DRUG MANUFACTURING LICENSE APPLICATION
PLEASE COMPLETE THIS FORM FULLY—INCOMPLETE APPLICATIONS WILL BE RETURNED
See Page 3 for Instructions

License Number (if not new): _____

☐ **NEW APPLICANT** ☐ **OWNERSHIP CHANGE**
☐ **RENEWAL APPLICANT** ☐ **RELOCATION**—Previous Address: _____

1. Name of Firm			6. Mailing Address (if different or P.O. Box number)		
2. DBA (Use other sheets as needed)			7. Mailing Address (continued)		
3. Facility Address (number, street)			8. City	State	ZIP Code
4. Facility Address (continued)			9. Country (if other than United States)		
5. City	State	ZIP Code	10. Website (URL)		

11. Interstate Commerce
☐ Product Shipped ☐ Product or Raw Materials Received ☐ N/A

12. Type ownership ***Please attach evidence of ownership****
☐ Individual/Sole Proprietorship ☐ Partnership ☐ Corporation ☐ Limited Liability Corporation
☐ Non Profit ☐ Other

13. Owner's Name/Corporate Name (if applicable)	State of Incorporation
14. Owner's or Officers' Names and Titles	Owner's or Officers' Names and Titles

15. Associated California Board of Pharmacy Number: _____

16. Size of facility (square feet): _____

Number of Employees at this Facility: _____ Business Days and Hours: _____

17. Intended Drug Destination (Check all that apply)
☐ Commercial Distribution ☐ Human Clinical Trials (Investigational Use) ☐ California Distribution Only ☐ U.S. Distribution ☐ Export Market

18. Type of Product
☐ Prescription ☐ Over-the-Counter ☐ Both

If *Prescription* or *Both* is checked complete the Disclosure Statement form (CDPH 53). Refer to PDMA requirements on instruction page 3.

19. Drug Products Manufactured at this Location (Check all that Apply)

DEA Number (Attach copy of DEA Certificate): _____

☐ 700 Bulk Pharmaceuticals (API)
☐ 701 Medical Gases
☐ 702 Radioactive
☐ 703 Veterinary
☐ 704 Controlled Substances Schedule: _____
☐ 705 Approved New Drug
☐ 706 Investigative New Drugs (IND)
☐ 707 Biotech
☐ 708 Biologics
☐ 709 Parenteral
☐ 710 Oral Dose (Solid/Liquid)
☐ 711 Pre-IND
☐ 712 Topical
☐ Other (Specify): _____

PLEASE CONTINUE TO NEXT PAGE

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20. Manufacturing processes or activities employed or planned in the manufacture of the drugs listed above. Indicate if these processes or activities will be done at this location (in-house) or by a contract. List other processes using additional sheets if necessary (Check all that apply)

Processes of Activities	In-House	Contract	Process or Activities	In-House	Contract
Aerosolization	☐	☐	Powder Mixing	☐	☐
Aseptic	☐	☐	Relabel Only	☐	☐
Coating	☐	☐	Repackage Only	☐	☐
Emulsification	☐	☐	Sterilization	☐	☐
Encapsulation	☐	☐	Suspension	☐	☐
Fermentation or Tissue culture viral vector or gene therapy	☐	☐	Tableting	☐	☐
Liquid Mixing	☐	☐	Other (Specify): _____	☐	☐

21. Payment Code (Check all that apply)

☐ A	$4,187.00	Base Fee	Fee is due at the time application is submitted and is NON-REFUNDABLE
☐ B	$ 200.00	PDMA	If applicable – see page 3
☐ C	$ 10.00	Late Fee	If over 30 days past license expiration date
	$ _____	TOTAL AMOUNT DUE	Payable to: CA Department of Public Health

22. If you meet one of the listed criteria below FDB can issue a license without first inspecting your facility. Check the appropriate box(es) and attach documentary evidence.

- ☐ A copy of a valid biologics license issued by the U.S. Food and Drug Administration (FDA)
- ☐ A copy of a valid establishment registration pursuant to Section 510 of the federal act and attestation that a federal inspection was completed within the last two years
- ☐ A copy of documentation demonstrating compliance with audits conducted pursuant to International Organization for Standardization (ISO) ISO standards (ISO 9000 series, ISO 13485:2003, ISO 15378:2006)
- ☐ A copy of an approved investigational new drug application

☐ None of the above apply (Inspection will be required)

The Food and Drug Branch **MUST BE NOTIFIED IMMEDIATELY** of any changes in the above information as provided by California Health and Safety Code, Section 111630. **Under penalties of perjury, I declare that the information included with this application and all attachments are true, correct, and complete. I also give permission for the below authorized representatives and/or signatories to speak about the application with CDPH.**

23.Owner's Signature	Owner's Printed Name	Title Owner/	Date

Authorized Representatives and/or Signatories:

24. Business Operator Name	25. Telephone Number	26. Emergency Number	27. E-Mail Address
28. Correspondent Name	29. Telephone Number	30. Alt Phone Number	31. E-Mail Address

End of Application. Please note: All boxes must be completed.

