Chapter Phar 12

MANUFACTURER REQUIREMENTS

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Phar 12.01 Authority. The rules in this chapter are adopted under authority in ss. 15.08 (5) (b), 227.11 (2) (a) and 450.07 (4), Stats.

History: Cr. Register, August, 1987, No. 380, eff. 9–1–87.

Phar 12.02 Definitions. In this chapter:

(1) "Device" has the meaning set forth in s. 450.01 (6), Stats.

(2) "Drug" has the meaning set forth in s. 450.01 (10), Stats.

(3) "Establishment" means a place of business under one management at one general physical location.

(4) "Manufacturer" means a person licensed by the board under this chapter.

(5) "Manufacturing" has the meaning set forth in s. 450.01 (13), Stats.

(6) "Prescription drug" has the meaning set forth in s. 450.01 (20), Stats.

History: Cr. Register, August, 1987, No. 380, eff. 9–1–87; am. (3), Register, August, 1991, No. 428, eff. 9–1–91.

Phar 12.03 License; application. (1) No person may engage in the manufacturing of any drug or device in this state unless a license is granted to the person by the board under this chapter.

(2) To obtain a license a person shall do all of the following:

(a) Submit an application on a form provided by the board.

(b) Pay the fee specified in s. 440.05 (1), Stats.

(c) Meet the inspection requirement under s. Phar 12.04.

(d) Register with the food and drug administration and comply with all applicable requirements of 21 CFR 200, 201, 202, 207, 210 and 211.

(e) If applicable, register with the drug enforcement administration and comply with all appropriate requirements of 21 CFR 1301, 1302, 1303, 1304, 1305, 1307, 1311 and 1312.

Note: An application form may be obtained from the board office, 1400 East Washington Avenue, Madison, Wisconsin 53702. Copies of federal applications, laws and regulations may be obtained from the Food and Drug Administration, 5600 Fischers Lane, Rockville, Maryland 20857 and the Drug Enforcement Administration, 500 Dirksen Federal Building, 219 Dearborn, Chicago, Illinois 60604.

(3) A manufacturer license may not be transferred from one establishment to another nor from one person to another. Each establishment requires a separate license.

(4) If the license is denied, the applicant may request a hearing before the board on the denial.

(5) The board shall act on the application for a license within 60 business days after receiving the completed application, as provided in s. SPS 4.03.

History: Cr. Register, August, 1987, No. 380, eff. 9–1–87; am. (2) (intro.), (a), (b), (c), (d) and (5), Register, December, 1998, No. 516, eff. 1–1–99; CR 00–157: am. (2) (d) and (e) Register May 2002 No. 557, eff. 6–1–02; correction in (5) made under s. 13.92 (4) (b) 7., Stats., Register November 2011 No. 671.

Phar 12.04 Inspections. Before a license is granted, an inspection of the establishment shall be conducted by the board or its representative to determine if the location meets the standards in 21 USC 351 and 352 (2022) and 21 CFR 210 and 211 (2022).

History: Cr. Register, August, 1987, No. 380, eff. 9–1–87; **CR 21–074: am. Register June 2023 No. 810, eff. 7–1–23.**

Phar 12.05 Compliance. Failure to comply with all applicable federal and state laws and regulations shall be subject to disciplinary action by the board under s. 450.10, Stats.

History: Cr. Register, August, 1987, No. 380, eff. 9–1–87.

Phar 12.06 Authorized distributors of record. A manufacturer shall maintain and update at least once per month a list of the manufacturer's authorized distributors of record.

History: EmR0815: emerg. cr. eff. 6–1–08; CR 08–051: cr. Register November 2008 No. 635, eff. 12–1–08.