TITLE 16 OCCUPATIONAL AND PROFESSIONAL LICENSING
CHAPTER 19 PHARMACISTS
PART 9 MINIMUM STANDARDS FOR MANUFACTURERS AND REPACKAGING FIRMS

16.19.9.1 ISSUING AGENCY: Regulation and Licensing Department - Board of Pharmacy, 1650 University Blvd, NE - Ste. 400B, Albuquerque, NM 87102, (505) 841-9102.
[02-15-1889...02-15-96; 16.19.9.1 NMAC – Rn, 16 NMAC 19.9.1, 03-30-02]

16.19.9.2 SCOPE: All manufacturers, packagers and distributors, other than wholesalers, of drugs, including radioactive pharmaceuticals.
[02-15-96; 16.19.9.2 NMAC – Rn, 16 NMAC 19.9.2, 03-30-02]

16.19.9.3 STATUTORY AUTHORITY: Section 61-11-6A(6) NMSA 1978 directs the Board of Pharmacy to provide for the licensing of drug manufacturers and for the inspection of their facilities and activities. Section 61-11-6(A) NMSA 1978 authorizes the Board to enforce the provisions of all state laws pertaining to the practice of pharmacy and the manufacture, production, sale or distribution of drugs, cosmetics or poisons, including the New Mexico Drug, Device and Cosmetic Act, Chapter 26, Article I NMSA 1978. Pursuant to Section 26-1-18 of the Drug, Device and Cosmetic Act, the Board is authorized to promulgate regulations for the efficient enforcement of the Act.
[02-15-96; A, 03-14-98; 16.19.9.3 NMAC – Rn, 16 NMAC 19.9.3, 03-30-02]

16.19.9.4 DURATION: Permanent
[02-15-96; 16.19.9.4 NMAC – Rn, 16 NMAC 19.9.4, 03-30-02]

16.19.9.5 EFFECTIVE DATE: February 15, 1996, unless another date is specified at the end of a section.
[02-15-96; A, 03-14-98; 16.19.9.5 NMAC – Rn, 16 NMAC 19.9.5, 03-30-02]

16.19.9.6 OBJECTIVE: The objective of Part 9 of Chapter 19 is to establish standards for the safe and competent manufacture, packaging, repackaging and distribution of drugs, including radioactive pharmaceuticals.
[02-15-96; 16.19.9.6 NMAC – Rn, 16 NMAC 19.9.6, 03-30-02]

16.19.9.7 DEFINITIONS: For the purpose of defining Section 26-1-11 A(3) NMSA Comp. the following definitions apply:

A. "Manufacturer" means the steps in the preparation, propagation, processing or compounding of a drug - the making by chemical, physical, biological or other procedures of any articles which meet the definition of drugs and includes manipulation, sampling or control procedures resulting in the finished dosage form. Manufacture includes all the steps performed on the product itself, which do not affect intrinsically the safety, purity or potency of the product.

B. "Manufacturers" means the person or company who manufacturers a drug in its' finished dosage form.

C. "Packager" or "Packer" means a person or firm, other than a wholesaler, who distributes drugs.

D. "Distributor" means the original selling agent, other than a wholesaler, who distributes drugs.

E. "The finished dosage form" of a prescription drug is defined as that form of the drug which is or is intended to be dispensed or administered to the patient and requires no further manufacturing or processing other than packaging and labeling.
[03-07-80...08-27-90; 16.19.9.7 NMAC – Rn, 16 NMAC 19.9.7 NMAC, 03-30-02]

16.19.9.8 MINIMUM STANDARDS:

A. The following minimum standards shall apply to all manufacturing establishments and repackaging firms for which licenses have been issued by the Board:

(1) All drugs and chemicals used in the manufacturing process or held for sale shall conform to the New Mexico Drug and Cosmetic Act and shall be stored, preserved and disposed of as prescribed by laws regulating the labeling and manufacture of drugs. When necessary, and/or according to label requirements, all drugs and chemicals which require refrigeration shall be stored and preserved under proper temperature.

(2) All manufacturers must conform to current good manufacturing practices as set forth in Title 21,

CFR, Subsection 211.1 to 211.208 inclusive. The definitions and interpretations contained in Section 201 of the Federal Food and Drug Act shall be applicable.