License Number	Expiration Date	Date Received	Payment Type	Amount $

DRUG MANUFACTURING LICENSE APPLICATION INSTRUCTIONS

A separate application is required for each place of business. Please complete and/or amend this application as is most appropriate to your facility. Include the appropriate fee for each application and make payable to: CA DEPARTMENT OF PUBLIC HEALTH. The fee must accompany this application or it cannot be processed. Unsigned or incomplete applications cannot be processed. The following are further instructions on how to complete this application:

New Applicant: Place an (X) in the box next to New Applicant if your firm has not previously applied for a Drug Manufacturing License at this location while under the current ownership. **This license is non-transferable.** If your firm has changed location, ownership, or both, place an (X) in the appropriate box **and also** in the box next to New Applicant. For renewal applications, place an (X) in the box next to Renewal. For any section that does not apply to your company, please indicate with (N/A). **Do not leave any sections blank.**

1. **Name of Firm:** Enter full name of business, corporation, company, or organization applying for licensure.
2. **DBA:** Enter any other name(s) your company is doing business as.

3.–5. **Facility Address:** Enter the number, street, city, state, and ZIP code for this facility location.

6.–8. **Mailing Address:** Enter the full mailing address if different from the facility address or P.O Box.

9. **Country:** Enter the country where your facility is located.
10. **Website:** Enter the website address for your business, if applicable.
11. **Interstate Commerce:** Place an (X) in all appropriate boxes that correctly describe your business' receipt or distribution of products or materials through or into interstate commerce.
12. **Type of ownership:** Place an (X) in the box next to the appropriate legal description of the facility's ownership. Attach evidence of ownership.
13. **Owner's or Corporate Name. State of Incorporation:** List the business owner's name or corporate name. Identify the state of incorporation.
14. **Owner's or Officers' Names and Titles:** List other business owner's names or officers' names and titles. Use additional sheets if necessary.
15. List the **Associated California Board of Pharmacy License Number** if applicable.
16. **Size of Facility:** Indicate the approximate size (in square feet) of the facility and the approximate number of employees at the facility and list the business days and hours.
17. **Intended Drug Destination:** Place an (X) in the box adjacent to the destination(s) for your manufactured products. Check all that apply.
18. **Type of Product:** Place an (X) in the box that applies to each type of drugs manufactured or to be manufactured. For human prescription (Rx) drug manufacturers, refer to PDMA requirements below.
19. **Drug Products Manufactured:** Place an (X) in the box adjacent to each product area that applies to the drugs manufactured or to be manufactured. Use additional sheets if necessary. (Attach a copy of the DEA certificate)
20. **Manufacturing Processes:** Place an (X) in the columns adjacent to all the applicable processes to be performed in-house and/or contracted out. Leave line blank if the indicated process will not be applied to the manufacturing to listed drugs. List additional processes or methods as needed herein or on additional sheets if necessary.

PLEASE CONTINUE TO NEXT PAGE

DRUG MANUFACTURING LICENSE APPLICATION INSTRUCTIONS

21. **Payment Code:** Place an (X) in the box adjacent to each applicable fee.

Payment Type	Fee	Description	Code
New, Relocation, Ownership change, or Renewal	$4,187	Base Fee, due at time of application	A
PDMA	$200	If applicable. See below	B
Late Fee	$10	Due if over 30 days past license expiration date	C

PDMA (Prescription Drug Marketing Act) Requirements: *If your firm manufactures human prescription (Rx) drugs, an additional **$200** must be added to the license fee and a **Disclosure Statement (Form CDPH 53) must be submitted for each person listed on lines #13, #14, and #24 (instructions provided therein)**.*

LICENSE FEES ARE NON-REFUNDABLE AND NON-TRANSFERABLE TO OTHER LOCATIONS OR ENTITIES

a. Enter license fee according to payment codes above. **(License valid for 2 years)**
b. Add $200 PDMA fee if it applies to your firm. **See PDMA requirements above.**
c. Enter Total Payment Due by adding "A" and "B" and "C".

22. **Inspection Criteria:** Attach U.S. Food and Drug (FDA) or International Organization for Standardization (ISO) Standard Documents. Place an (X) in the appropriate box(es) for the items that you are submitting with the application. For more information regarding this requirement refer to the California Health and Safety Code Section 111635. If you meet any of the listed criteria on the application by providing documentary evidence, FDB can issue a license without first inspecting your place of business. The documentary evidence must be valid for your current establishment. If no criteria are met, an inspection will be required.
23. **Owner's Signature:** Sign the application. Print the signer's signature, title, and indicate signature date. All signatures must be original.

24.-27. **Business Information:** Print the business operator's name, title, business and emergency telephone number, and E-Mail address.

28.-31. **Correspondent Information:** Please print the correspondent's name, title, telephone number, and email address.

Please make all checks payable to: **CA Department of Public Health** Mail Application and checks to:			
Regular Mail:	California Department of Public Health Food and Drug Branch – Cashier MS 7602 P.O. Box 997435 Sacramento, CA 95899-7435	Overnight Mail:	California Department of Public Health Food and Drug Branch – Cashier 1500 Capitol Avenue, MS-7602 Sacramento, CA 95814

If you have any questions about this application, please contact the FDB License Desk for Drug Manufacturing at (916) 650-6500, (800) 495-3232.