

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 <input type="checkbox"/> Product Shipped <input type="checkbox"/> Product or Raw Materials Received <input type="checkbox"/> N/A		
20. Type of Ownership <input type="checkbox"/> Individual/Sole Proprietorship <input type="checkbox"/> Partnership <input type="checkbox"/> Corporation/Limited Liability Company <input type="checkbox"/> Nonprofit <input type="checkbox"/> 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. Size of Facility (square feet): _____
 Number of Employees at this Facility _____ Business days and hours _____

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

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 Drug Product (check all that apply) ***If Prescription or Both is checked complete the Disclosure Statement form (CDPH 53); Refer to PDMA requirements on instruction page 2.**
 Prescription* Over-the-counter Both*

27. 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): _____

28. 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	<input type="checkbox"/>	<input type="checkbox"/>	Powder Mixing	<input type="checkbox"/>	<input type="checkbox"/>
Aseptic	<input type="checkbox"/>	<input type="checkbox"/>	Relabel Only	<input type="checkbox"/>	<input type="checkbox"/>
Coating	<input type="checkbox"/>	<input type="checkbox"/>	Repackage Only	<input type="checkbox"/>	<input type="checkbox"/>
Emulsification	<input type="checkbox"/>	<input type="checkbox"/>	Sterilization	<input type="checkbox"/>	<input type="checkbox"/>
Encapsulation	<input type="checkbox"/>	<input type="checkbox"/>	Suspension	<input type="checkbox"/>	<input type="checkbox"/>
Fermentation/tissue culture viral	<input type="checkbox"/>	<input type="checkbox"/>	Tableting	<input type="checkbox"/>	<input type="checkbox"/>
vector/gene therapy	<input type="checkbox"/>	<input type="checkbox"/>	Other (Specify): _____	<input type="checkbox"/>	<input type="checkbox"/>
Liquid Mixing	<input type="checkbox"/>	<input type="checkbox"/>			

29. Payment Code **A — \$2600 (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

30. 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.

31. Signature	Printed Name	Title	Date
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PLEASE DO NOT WRITE BELOW THIS LINE.

License Number	Expiration Date	Date Received	Payment Type	Amount \$
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