# DRUG MANUFACTURING LICENSE APPLICATION

**All fields must be completed. Incomplete applications will result in delayed license issuance.**

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. Mailing City | State | ZIP Code |
| 4. Facility Address (continued) | | | 9. Country (if other than United States) | | |
| 5. Facility City | State | ZIP Code | 10. Website (URL) | | |

## Authorized Representatives:

| | | | |
|---|---|---|---|
| 11. Owner or Manager Name | 12. Telephone Number | 13. Emergency Number | 14. E-Mail Address |
| 15. Contact Name for Facility | 16. Telephone Number | 17. Alternate Cell Phone # | 18. E-Mail Address |

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

20. Type of Ownership (**Must attach evidence of ownership)**
☐ Individual/Sole Proprietorship ☐ Partnership ☐ Corporation
☐ Limited Liability Corporations ☐ Non-Profit ☐ Other:

| | |
|---|---|
| 21. Corporate Name (if applicable) | State of Incorporation |
| 22. Owner's and/or Corporate Officers' Names and Titles | Owner's and/or Corporate Officers' Names and Titles |
| | |

23. Associated California Board of Pharmacy Number:

24. Size of facility
(square feet): No. of Employees at this Facility: Business Days and Hours:

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

| | |
|---|---|
| 26. Type of Product<br>☐ 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. |

**-Continue-**

27. **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):

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

29. Payment Code (Check all that apply)

| | | | |
|---|---|---|---|
| ☐ A | $4,616.00 | Base Fee | Fee is due at the time application is submitted and is NON-Refundable |
| ☐ B | $ 200.00 | PDMA | If applicable-see page 4. |
| ☐ C | $ 10.00 | Late Fee | If over 30 days past license expiration date-see page 4. |
| | $_____ | **TOTAL AMOUNT DUE** | **Payable to CA Department of Public Health** |

30. 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.**

| 31.Owner's Signature | Owner's Printed Name | Title Owner/ | Date |
|---|---|---|---|
| | | | |

**-End of Application-**

**Please review you application to ensure all fields have been completed.**

**Do not write below this line. CDPH FDB use only.**

| License Number | Expiration Date | Date Received | Payment Type | Amount $ |
|---|---|---|---|---|
| | | | | |

## DRUG MANUFACTURING LICENSE APPLICATION INSTRUCTIONS

(Do not send Instructions with completed Application)

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.

11-14. **Owner/Manager Contact Information:** Enter the owner's or manager of facility's telephone number, emergency number where the facility may be reached in the event of an emergency and e-mail address.

15-18. **Facility Representative's Contact Information:** Enter the facility's representative's name, phone number, alternate cell phone number and e-mail address.

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. Attach evidence of ownership.
21. **Corporate Name. State of Incorporation:** If applicable, enter the corporate name here.
22. **Owner's or Officers' Names and Titles:** List the business owner's or officers' names and titles. Use additional sheets if necessary.
23. List the **Associated California Board of Pharmacy License Number** 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 the business days and hours.
25. **Intended Drug Destination:** Place an (X) in the box adjacent to the destination(s) for your manufactured products. Check all that apply.
26. **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.
27. **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)

28. **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.
29. **Payment Code:** Place an (X) in the box adjacent to each applicable fee.

| Payment Type | Fee | Description | Code |
|---|---|---|---|
| New, Relocation, Ownership change, or Renewal | **$4,616** | 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)**.*

**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".

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

30. **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.
31. **Owner's Signature:** Sign the application. Print the signer's signature, title, and indicate signature date. All signatures must be original.

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