(3) All manufacturers must conform to (1141) Packaging, Storage, and Distribution of Pharmacopeial Articles, the United States Pharmacopeia. These include the following stability protocols:

(4) Stability of manufactured dosage forms must be demonstrated by the manufacturer by the use if the methods adequate for the purpose. Monograph assays may be used for stability testing if they are stability-indicating (i.e., if they accurately differentiate between the intact drug molecules and their degradation products). Stability considerations should include not only the specific compendial requirements, but also changes in physical appearance of the product that would warn, users that the product's continued integrity is questionable.

(5) Stability studies on active substances and packaged dosage forms must be conducted by means of "real time", long-term tests at specific temperatures and relative humidities representing storage and shipping conditions experienced in the distribution chain of the climatic zones of the country or region of the world concerned. Labeling of the packaged active substance or dosage form shall reflect the effects of temperature, relative humidity, air, and light on its stability. Label temperature storage warnings will reflect both the results of the real-time storage tests and also allow for expected seasonal excursions of temperature during distribution.

(6) All persons in the distribution or dispensing chain shall comply with the manufacturers directions.

B. RADIOACTIVE PHARMACEUTICALS

(1) Radioactive pharmaceuticals require specialized techniques in their handling and testing in order that correct results may be obtained and hazards to personnel be minimized.

(2) The following minimum requirements must be met for a manufacturing establishment preparing radiopharmaceutical products. These requirements are in addition to the regulatory requirements of the Federal Atomic Energy Commission, the Federal Food and Drug Administration, the U.S. Public Health Service regulations and the New Mexico Radiation Protection Act administered by the Environmental Improvement Agency. **Minimum equipment and accessory standards:**

- **(a)** Fume hood - minimum of 30 inches
- **(b)** Laminar flow hood
- **(c)** Dose calibrator
- **(d)** Refrigerator (lead lined)
- **(e)** Mettler balance
- **(f)** Spectrophotometer
- **(g)** Drawing Station (lead glass and lead)

(3) Glassware:

- **(a)** 3 beakers 50 ml
- **(b)** 3 beakers 150 ml
- **(c)** 1 beaker 500 ml
- **(d)** 2 volumetric flasks 50 ml
- **(e)** 6 volumetric flasks 100 ml
- **(f)** 2 graduated cylinders 10 ml
- **(g)** 2 graduated cylinders 100 ml

(4) Radiochromatographic strip scanner and/or well counter

(5) Supplies:

- **(a)** disposable syringes 1,3 and 5 cc
- **(b)** multidose vials 10, 20 and 30 cc
- **(c)** disposable alcohol swabs
- **(d)** disposable gloves

(6) Reference books:

- **(a)** American Hospital Formulary Service
- **(b)** National Formulary
- **(c)** United States Pharmacopoeia

(7) Space: The radiopharmaceutical manufacturing or preparation area shall be an undivided area of not less than 240 square feet for the hot lab and storage area. The area shall contain adequate sink with hot and cold water facilities.

[03-07-80...08-27-90;A, 03-14-98; 16.19.9.8 NMAC - Rn & A, 16 NMAC 19.9.8, 03-30-2002]

16.19.9.9 LICENSURE OR REGISTRATION: Wholesale distributor and manufacturer distributor or

manufacturer.

A. No manufacturer shipping dangerous drugs into New Mexico or who sells or distributes dangerous drugs in this state through any person or media, other than a wholesaler who has obtained a license, shall conduct the business of selling or distributing dangerous drugs without obtaining an out-of-state drug license from the Board.

B. Applications for an out-of-state drug distributor's license under this section shall be made on a form furnished by the Board of Pharmacy. The Board may require such information as it deems is reasonably necessary to carry out the purposes of this section. This requirement does not include the licensure of a parent corporation of a corporation or division.

C. The license fee shall be as specified in 16.19.12 NMAC, Fees, and shall be renewed annually before the last day of December each year.

D. No person acting as principal or agent (detail man) for any out-of-state manufacturer, wholesaler or distributor who has not obtained a license from the Board shall conduct the business of selling or distributing dangerous drugs within the state.

