			
16			
17			
18			

VCRP Online

Request Account (Form FDA 2511 and 2512)

VCRP Menu >> Request Account

Only authorized owners or operators of a cosmetic company may open VCRP accounts.

Authorized Individual

Company Name	
First Name	
Last Name	
Title (Owner, president, or manager)	
Phone Number	
Email	
Country/Area	
User Name	

Alterantive Authorized Individual (if any)

[Add More](#)

First Name	
Last Name	
Title (Consultant or attorney)	
Phone Number	
Email	

[Submit](#)

Step 1: Enter Company Information (Form FDA 2512)

VCRP Menu >> File New Establishment and Formulation

Step 1 Company	Step 2 Product Information	Step 3 Ingredients	Step 4 Confirm
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Step 1: Enter Company Information

Labeler (As Listed on Label)	<input type="text"/>	<input type="button" value="Add Labeler"/>
Manufacturer (Including Contract Manufacturer)	<input type="text"/>	<input type="button" value="Add Manufacturer
Establishment"/>
Packer (Including Contract Packer)	<input type="text"/>	<input type="button" value="Add Packer
Establishment"/>
Who is filing this statement?	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Packer <input type="checkbox"/> Distributor <input type="checkbox"/> Other (Retailer)	

Add New Labeler (Form FDA 2512)

VCRP Menu >> File New Establishment and Formulation

Step 1 Company	Step 2 Product Information	Step 3 Ingredients	Step 4 Confirm
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Step 1: Enter Company Information

Add New Labeler

Labeler Type of Business (As Listed on Label)	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Packer <input type="checkbox"/> Distributor
Labeler Name (As Listed on Label)	
Labeler Address (As Listed on Label)	

<< Previous

Submit Labeler

Register New Establishment (Form FDA 2511)

VCRP Menu >> File New Establishment and Formulation

Step 1 Company	Step 2 Product Information	Step 3 Ingredients	Step 4 Confirm
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Step 1: Enter Company Information

Register New Establishment

Type of Establishment	<input type="checkbox"/> Manufacturer <input type="checkbox"/> Packer <input type="checkbox"/> Other (Distributor or Retailer)
Establishment Name	
Are you the owner or operator of this facility?	<input type="radio"/> Yes <input type="radio"/> No
Parent Company Name (if any)	
Street Address	
City	
State (USA Only)	
ZIP / Postal Code	
Country / Area	
Is the address on this form the location of a cosmetic manufacturing and/or packing facility?	<input type="radio"/> Yes <input type="radio"/> No
Other Business Trading Names (if any)	<input type="button" value="Add More"/>

<< Previous

Submit Establishment

Step 2: Enter Product Information (Form FDA 2512)

VCRP Menu >> File New Establishment and Formulation

Step 1 Company	Step 2 Product Information	Step 3 Ingredients	Step 4 Confirm
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Step 2: Enter Product Information

Is this Product Currently Commercially Distributed (annual sales exceed \$1000) in the United States?	<input type="radio"/> Yes <input type="radio"/> No
Product Website	
Upload images of the front and back product labels	<input type="button" value="Upload Labels"/>
Product Category	

Add Brand / Specific Product Name (ex. Cosmetico Moisturizing Skin Cream)

<input type="button" value="Submit"/> Enter each brand name that you use for this formulation. After each entry, click "Submit".
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Brand / Specific Product Name

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<< Previous

Next >>

Step 3: Enter Ingredients (Form FDA 2512a)

VCRP Menu >> File New Establishment and Formulation

Step 1 Company	Step 2 Product Information	Step 3 Ingredients	Step 4 Confirm
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Step 3: Enter Ingredients

#	Common, Usual, or Chemical Name (Exactly as it appears on label)	VCRP Code #
1		
2		
3		
4		
5		

<< Previous

Next >>

Step 4: Confirm Formulations

VCRP Menu >> File New Establishment and Formulation

Step 1 Company	Step 2 Product Information	Step 3 Ingredients	Step 4 Confirm
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Step 4: Confirm Formulations

Please verify that all information is accurate.

You can click the "Previous" button to go back and make corrections.

Date Received	
Statement Filed By	
Labeler	
Manufacturer	
Packer	

Brands

#	Brand / Specific Product Name
1	

Ingredients

#	Common, Usual, or Chemical Name (Exactly as it appears on label)	VCRP Code #
1		
2		
3		
4		
5		

<< Previous

Submit Formulation