

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

**Application for a Cosmetic Manufacturer
 Form No.: DBPR-DDC-206**

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

APPLICATION	APPLICATION REQUIREMENTS
<p>Application for Permit as a Cosmetic Manufacturer</p>	<ul style="list-style-type: none"> <input type="checkbox"/> Submit fee of \$950.00, which includes \$800.00 application fee and \$150.00 initial application/on-site inspection fee. If establishment is applying for multiple manufacturing permits in the applicant’s name and at applicant’s address, you are only required to pay for the permit with the highest fee. <input type="checkbox"/> Make cashier’s check or money order payable to the Florida Department of Business and Professional Regulation. <input type="checkbox"/> If you answer “Yes” to any question in Section IV, be sure to provide a detailed explanation along with any relevant documentation. <input type="checkbox"/> Sign and date the Affidavit section of the application.
	<p>Submit the completed application with enclosures to: Department of Business and Professional Regulation 1940 North Monroe Street Tallahassee, FL 32399</p>

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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
<input type="checkbox"/> New Application [3306/1020]
<input type="checkbox"/> New Application due to change in ownership. If checked, provide legal documentation for the change of ownership (i.e. Bill of Sale, stock transfer, merger). [3306/1020] Current Permit Number _____

Section II – Applicant Information

APPLICANT INFORMATION		
Federal Tax Identification Number:		
FULL LEGAL NAME		
Applicant's Full Legal Name:		
FICTITIOUS, TRADE OR BUSINESS NAME (applies only if different from full legal name)		
Full Fictitious, Trade or Business Name (sometimes "d/b/a" or "dba"):		

Note: This name will appear on the permit and must be used on the applicant's operational documents for permitting activities.		
If the applicant intends to operate under a fictitious, trade or business name, provide the corresponding registration number from the Florida Secretary of State, Division of Corporations: _____		
APPLICANT'S MAILING ADDRESS		
Street Address or P.O. Box:		

City:	State:	Zip Code (+4 optional):
PHYSICAL ADDRESS OF ESTABLISHMENT TO BE PERMITTED		
Street Address:		

City:	State:	Zip Code (+4 optional):
County (if located in Florida):	Country:	
E-Mail Address:	Phone Number:	Fax Number:
_____	_____	_____

APPLICATION CONTACT			
Whom should the department contact with questions regarding this application?			
Last/Surname:	First:	Middle:	Suffix:
Address:			
City:		State:	Zip Code (+4 optional):
Telephone Number:		Fax Number:	
E-Mail Address:			
EMERGENCY CONTACT INFORMATION			
Last/Surname:	First:	Middle:	Suffix:
Position/Title:			
Residence Address (must be different than establishment physical address):			
City:		State:	Zip Code (+4 optional):
Residence Phone Number:		E-Mail Address:	
OPERATING HOURS			
List Operating Hours – minimum 10 total per week (M-F) between 8:00 a.m. and 5:00 p.m. Eastern Standard Time, and at least 2 consecutive hours on at least 1 day:			
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 III – Ownership Information

TYPE OF OWNERSHIP		
<input type="checkbox"/> Publicly Held Corporation	<input type="checkbox"/> Closely Held Corporation	<input type="checkbox"/> Limited Liability Company
<input type="checkbox"/> Charitable Organization—501(c)(3)	<input type="checkbox"/> Sole Proprietorship	<input type="checkbox"/> Government
<input type="checkbox"/> Partnership – General	<input type="checkbox"/> Professional Corporation or Association	<input type="checkbox"/> Professional Limited Liability Company
<input type="checkbox"/> Partnership – Other, Including Limited Liability Partnership and Limited Partnership	<input type="checkbox"/> Other: _____	
List the state of incorporation or state of organization (except Partnership – General or Sole Proprietorship). Business entities organized under non-U.S. laws list the country of organization.		
State:		

List name and address of the applicant's registered agent for service of process in Florida (except Sole Proprietorship or Partnership – General).

Name:

Address:

List the name, position/title, date of birth and percentage of ownership, if applicable, for the applicant's owners, partners, members, managers, and corporate officers/directors.

Name	Position/Title	Date of Birth	% of Ownership

List all trade or business names used by the applicant. Use additional sheet(s) if necessary.

Is the applicant a subsidiary of another company? (If yes, provide a listing of all parent companies with percentages of ownership. Please note: A permit issued pursuant to this application is only valid for the applicant's name and address.) Yes No

Parent Company Name	% of Ownership

Section IV – Background Questions

BACKGROUND QUESTIONS			
1.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant or any "affiliated party" (defined below) been found guilty (regardless of adjudication) or pled nolo contendere in any jurisdiction of a violation of law that directly relates to a drug, device or cosmetic?
2.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant or any affiliated party been fined or disciplined by a regulatory agency in any state (including Florida) for any offense that would constitute a violation of Chapter 499, F.S.?
3.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant or any affiliated party been convicted (regardless of adjudication) of any felony under a federal, state (including Florida), or local law?
4.	<input type="checkbox"/> Yes If yes, explain in detail in Section V	<input type="checkbox"/> No	Has the applicant or any affiliated party been denied a permit or license in any state (including Florida) related to an activity regulated under Chapters 456, 465, 499, 893, F.S.?

Section VI – Other Permits or Licenses

PERMITS OR LICENSES			
1.	Are there any other permits or licenses issued by any agency of the State of Florida that authorize the purchase or possession of prescription drugs at the applicant's establishment or address? (If yes, provide the name in which the permit is issued, the permit type, & permit number.)		<input type="checkbox"/> Yes <input type="checkbox"/> No
1a.	Permit/License Name	Permit/License Type	Permit/License Number

Section VII – Cosmetic Manufacturing Activity

MANUFACTURING ACTIVITIES			
Identify type of operation.			
<input type="checkbox"/> Mixing	<input type="checkbox"/> Repackaging	<input type="checkbox"/> Final Labeling for Distribution	
Provide your Federal Food and Drug Administration (FDA) establishment registration number.			
FDA Establishment Registration Number: _____			
1.	Are products distributed under this permit intended for export?		<input type="checkbox"/> Yes <input type="checkbox"/> No
2.	Are all required records stored and maintained at applicant's physical address? (If no, provide the establishments address where all required records will be stored and maintained below.)		<input type="checkbox"/> Yes <input type="checkbox"/> No
2.a	Physical address where required records are stored Street Address:		
	City:	State:	Zip Code (+4 optional):
3.	Are the required records computerized, automated or stored electronically? If yes, do you have a back-up procedure to be able to provide required records?		<input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> Yes <input type="checkbox"/> No
4.	Are you submitting a product registration application and labels of your products with this application? (If no, explain on a separate sheet providing accurate details.)		<input type="checkbox"/> Yes <input type="checkbox"/> No
5.	Do you have labels of your products ready for inspection?		<input type="checkbox"/> Yes <input type="checkbox"/> No
6.	Do you manufacture a product that has a sunscreen (SPF)? (If yes, and Over-the-Counter Drug Manufacturer permit is required.)		<input type="checkbox"/> Yes <input type="checkbox"/> No
7.	Do you intend to comply with all Federal and State "Current Good Manufacturing Practices"?		<input type="checkbox"/> Yes <input type="checkbox"/> No
8.	Does the applicant have written policies and procedures to include: storage, distribution/disposition, record maintenance/retrieval/retention, recalls and withdrawals?		<input type="checkbox"/> Yes <input type="checkbox"/> No
9.	Provide the date the establishment will be ready and available for inspection.		____/____/20____ This is the earliest date the application may be deemed complete.

Section VIII – 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 owner or corporate officer 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.

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