State of Florida
Department of Business and Professional Regulation
Division of Drugs, Devices, and Cosmetics

Application for Product Registration – Cosmetics (Main & Identical)
Form No.: DBPR-DDC-228

APPLICATION CHECKLIST – IMPORTANT – Submit all items on the checklist below with your application to ensure faster processing.

APPLICATION	APPLICATION REQUIREMENTS
Application for Product Registration	☐ The biennial registration fee is $30 per MAIN product, $15 per IDENTICAL product. ☐ The registration fee for an amendment to an existing product registration that expires in less than 12 months is $15 PER product. ☐ Make cashier's check, corporate or business check, or money order payable to the Florida Department of Business and Professional Regulation. ☐ Sign and date the Affidavit section of the application.
	Submit the completed application with enclosures to: Department of Business and Professional Regulation 2601 Blair Stone Road Tallahassee, FL 32399-1047

General Application Instructions	
1.	You are ONLY REQUIRED to register products that are physically manufactured, packaged, repackaged, labeled or relabeled IN FLORIDA. If your products ARE NOT physically manufactured, packaged, repackaged, labeled or relabeled IN FLORIDA you DO NOT have to register them.
2.	Although you are not required to register your products with the federal Food and Drug Administration, your product and the accompanying label and labeling must comply with the requirements set forth in 21 CFR 700 (General Cosmetic requirements), 21 CFR 701 (Cosmetic Labeling requirements), and 21 CFR 740 (Cosmetic Product Warning Statement requirements).
3.	If your product is intended to treat or prevent disease or otherwise affect the structure or any function of the human body, it may need to be registered as either an over the counter (OTC) or prescription (Rx) drug.
4.	If your product label or labeling indicates, infers, or otherwise states or represents that the product treats or prevents disease or otherwise affects the structure or any function of the human body, it may need to be registered as either an over the counter (OTC) or prescription (Rx) drug.
5.	If you are manufacturing and/or shipping bulk drug product which product is to be processed, labeled, or repacked at an establishment other than the establishment where the drug was originally processed or packed, you may be exempt from the labeling requirements. [Please see 21 CFR 701.9] If you believe you are exempt, please provide copies of the quality agreements between the manufacturing establishments.
6.	ALL THE INGREDIENTS in the product being registered must be safe for use in cosmetic products for humans. Based upon the initial review of the ingredients, you may be required to provide documentation (e.g. information from the FDA, Cosmetic Ingredient Review Board, or other entities) supporting the safety of the ingredients.
7.	Section 499.015(1)(b), F.S., states: "The department **may not** register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department **does not** mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended."

Section	Specific Application Instructions
I	New vs. Amended Application: If the establishment does not have cosmetic products registered with the department, it is a **NEW** application. If the establishment has cosmetic products registered with the department and this is a new product to add to the existing registration, it is an **AMENDED** application. Product Registration Permit Number: Please list the current DBPR issued permit number for cosmetics registered with the department. If this is a new application and you do not currently have products registered with the department, leave this blank. Florida Cosmetic Manufacturer Permit Number: Please list the current DBPR issued permit for the cosmetic manufacturing establishment. If the establishment is exempt from licensure because containers are not opened, write "**EXEMPT**".
II	Provide the requested information pertaining to the establishment's name, address, etc. If the establishment is **EXEMPT** from licensure, complete this section and complete Section III. Telephone, email, and fax contact information is used to quickly resolve questions with applications. If such information is not provided, questions regarding applications will be mailed to the application contact's mailing address and may take longer to resolve.
III	Provide the requested information pertaining to the establishment's name, ownership, registered agent, and operating hours.
IV	This section is divided into two parts (A) main cosmetic products and (B) identical cosmetic products. For each cosmetic product you register, provide the cosmetic category, name (on the label), and manufacturer's information, and indicate whether the cosmetic is for professional use only. Use the attached CFR cosmetic product category table to assist with your selections. Product Name: The name must be recorded as it will appear on the product label. Note: The adding of color, flavor, or scents does **NOT** make a separate and distinct cosmetic product for each variation and should be listed only once on this application. The additional colors, flavors and scents must be listed on an Identical Product Form. Manufacturer (Preparer/Producer): If you are a labeler or repackager who does not add substances to the product, or you only add color, flavor or fragrances to a product made by another, provide the name, city and state of the manufacturer (preparer/producer).
V	Pursuant to Rule 61N-1.016(1)(b), Florida Administrative Code, a formula marketed under different brand names, sizes, quantities, or distributors is not considered a separate and distinct product for registration purposes. Furthermore, the adding of color, flavor, or scents to a formula does not make a separate and distinct product for registration purposes, even for fragrance preparations where the scent is the primary product. Identical products must offer identical labeling, i.e. same directions for use, same warnings and precautions, etc. However, the variations must be listed on this form. Product labels (including packing inserts, external labels, user's manuals, etc.) and a $15.00 fee are collected for each identical product listed.
VI	This section is the section where you calculate your product registration fee. The section also serves as a final checklist of items that will assist the applicant with completing the application correctly.
VII	An authorized representative of applicant must sign and date this form. The authorized representative should be an owner, officer or employee with authority to bind the establishment to the representations made on the registration application. Include the representative's title (president, owner/operator, facility manager, etc.).

