

DISCLOSURE STATEMENT—Human Prescription Drug Manufacturers

(Instructions on reverse)

1. Name of individual applicant (last / first / middle)		Present position	
2. Address of individual applicant (number, street)		Phone number	
City	ZIP code	()	
3. Company Name		Phone number	
Address (number, street)		()	
City	ZIP code		
4. What are your responsibilities with the firm?			
CHECK APPROPRIATE BOX FOR EACH OF THE FOLLOWING ITEMS If the answer to questions 5 through 8 is "Yes," you must attach a written explanation giving full details for each affirmative response. Failure to provide an explanation will delay processing of your application.		YES	NO
5. Have you had a drug or device manufacturing license, or any professional or vocational license denied, suspended, revoked, or placed on probation, or other disciplinary action taken by this or any other governmental authority?		<input type="checkbox"/>	<input type="checkbox"/>
6. Have you been associated in business with any individual, sole proprietorship, partnership, corporation, or other entity whose drug or device manufacturing license, or any professional or vocational license, was denied, suspended, revoked, or placed on probation, or other disciplinary action taken by this or any other governmental authority?		<input type="checkbox"/>	<input type="checkbox"/>
7. Have you ever been convicted of or pled no contest to a violation of any law of a foreign country, the United States, any state, or a local ordinance? You must include all convictions, including those that have been set aside under Penal Code Section 1203.4 (Traffic violations of \$100 or less need not be reported.).		<input type="checkbox"/>	<input type="checkbox"/>
8. Have you ever been addicted to, or treated for the habitual use of, any narcotic, prescription drug, or alcoholic beverage?		<input type="checkbox"/>	<input type="checkbox"/>

I certify under penalty of perjury under the laws of the State of California to the truth and accuracy of the foregoing. I am also aware that I am bound by the applicable federal, state, and local drug laws and regulations.

Date: _____ Signature: _____

All items of information requested in this application are mandatory. Failure to provide any of the requested information will result in the application being rejected as incomplete. The information will be used to determine qualifications for manufacturing human prescription drugs under the California Health and Safety Code. Application and license information is maintained by the Department of Public Health, Food and Drug Branch, at the address listed page 2. The information may be transferred to another government agency such as a law enforcement agency, if necessary, for it to perform its duties. Each individual has the right to review the files or records maintained on her/him by the Department unless the records are identified as confidential information and exempted by Section 1798.3 of the Civil Code.

DISCLOSURE STATEMENT—INSTRUCTIONS

- A. The Disclosure Statement Form (CDPH 53) must be completed and submitted by the following individuals, pursuant to Title 17, Code of California Regulations, Section 10376:
1. Every “Facility Operator(s)” identified on line 14 of the New Drug Manufacturing License Application (CDPH 8595) as having responsibility over human prescription drug manufacturing operations of the applicant firm, and...
 2. Those individuals identified on line 9 of the Drug Manufacturing License Application (CDPH 8595) who are as follows:
 - a. The five highest ranking Corporate Officers (and/or Directors, if the number of Officers is less than five); **or**
 - b. The listed principal Owner(s), Partner(s), or Business Association Members (up to 5 individuals).
- B. When a New Drug Manufacturing License Application (CDPH 8595) is filed due to a change in ownership, **or** there is a change of a principal individual, partner, or corporate officer, as described in (A) above, each **new** individual must complete this Form (CDPH 53).

Please provide the following information on the reverse page:

1. **Applicant’s full name and current position**
 2. **Applicant’s home address and phone number**
 3. **Company’s name, address, and phone number**
 4. **Description of applicant’s responsibilities at the company**
 5. **Description of any adverse actions taken against any license previously or currently held**
 6. **Description of any association with individuals or entities subject to any adverse actions**
 7. **Description of any convictions or no contest pleadings of a violation of law**
 8. **Description of any addiction to, or treatment for use of, narcotics, prescription drugs, or alcoholic beverages**
 9. **Sign and date**
- C. Attach a listing of your experience in drug manufacturing or related firms. (A resumé is acceptable.)
- D. Submit this Disclosure Statement Form (CDPH 53) with original signatures, and attachments, **along with...**:
1. A COPY of the corresponding License application form (CDPH 8595) for the employing company;
 2. A COPY of the drafted check covering the appropriate Drug Manufacturing Licensing fee listed on application form (CDPH 8595);

TO: (Regular Mail):

California Department of Public Health
Food and Drug Branch - Cashier
PO Box 997435, MS 7602
Sacramento, CA 95899-7435

(Overnight Mail):

California Department of Public Health
Food and Drug Branch - Cashier
1500 Capitol Avenue, MS 7602
Sacramento, CA 95814