E. Any person acting as principal or agent for any manufacturer, wholesaler or distributor who is licensed by the Board and who possesses or distributes dangerous drugs, shall register as principal or agent for the licensed manufacturer, wholesaler or distributor.

F. Registration of persons under this section shall be made on a form furnished by the Board. The Board may require such information as it deems is reasonably necessary to carry out the purpose of this section, including, but not limited to, the name and address of the registrant and the name and address of the manufacturer whose drugs he is selling or distributing.

G. The Board may deny, revoke or suspend such person's registration for any violation of the State Drug Laws.

[03-07-80...08-27-90; Rn, 16.19.9.10.7, 03-14-98; 16.19.9.9 NMAC – Rn, 16 NMAC 19.9.9, 03-30-02; A, 12-01-2003]

16.19.9.10 LABELS: Labels for legend drugs in package form shall conspicuously state the name and place of business of the manufacturer of the finished dosage form and the name and place of business of the packer or distributor.

[03-07-80...08-27-90; Rn, 16.19.9.11.1, 03-14-98; 16.19.9.10 NMAC – Rn, 16 NMAC 19.9.10, 03-30-02]

16.19.9.11 FINISHED DOSAGE FORMS: Where the manufacturer of the finished dosage form and the packer or distributor are the same person, only the name and place of business of such persons are required to be on the labels, no qualifying language is necessary.

[03-07-80...08-27-90; Rn, 16.19.9.12.1, 03-14-98; 16.19.9.11 NMAC – Rn, 16 NMAC 19.9.11, 03-30-02]

16.19.9.12 FINISHED DOSAGE FORMS - QUALIFYING LANGUAGE: Where the manufacturer of the finished dosage form and the packer or distributor are different persons, the labels shall contain qualifying language that states the connection such persons have with the drugs: i.e., "Manufactured by _____, distributed by _____, "Manufactured by _____, for _____", or other wording which adequately expresses the facts.

[03-07-80...08-27-90; Rn, 16.19.9.13.1, 03-14-98; 16.19.9.12 NMAC – Rn, 16 NMAC 19.9.12, 03-30-02]

16.19.9.13 FINISHED DOSAGE FORMS - CORPORATE NAME: In the case of a corporation, only the actual corporate name, which may be preceded or followed by the name of the particular division of the corporation shall be required. In the case of an individual partnership or association, the name under which the business is conducted shall be used.

[03-07-80...08-27-90; Rn, 16.19.9.14.1, 03-14-98; 16.19.9.13 NMAC – Rn, 16 NMAC 19.9.13, 03-30-02]

16.19.9.14 FINISHED DOSAGE FORMS - PLACE OF BUSINESS: If a person manufactures, packs or distributes a drug at a place other than his principle place of business, the label may state the principle place of business in lieu of the actual place where such drug is manufactured or packed or is to be distributed, unless such statement would be misleading.

[03-07-80...08-27-90; Rn, 16.19.9.15.1, 03-14-98; 16.19.9.14 NMAC – Rn, 16 NMAC 19.9.14, 03-30-02]

History of 16.19.9 NMAC:

Pre-NMAC History:
Material in this part was derived from that previously filed with the commission of public records - state records center and archives as:
Regulation No. 9, Minimum Standards for Manufacturers and Repackaging, filed 02-07-80;
Regulation No. 9, Minimum Standards for Manufacturers and Repackaging Firms, filed 10-23-85;
Regulation No. 9, Minimum Standards for Manufacturers and Repackaging Firms, filed 02-02-87;
Regulation No. 9, Minimum Standards for Manufacturers and Repackaging Firms, filed 07-27-90.

History of Repealed Material:
16 NMAC 19.9, Minimum Standards for Manufacturers and Repackaging Firms, filed 03-03-98.

Other History:
Regulation No. 9, Minimum Standards for Manufacturers and Repackaging Firms, filed 07-27-90 renumbered and reformatted to 16 NMAC 19.9, Minimum Standards for Manufacturers and Repackaging Firms, filed 02-02-96;
16 NMAC 19.9, Minimum Standards for Manufacturers and Repackaging Firms, filed 03-03-98 - **replaced by 16.19.9 NMAC, Minimum Standards for Manufacturers and Repackaging Firms, effective 06-27-01**.