

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): _____ <input type="checkbox"/> Number of Employees at this Facility _____ <input type="checkbox"/> Business days and hours _____					
24. Stage of Manufacture at Date of Application (check all that apply) <input type="checkbox"/> Manufacturing products <input type="checkbox"/> Validation – Completion Date: _____ Other (specify): _____					
25. Intended Drug Destination (check all that apply) <input type="checkbox"/> Commercial distribution <input type="checkbox"/> Human clinical trials (investigational use) <input type="checkbox"/> California distribution only <input type="checkbox"/> U.S. distribution <input type="checkbox"/> 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. <input type="checkbox"/> Prescription* <input type="checkbox"/> Over-the-counter <input type="checkbox"/> Both*					
27. Drug Products Manufactured at this Location (check all that apply) <input type="checkbox"/> 700 Bulk pharmaceuticals (API) <input type="checkbox"/> 704 Controlled substances (schedule: _____ DEA#: _____ (attach copy of DEA certificate) <input type="checkbox"/> 701 Medical gases <input type="checkbox"/> 706 Investigational New Drugs (IND) <input type="checkbox"/> 710 Oral Dose (solid/liquid) <input type="checkbox"/> 702 Radioactive <input type="checkbox"/> 707 Biotech <input type="checkbox"/> 711 Pre-IND <input type="checkbox"/> 703 Veterinary <input type="checkbox"/> 708 Biologics <input type="checkbox"/> 712 Topical <input type="checkbox"/> 705 Approved New Drug <input type="checkbox"/> 709 Parenteral <input type="checkbox"/> 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	
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 vector/gene therapy	<input type="checkbox"/>	<input type="checkbox"/>	Tableting	<input type="checkbox"/>	<input type="checkbox"/>
Liquid Mixing	<input type="checkbox"/>	<input type="checkbox"/>	Other (Specify): _____	<input type="checkbox"/>	<input type="checkbox"/>
29. Payment Code <input type="checkbox"/> A — \$3,380 (Fee is due at the time application is submitted and is Non-Refundable) <input type="checkbox"/> B — \$ 200 PDMA* (if Applicable – see page 2) <input type="checkbox"/> C — \$ 10 Late Fee (if over 30 days late) \$ Total Payment Due					
30. Please attach: <input type="checkbox"/> Evidence of ownership and one of the following: <input type="checkbox"/> A copy of a valid biologics license issued by the U.S. Food and Drug Administration (FDA) <input type="checkbox"/> 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 <input type="checkbox"/> 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) <input type="checkbox"/> 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
PLEASE DO NOT WRITE BELOW THIS LINE.					
License Number	Expiration Date	Date Received	Payment Type	Amount \$	

