

Date App Recd _____	Check _____
Date Permit issued _____	Permit No. _____
(leave blank for Board use)	



CANNON BUILDING
861 SILVER LAKE BLVD., SUITE 203
DOVER, DELAWARE 19904-2467

STATE OF DELAWARE
DEPARTMENT OF STATE
DIVISION OF PROFESSIONAL REGULATION
BOARD OF PHARMACY
APPLICATION FOR MANUFACTURER PERMIT

TELEPHONE: (302) 744-4500
FAX: (302) 739-2711
WEBSITE: WWW.DPR.DELAWARE.GOV

(For Board of Pharmacy Use Only) :	
_____	_____
Office Apprvl.	Inspection

This application must be accompanied by a non-refundable processing fee.
Please refer to the Fee Schedule at www.dpr.delaware.gov for the correct fee.

To Manufacture or package Drugs, Medicines, Toilet Articles, Dentifrices or Cosmetics.

THE UNDERSIGNED hereby makes application for a permit to manufacture drugs, medicines, toilet articles, dentifrices or cosmetics in pursuance of Title 24 *Del. C.* §2541, which provides in part as follows:

"No drugs, or medicines, or toilet articles, or dentifrices or cosmetics, shall be manufactured, made, produced, packed, packaged, or prepared within this State, except under the personal and immediate supervision of a registered pharmacist or such other persons as may be approved by the Delaware State Board of Pharmacy after an investigation and determination by the said Board that they are qualified by scientific or technical training and/or experience to perform such duties of supervision as may be necessary to protect the public health and safety; and no person shall manufacture, make, produce, pack, package or prepare any such articles without first obtaining a permit to do so from the said Board of Pharmacy. Such permit shall be subject to such rules and regulations, with respect to sanitation and/or equipment, as the said Board of Pharmacy may from time to time adopt for the protection of the public health and safety."

According to 24 *Del. C.* §2543 permits are not transferable and expire on the last day of September biennially even years. Separate applications shall be made and separate permits issued for each separate place of manufacture, making, production, packing, packaging or preparation."

"Any person, firm or corporation violating any of the provisions of this section, and any permittee hereunder who shall violate any of the conditions of his permit or any of the rules or regulations adopted by the said Board of Pharmacy in pursuance of the power hereby conferred, shall, upon conviction, be deemed guilty of a misdemeanor and fined not more than fifty (\$50) dollars for each offense, and each and every day such violation continues shall constitute a separate and distinct offense; and, upon conviction of a permittee hereunder, his permit shall also forthwith be revoked and become null and void."

Section 1. Name of manufacturer or packager: _____
Address: _____
Phone: (___) _____
Email: _____

Section 2. When was business established? _____

Section 3. States in which you conduct a similar business? If yes, give dates and locations: _____

Section 4. If corporation, give date of charter and names of principal officers:

Section 5. By what State was charter granted? _____

Section 6. If partnership, give names of all active partners: _____

Section 7. If individually owned, give name and address of owner:

Name: _____

Address: _____ City: _____ State: _____ Zip _____

Section 8. Will the firm be trading under another name? Yes No

Section 9. Has corporation or any officers thereof, or any partner, or the individual owner ever been convicted of violations of any Federal laws or State Laws dealing with drugs or alcohol? Yes No

Section 10. Has the firm been found guilty of violating any Statutes or regulations by any State or Federal Drug Agency: (example Food and Drug Administration or Drug Enforcement Administration). If yes, provide detailed information. Yes No

Section 11. Is firm now registered with the Food and Drug Administration or the Drug Enforcement Administration? Attach results of last GMP inspection. Yes No

Section 12. List the products the firm will package or manufacture: _____

Section 13. Scientific and technical personnel:

Names of registered pharmacists employed: _____

(2) If no registered pharmacists are employed, give:

(a) Names of persons personally supervising scientific or technical operations in the plant.

(b) Attach, in each case, the scientific and technical training and/or experience of persons listed in the preceding paragraph, including colleges attended and scholastic degrees.

Section 14. Specify, in sufficient detail, all apparatus and equipment used in the manufacture of products:

Section 15. Sanitation: Give an adequate description of the general sanitary facilities of the plant including sanitary plumbing, light and ventilation, soap, towels, etc. (use additional sheets)

To assure consideration of your license application at the next Board meeting, the Board office must receive all of these items no later than 4:30 PM ten full working days before the Board's meeting date:

- Completed, signed and notarized application form
- Fee payment
- All required supporting documentation.

Please note: When your application is complete, please allow 4-8 weeks to receive your license. A complete application is one that includes all required documentation and correct payment.

Applications that are not complete within six (6) months of filing may be considered abandoned and discarded. The Board office will attempt to notify you before disposing of an abandoned application.

(Signed)

(Official Title)

Subscribed and sworn to before me

This _____ day of _____

Notary Public