

DEPARTMENT OF HEALTH AND HUMAN SERVICES

FOOD AND DRUG ADMINISTRATION

College Park, MD 20740-3835

REGISTRATION OF COSMETIC PRODUCT ESTABLISHMENT

(In accordance with 21 CFR 710)

*Form Approved: OMB No. 0910-0027.
Expiration Date: April 30, 2014. See Reverse.*

FOR FDA USE ONLY

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.

TYPE OF SUBMISSION (*CHECK ONE*)

(If this is an amended submission enter Registration Number)

ORIGINAL AMENDMENT
 CANCELLATION

E _____

ALL CARDS

REGISTRATION NO.

E

CARD NO.
(9-11)

ESTABLISHMENT NAME (12-46)

110

KIND OF BUSINESS (47-48)

MANUFACTURER PACKER

AF NO. (86-72)

REGISTRATION DATE (73-80)

111

NAME OF PARENT COMPANY (If any) (12-46)

112

STREET ADDRESS (12-46)

113

CITY (12-36)

STATE (37-38)

ZIP CODE (39-43)

COUNTRY (If other than USA) (44-72)

220

(12-13)

OTHER BUSINESS TRADING NAMES (14-48)

TYPE OF ACTION (48-72)

01

02

03

04

05

06

SIGNATURE BLOCK

TYPED NAME AND TITLE OF AUTHORIZED INDIVIDUAL

DATE COMPLETED (73-80)

SIGNATURE OF AUTHORIZED INDIVIDUAL

INSTRUCTIONS FOR COMPLETING FORM FDA 2511

Complete the form as described below. Indicate the type of submission by checking the appropriate box. Items not covered in these Instructions are self-explanatory. Type all entries in CAPITAL LETTERS. Use standard abbreviations wherever possible. Omit all punctuation. Complete a separate Form FDA 2511 for each establishment location. Leave completed and signed form intact and forward to:

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
Office of Cosmetics and Colors
Voluntary Cosmetic Registration Program (HFS-125)
5100 Paint Branch Parkway
College Park, MD 20740-3835**

SPECIFIC INSTRUCTIONS

CARD NO(S)	COLUMN NO(S)	ITEM
ALL	1-8	REGISTRATION NUMBER. This number will be assigned by FDA. Firms having more than one location will have a different number for each location. This number will appear on the validated copy which is returned to the establishment. (Correspondence with FDA concerning this Registration must reference the Registration Number.)
110	12-46	ESTABLISHMENT NAME. Enter the name under which the establishment is to be registered at this one general physical location under one management.
	47-48	KIND OF BUSINESS. Check appropriate box or combination of boxes.
111	12-46	NAME OF PARENT COMPANY <i>(if any)</i> . A second line has been provided for the name of the parent company of the establishment as shown in the example in CARD 110, Columns 12-46.
112	12-46	STREET ADDRESS. Enter establishment physical street location. A P.O. Box number may only be added as additional information for postal communications.
113	37-38	STATE. Use Official Post Office 2 letter State Code.
220	14-48	OTHER BUSINESS TRADING NAMES. Defined as subsidiary or related firm names used on a cosmetic product label, which are owned by the cosmetic manufacturer or packer, but different from the principal name under which the cosmetic product manufacturer or packer is registering or is registered. If you require more than 6 Other Business Trading Names, use a second form. Complete entries in CARD 110, Columns 12-46; CARD 112, Columns 12-46; CARD 113, Columns 12-72; then continue to enter Other Business Trading Names in CARD 220, Columns 14-48. Also, complete pagination at bottom of the form when there are more than 6 Other Business Trading Names.

INSTRUCTIONS FOR AMENDED OR CANCELED SUBMISSIONS

Changes in the information on a validated Form FDA 2511 must be entered on a NEW Form FDA 2511 as an AMENDMENT within 30 days of such changes. This includes notification to cancel the registration or to delete any part of the information in the original file. Check the amended or canceled Submission

box at the top of the form and enter the Registration Number in the place provided. (The Registration Number is found in the upper right corner of the validated copy and must be entered exactly as it appears including the leading zeros.)

CANCELLATION OF REGISTRATION

When Establishment no longer conducts business under this name or when Establishment name is changed, complete:

Type of Submission. Check CANCELLATION box.
CARD 110, Columns 12-46
Signature Block

CHANGE OF ADDRESS

Self-explanatory. Complete:

Type of Submission. Check AMENDMENT box.
CARD 110, Columns 12-46
CARD 112, Columns 12-46
CARD 113
Signature Block

ADDITIONS OR DELETIONS TO OTHER BUSINESS TRADING NAMES

Any change in Other Business Trading Name is handled as either an addition or deletion. Describe Type of Action as either ADD or DELETE. Complete:

Type of Submission. Check AMENDMENT box.
CARD 110, Columns 12-46
CARD 220, one or more items, ALL Columns
Signature Block

Public reporting burden for this collection of information is estimated to average 12 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
1350 Piccard Drive, Room 400
Rockville, MD 20852

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 control number.