State of Florida
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If you have any questions or need assistance in completing this application, please contact the Department of Business and Professional Regulation, Division of Drugs, Devices and Cosmetics, at **850.717.1800.** ***For additional information see the Instructions at the beginning of this application.***

Section I- Application Type

CHECK ONE OF THE APPLICATION TYPES
☐ New Application (Does not hold current product registration number) [3308/1023]
☐ Amended Application. (Adding new products to existing product registration) [3308/3020]
Product Registration Permit Number: _____
Florida Cosmetic Manufacturer Permit Number: _____

Section II – Applicant Information

APPLICANT'S NAME (Name in which registration will be issued)		
Name:		FEID No.:
PHYSICAL ADDRESS OF ESTABLISHMENT		
Street Address:		
City:	State:	Zip Code (+4 optional):
County (if Florida address):	Country:	
E-Mail Address:	Phone Number: Fax Number:	
MAILING ADDRESS (If different from physical address)		
Street Address:		
City:	State:	Zip Code (+4 optional):
E-Mail Address:	Phone Number: Fax Number:	
APPLICATION CONTACT – Name of the person the department should contact if there are questions regarding this application.		
Last/Surname: First:	Middle:	Suffix:
Address:		
City:	State:	Zip Code (+4 optional):
Telephone Number:	Fax Number:	
E-Mail Address:		

Section III – **Applicants NOT already permitted under Chapter 499, F.S. must provide the following:**

CORPORATE NAME (If different from applicant name)	
Name:	FEID No.:

TYPE OF OWNERSHIP

☐ Publicly Held Corporation	☐ Closely Held Corporation	☐ Limited Liability Company
☐ Not-for-Profit Corporation	☐ Sole Proprietorship	☐ Government
☐ Partnership – Including Limited Liability Partnership and Limited Partnership	☐ Professional Corporation	☐ Professional Limited Liability Company
	☐ Other:_____	

If you checked ANY "Type of Ownership" OTHER THAN "Sole Proprietorship" please list the State of Incorporation or State of Organization.

State:

If you checked ANY "Type of Ownership" OTHER THAN "Sole Proprietorship" please list the name and address of the applicant's Registered Agent for service of process in Florida.

Name:

Address:

City:	State:	Zip Code

OPERATING HOURS

Mon ____:____ am/pm to ____:____ am/pm	Fri ____:____ am/pm to ____:____ am/pm
Tue ____:____ am/pm to ____:____ am/pm	Sat ____:____ am/pm to ____:____ am/pm
Wed ____:____ am/pm to ____:____ am/pm	Sun ____:____ am/pm to ____:____ am/pm
Thu ____:____ am/pm to ____:____ am/pm	

