BIENNIAL DRUG MANUFACTURING LICENSE RENEWAL APPLICATION

PLEASE COMPLETE THIS FORM FULLY—INCOMPLETE APPLICATIONS WILL BE RETURNED

See Page 2 for Instructions

1. Legal Name of Firm	9. Facility Operator (name and title)
2. DBA (List additional DBAs on separate sheet if necessary.)	10. Facility Telephone Number ( ) / 11. Facility FAX Number ( )
3. Facility Address (number, street)	12. 24-Hour Emergency Telephone Number ( ) / 13. E-Mail Address
4. Facility Address (continued)	14. Correspondent (name and title)
5. City / State / ZIP Code	15. Correspondent Telephone Number ( ) / 16. Correspondent FAX Number ( )
6. Mailing Address (if different or P.O. Box number)	17. County
7. Mailing Address (continued)	18. Website (URL)
8. City / State / ZIP Code	19. Interstate Commerce ☐ Product Shipped ☐ Product or Raw Materials Received ☐ N/A

20. Type of Ownership ☐ Individual/Sole Proprietorship ☐ Partnership ☐ Corporation/Limited Liability Company ☐ Nonprofit ☐ Other:_____

21. Corporate Name (if applicable)	State of Incorporation
22. Owners' or Officers' Names and Titles	Owners' or Officers' Names and Titles (Attach separate sheet if necessary)
23. Previous CDPH - FDB License Number(s): _____	Associated California Board of Pharmacy License Number:_____

24. Size of Facility (square feet):_____
☐ Number of Employees at this Facility_____ ☐ Business days and hours_____

25. Stage of Manufacture at Date of Application (check all that apply)
☐ Manufacturing products ☐ Validation – Completion Date:_____ Other (specify):_____

26. Intended Drug Destination (check all that apply)
☐ Commercial distribution ☐ Human clinical trials (investigational use) ☐ California distribution only ☐ U.S. distribution ☐ Export market

27. Type of Drug Product (check all that apply)
☐ Prescription* ☐ Over-the-counter ☐ Both*
***If *Prescription* or *Both* is checked complete the Disclosure Statement form (CDPH53); Refer to PDMA requirements on instruction page 2.**

28. Drug Products Manufactured at this Location (check all that apply)

☐ 700 Bulk pharmaceuticals (API)	☐ 704 Controlled substances (schedule: _____ DEA#:_____ (attach copy of DEA certificate)	
☐ 701 Medical gases	☐ 706 Investigational New Drugs (IND)	☐ 710 Oral Dose (solid/liquid)
☐ 702 Radioactive	☐ 707 Biotech	☐ 711 Pre-IND
☐ 703 Veterinary	☐ 708 Biologics	☐ 712 Topical
☐ 705 Approved New Drug	☐ 709 Parenteral	☐ Other (specify):_____

29. Manufacturing processes/activities employed or planned in the manufacture of the drugs listed above. Indicate if these processes/activities will be done at this location (in-house) or by a contract. List other processes using additional sheets, if necessary. (Check at least one or more.)

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

30. Payment Code
☐ **A — $3,988 (Fee is due at the time application is submitted and is Non-Refundable)**
☐ **B — $ 200 PDMA*** (if Applicable – see page 2)
☐ **C — $ 10** Late Fee (if over 30 days late)
$ Total Payment Due

31. Please attach: ☐ Evidence of ownership **and** one of the following:
☐ 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** an 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

The Food and Drug Branch MUST BE NOTIFIED of any change in the application information as provided by CA Health and Safety Code, §111630.

By signature, I declare under penalty of perjury that all information provided herein, including any supplemental documentation hereto, is true and correct.

32. Signature	Printed Name	Title	Date

PLEASE DO NOT WRITE BELOW THIS LINE.

Biennial Drug Manufacturing License Renewal 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 check payable to: CA DEPARTMENT OF PUBLIC HEALTH. The fee must accompany this application or it cannot be processed. **Please apply within 30 days of expiration**; failing to do so requires an additional $10 penalty added to the renewal fee before the license is issued. Unsigned or incomplete applications cannot be processed. The following are further instructions on how to complete this application:

Renewal Status: This license is non-transferable. If your firm has changed location, ownership, or both, use the application titled "New Drug Manufacturing License Application" (CDPH 52N). For any section that does not apply to your company, please indicate with (N/A). **Do not leave any sections blank**.

1. **Legal 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.

9. **Facility Operator:** Enter the full name(s) of the person(s) in charge of drug manufacturing at this facility and their title(s).
10. **Facility Telephone Number:** Enter daytime business telephone number of this facility.
11. **Facility FAX Number:** Enter facility FAX number.
12. **24-Hour Emergency Telephone Number:** Enter telephone number to be called in the event of an emergency.
13. **E-mail Address:** Enter facility e-mail address.
14. **Correspondent:** Enter the name of the person to contact for information regarding this application and their title.
15. **Correspondent Telephone Number:** Enter the daytime business telephone number of the contact person.
16. **Correspondent FAX Number:** Enter the daytime business FAX number of the contact person.
17. **County:** Enter where your facility is located, if outside the United States
18. **Website:** Enter the website address for your business, if applicable.
19. **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.
20. **Type of Ownership:** Place an (X) in the box next to the appropriate legal description of the facility's ownership.
21. **Corporate Name:** Enter corporate name if applicable. Enter state of incorporation if applicable.
22. **Owners' or Officers' Names:** List the business owners' or officers' names and titles. *USE ADDITIONAL SHEETS IF NECESSARY*.
23. List **previous California Department of Public Health - Food and Drug Branch License Number(s)** if applicable.
24. **Size of Facility**: Indicate the approximate size (in square feet) of the facility and the approximate number of employees at the facility and list business days and hours.
25. **Stage of Manufacture:** Place an (X) in the box next to the stage of manufacture your products are in at the time of application submission. Check all that apply.
26. **Intended Drug Destination:** Place an (X) in the box adjacent to the destination(s) for your manufactured products. Check all that apply.
27. **Types of Products:** Place an (X) in each box that applies to each type of drugs manufactured or to be manufactured. For human prescription (Rx) drug manufacturers, refer to PDMA requirements below*****.
28. **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.
29. **Manufacturing Processes:** Place an (X) in the columns adjacent to all 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 of listed drugs. List additional processes or methods as needed herein or on additional sheets if necessary.
30. **Payment Fee Code:** Your license fee is based on the application type ******.

Application Type	*Fee*	*Payment Interval*	*Payment Code*
Renewal	$3,988	Biennially on Renewal	A
*PDMA	$ 200	Biennially on Renewal	B
	$ 10	Late Fee (if over 30 days late)	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 #9 and #22 (instructions provided therein)**. Information relevant to the PDMA, (e.g., Disclosure Statements and Applicant Fingerprint Live Scan requirements) can be reviewed in the online application.*

**** 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. Add $10 late fee due, if renewal application is over 30 days late.
D. Enter Total Payment Due by adding A, B, and C.

31. Attach **Evidence of Ownership and U.S. Food and Drug Administration (FDA) or International Organization for Standardization (ISO) Standards Documents** and place an (X) in the appropriate box(es) for the items that you are submitting with this application. For more information regarding this requirement, please refer to the California Health and Safety Code Section 111635.

32. Sign the application, print your name, print your title, and enter the date. All signatures must be original.

Make checks payable to: CA DEPARTMENT OF PUBLIC HEALTH Mail Application and Check to: (below)

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 at (916) 341-7354, (800) 495-3232, or visit our website.