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

Application for Product Registration – OTC Drugs (Main & Identical)
Form No.: DBPR-DDC-231

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 1940 North Monroe Street Tallahassee, FL 32399

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.	For each FDA-approved drug, please provide the FDA approval letter or other evidence, such as a printout from the FDA website (http://www.accessdata.fda.gov/Scripts/cder/drugsatfda/index.cfm) reflecting the FDA approval to market the drug in the United States.
3.	If you are relying on an OTC monograph as the basis for your being able to market the drug in the United States, YOU MUST provide the citation to the specific OTC monograph from the Code of Federal Regulations; failure to provide citation to the OTC monograph will result in denial of the application.
4.	For each drug that is not approved by the FDA, e.g. drugs that are the subject of pending Drug Efficacy Study Implementation (DESI) proceeding(s), drugs that are marketed pursuant to the grandfather provisions under the federal Food, Drug and Cosmetic Act, etc., YOU MUST provide documentation that the product is currently able to be distributed into interstate commerce as per the FDA regulations as described in Rule 61N-1.016(2), F.A.C.; failure to provide the requested documentation may result in denial of the application.
5.	If you are manufacturing and/or distributing a drug in bulk package, except tablets, capsules, or other dosage unit forms, intended for processing, repackaging, or use in the manufacture of another drug, you may be exempt from the labeling requirements. [Please see 21 CFR 201.122].
6.	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 201.150]. If you believe you are exempt, please provide copies of the quality agreements between the manufacturing establishments.
7.	PLEASE DO NOT attempt to register a product if it is pending FDA review and approval; submitting such a product slows down the division's review process.
8.	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 drug products registered with the department, it is a **NEW** application. If the establishment has drug 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: Record the current DBPR issued permit number for drugs registered with the department. Leave blank if this is a new application. Florida Over-the-counter Drug Manufacturer Permit Number: Please list the current DBPR issued permit for the drug establishment.
II	Provide the requested information pertaining to the establishment's name, address, etc. 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 OTC drug products and (B) identical OTC drug products. List each product separately, providing the requested information for each product. Product Name: The name must be recorded as it will appear on the product label. Manufacturer: If the establishment registering the product is not the preparer or producer of the product, provide the name of the preparer or producer along with the city and state where the product was manufactured. Labeling: Please provide the product labeling for all products. If the lot # and expiration date are on the immediate container at the time of manufacturing, the labeling provided for review by the Department must include a visual representation of the final labeling which accurately represents the placement of the lot# and expiration date. IF THE PRODUCT LABELS AND LABELING HAVE BEEN APPROVED BY THE FDA, PLEASE SUBMIT THE SAME LABELS AND LABELING FOR REVIEW. PLEASE ENSURE THAT THE LABELING IS OF SUFFICIENT SIZE THAT IT CAN BE READ, EVEN IF THIS MEANS THE LABELING PROVIDED IS LARGER THAN THE ACTUAL LABELING INCLUDED WITH THE PRODUCT.
V	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.
VI	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.).

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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) [3308/1022] ☐ Amended Application. (Adding new products to existing product registration) [3308/3020] Product Registration Permit Number: _____ Florida Over-the-Counter Drug 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 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 OTC Products

Main OTC Drug Products				
	Drug information (Name should be the same as it appears on the label):			Manufacturer (if different from applicant): Name, City and State
1.	Name:			FDA Establishment no: _____ Name:
	Strength:	Dosage Form:	Bulk? ☐ Yes ☐ No	
	☐ NDC# ☐ n/a _____			☐ Citation to OTC Monograph: _____
2.	Name:			FDA Establishment no: _____ Name:
	Strength:	Dosage Form:	Bulk? ☐ Yes ☐ No	
	☐ NDC# ☐ n/a _____			☐ Citation to OTC Monograph: _____
3.	Name:			FDA Establishment no: _____ Name:
	Strength:	Dosage Form:	Bulk? ☐ Yes ☐ No	
	☐ NDC# ☐ n/a _____			☐ Citation to OTC Monograph: _____
4.	Name:			FDA Establishment no: _____ Name:
	Strength:	Dosage Form:	Bulk? ☐ Yes ☐ No	
	☐ NDC# ☐ n/a _____			☐ Citation to OTC Monograph: _____
5.	Name:			FDA Establishment no: _____ Name:
	Strength:	Dosage Form:	Bulk? ☐ Yes ☐ No	
	☐ NDC# ☐ n/a _____			☐ Citation to OTC Monograph: _____
6.	Name:			FDA Establishment no: _____ Name:
	Strength:	Dosage Form:	Bulk? ☐ Yes ☐ No	
	☐ NDC# ☐ n/a _____			☐ Citation to OTC Monograph: _____
7.	Name:			FDA Establishment no: _____ Name:
	Strength:	Dosage Form:	Bulk? ☐ Yes ☐ No	
	☐ NDC# ☐ n/a _____			☐ Citation to OTC Monograph: _____
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 OTC Drug Products

Identical OTC Drug Products			
Main Product Name: Example DRUG-NAME; Active Ingredients 5%, Single Dose; Quantity			Main Product ID No. (issued by DBPR): #01234
1.	Name of Identical Product being Registered IDENTICAL DRUG-NAME, Active ingredient, 5%, Single Dose	Size 32 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 provide documentation as required by 61N-1.016(2)(a), F.A.C., for the drugs you are registering that are not FDA approved (e.g., DESI, grandfathered, other, etc.)?	Yes ☐ No ☐ N/A ☐
b.	If you are relying on an OTC monograph as the basis for your being able to market the drug in the United States, did you provide the citation to the OTC monograph from the Code of Federal Regulation?	Yes ☐ No ☐ N/A ☐
c.	Did you review 21 CFR 201.122 and 21 CFR 201.50 to determine if you are exempt from the labeling requirements?	Yes ☐ No ☐ N/A ☐
d.	If you are exempt under 21 CFR 201.50 did you provide the quality agreement between the drug manufacturing establishments? If not, please include the quality agreements for review.	Yes ☐ No ☐ N/A ☐
e.	Did you remember to ensure that your labeling is in English?	Yes ☐ No ☐
f.	Did you remember to ensure that your labeling includes directions for use? Indications? Warnings? Inactive Ingredients?	Yes ☐ No ☐
g.	Did you remember to ensure that your labeling was sufficiently large enough that it could be easily read by the reviewer?	Yes ☐ No ☐
h.	Did you remember to ensure that labeling on your bulk products include recommended or usual dosage and the type of container to be used to dispense the product?	Yes ☐ No ☐ N/A ☐

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
1940 North Monroe Street
Tallahassee, FL 32399