Section IV
A. Main Cosmetic Products

Main Cosmetic Products				
CFR Category (1) – (13):		Name of Cosmetic Product (on label):	Professional Use Only (Y/N):	Manufacturer (if different from applicant): Name, City and State
1.				
2.				
3.				
4.				
5.				
6.				
7.				
8.				
9.				
10.				
11.				
12.				
13.				
14.				
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16.				
17.				
18.				
19.				
20.				
21.				
22.				
23.				
24.				
25.				
YOU MUST ATTACH PRODUCT LABELING FOR EACH PRODUCT YOU ARE SEEKING TO REGISTER. LABELING INCLUDES ALL LABELS AND OTHER WRITTEN, PRINTED OR GRAPHIC MATERIAL ON OR ACCOMPANYING THE PRODUCT.				

Section IV
B. Identical Cosmetic Products:

Identical Cosmetic Products				
Main Product Name: Example COSMETIC-NAME				Main Product ID No. (issued by DBPR): #01234
1.	Name of Identical Product being Registered IDENTICAL COSMETIC-NAME	Size 8 Oz	Manufacturer (if different from applicant): Name, City and State EXAMPLE COMPANY, Tallahassee, FL	
Main Product Name:				Main Product ID No.:
1.	Name of Identical Product being Registered:	Size:	Manufacturer (if different from applicant):	
2.				
3.				
4.				
Main Product Name:				Main Product ID No.:
1.	Name of Identical Product being Registered:	Size:	Manufacturer (if different from applicant):	
2.				
3.				
4.				
Main Product Name:				Main Product ID No.:
1.	Name of Identical Product being Registered:	Size:	Manufacturer (if different from applicant):	
2.				
3.				
4.				
Main Product Name:				Main Product ID No.:
1.	Name of Identical Product being Registered:	Size:	Manufacturer (if different from applicant):	
2.				
3.				
4.				

YOU MUST ATTACH PRODUCT LABELING FOR THE MAIN PRODUCT AND EACH IDENTICAL PRODUCT YOU ARE SEEKING TO REGISTER. LABELING INCLUDES ALL LABELS AND OTHER WRITTEN, PRINTED OR GRAPHIC MATERIAL ON OR ACCOMPANYING THE PRODUCT.

Section V – Final Checklist

FINAL CHECKLIST			
1.	Appropriate Fee Included? Use the space below to calculate your fee.		
	a. Main Product Registrations	(# of products) _____ x $30 = _____	
	b. Amended Product Registrations for product registrations expiring in less than 12 months:	(# of products) _____ x $15 = _____	
	c. Identical Product Registrations	(# of products) _____ x $15 = _____	
		Total Fee: _____	
2.	Product Labeling		
	a.	Did you review 21 CFR 701.9 to determine if you are exempt from the labeling requirements?	Yes ☐ No ☐
	b.	If you are exempt under 21 CFR 701.9 did you provide the quality agreement between the manufacturing establishments? If not, please include the quality agreements for review.	Yes ☐ No ☐
	c.	Did you ensure that your labeling includes warning statements and directions for safe use of the product?	Yes ☐ No ☐
	d.	Did you remember to ensure that your labeling is in English?	Yes ☐ No ☐
	e.	Did you remember to ensure that your labeling was sufficiently large enough that it could be easily read by the reviewer?	Yes ☐ No ☐
	f.	Did you remember to ensure that the principal display panels of your products have a “statement of identity” as required by 21 CFR 701.11?	Yes ☐ No ☐
	g.	Did you remember to ensure that your product label bears a declaration of net quantity of contents as required by 21 CFR 701.13?	Yes ☐ No ☐
	h.	Did you remember to ensure that your product label contain the warnings required by 21 CFR 740?	Yes ☐ No ☐

Section VI – Affidavit

AFFIDAVIT

Each application for a license or renewal of a license issued by the Department of Business and Professional Regulation shall be signed under oath or affirmation by the applicant, or owner or chief executive of the applicant without the need for witnesses unless otherwise required by law.

I certify that I am empowered to execute this application as required by Section 559.79, Florida Statutes. I understand that my signature on this application has the same legal effect as if made under oath. To the best of my knowledge, all information contained on this application is true and correct. I understand the falsification of any information on this application may result in administrative action, including a fine, suspension, or revocation of the license.

