

STATE OF NEVADA  
 DIVISION OF PUBLIC AND BEHAVIORAL HEALTH  
 COMMUNITY SERVICES  
 ENVIRONMENTAL HEALTH SECTION  
[www.dpbh.nv.gov](http://www.dpbh.nv.gov)  
**INFORMATION FOR  
 DRUG MANUFACTURING PERMIT**



All persons intending to operate a drug manufacturing facility in Nevada must obtain a permit from the Division of Public and Behavioral Health, Environmental Health Section. A drug is any component ingredient used in the manufacture of drugs in dosage form, whether or not the ingredient appears in the finished product. The term includes amygdalin (laetrile) or procaine hydrochloride with preservatives and stabilizers.

**REGULATIONS**

State of Nevada	Nevada Administrative Code 585 & Nevada Administrative Code (NAC) Chapter 585.010 to 585.670	<a href="https://www.leg.state.nv.us/NAC/NAC-585.html">https://www.leg.state.nv.us/NAC/NAC-585.html</a>
Code of Federal Regulations Title 21	"Federal Act" means the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 et seq., as that act exists on June 30, 1983.	<a href="http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211">http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=211</a>

**DRUG MANUFACTURING FACILITY FEES**

Initial licensing fee and renewal fees	\$2,000
Initial licensing fee and renewal fees of drugs with amygdalin (laetrile) or procaine hydrochloride with preservatives and stabilizers	\$30,000

The Commissioner will not issue a license pursuant to NRS/NAC 585 unless the applicant has satisfied the Commissioner that the applicant is competent and has adequate business experience to conduct the activity for which the application for a license is made.

**How to apply for a license:**

**\* Please see NAC 585 for complete language for licensing requirements.\***

1. An application for a license to operate a drug manufacturing plant must be completed and sent to the Commissioner.
2. The applicant must provide the Commissioner with complete information regarding ownership and must report promptly all significant changes in ownership. If the applicant is a publicly held corporation, only the information regarding the person holding a majority interest need be so provided.
3. A corporate applicant must provide the Commissioner with the name and address of each of its officers, directors and managers. An applicant who is not a corporation must provide the Commissioner with the name and address of each of his or her managerial employees. An applicant shall notify the Commissioner of any change in this information.
4. An applicant must state the proposed hours of operation of the plant. The applicant shall notify the Commissioner of any change in the hours of operation.

**Plan Review Requirements:** The plans must include, but is not limited to:

- (a) The layout and arrangement of the plant;
- (b) The materials to be used in construction; and
- (c) The location, size and type of any fixed equipment and facilities.
- (d) The formula for the drug, including all its components; and
- (e) The procedures to be used in processing the drug.

The Commissioner's approval of a plan does not constitute his or her final approval of the facility. An actual inspection of the completed facility must be made before a final approval will be given to the applicant. Until such inspection is made and final approval of the facility is granted, the Commissioner will not issue a license.