I certify that the products listed on this form, which are marketed under different brand names, quantities and/or distributors are the same formula as the referenced product which is registered with the department; the labeling of these products contains identical information in the same manner except for the brand name, quantity and/or distributor.

I CERTIFY THAT I UNDERSTAND THAT THE DIVISION'S REGISTRATION OF ANY OF THE PRODUCTS LISTED IN THIS APPLICATION IS NOT AN ACKNOWLEDGEMENT BY THE DIVISION THAT SUCH PRODUCT COMPLIES WITH THE PROVISIONS OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED, OR FLORIDA'S LAWS AND RULES PERTAINING TO COSMETIC PRODUCTS.

Signature of Owner or Officer:*	Date:
Print Name:	Title:

*** If signed by someone other than an owner or officer, you must submit a letter from an owner or officer authorizing the signer to bind the applicant.**

Mail completed application to:

Department of Business and Professional Regulation
2601 Blair Stone Road
Tallahassee, FL 32399-1047

CFR Product Category: Select the appropriate cosmetic product category to indicate the product's use.	
(1) Baby products.	a) Baby shampoos; b) Lotions, oils, powders, and creams; c) Other baby products
(2) Bath preparations.	a) Bath oils, tablets, and salts; b) Bubble baths; c) Bath capsules; d) Other bath preparations
(3) Eye makeup preparations.	a) Eyebrow pencil; b) Eyeliner; c) Eye shadow; d) Eye lotion; e) Eye makeup remover; f) Mascara; h) Other eye makeup preparations
(4) Fragrance preparations.	a) Colognes and toilet waters; b) Perfumes; c) Powders (dusting and talcum) (excluding aftershave talc); d) Sachets; e) Other fragrance preparations
(5) Hair preparations (noncoloring).	a) Hair conditioners; b) Hair sprays (aerosol fixatives); c) Hair straighteners or Permanent waves; d) Rinses (noncoloring); e) Shampoos (noncoloring); f) Tonics, dressings, and other hair grooming aids; g) Wave sets; h) Other hair preparations
(6) Hair coloring preparations.	a) Hair dyes and colors (all types requiring caution statement and patch test); b) Hair tints; c) Hair rinses (coloring); d) Hair shampoos (coloring); e) Hair color sprays (aerosol); f) Hair lighteners with color; g) Hair bleaches; h) Other hair coloring preparations
(7) Makeup preparations (not eye).	a) Blushers (all types); b) Face powders; c) Foundations; d) Leg and body paints; e) Lipstick; f) Makeup bases; g) Rouges; h) Makeup fixatives; i) Other makeup preparations
(8) Manicuring preparations.	a) Basecoats and undercoats; b) Cuticle softeners; c) Nail creams and lotions; d) Nail extenders; e) Nail polish and enamel; f) Nail polish and enamel removers; g) Other manicuring preparations
(9) Oral hygiene products.	a) Dentifrices (aerosol, liquid, pastes, and powders); b) Mouthwashes and breath fresheners (liquids and sprays); c) Other oral hygiene products
(10) Personal cleanliness.	a) Bath soaps and detergents; b) Deodorants (underarm); c) Douches; d) Feminine hygiene deodorants; e) Other personal cleanliness products
(11) Shaving preparations.	a) Aftershave lotions; b) Beard softeners; c) Men's talcum d) Preshave lotions (all types); e) Shaving cream (aerosol, brushless, and lather); f) Shaving soap (cakes, sticks, etc.); g) Other shaving preparation products
(12) Skin care preparations, (creams, lotions, powder, and sprays).	a) Cleansing (cold creams, cleansing lotions, liquids, and pads); b) Depilatories; c) Face and neck (excluding shaving preparations); d) Body and hand (excluding shaving preparations); e) Foot powders and sprays; f) Moisturizing; g) Night; h) Paste masks (mud packs); i) Skin fresheners; j) Other skin care preparations
(13) Suntan preparations.	a) Suntan gels, creams, and liquids; b) Indoor tanning preparations; c) Other suntan preparations.