CR 86-4

State of Wisconsin \ DEPARTMENT OF REGULATION & LICENSING

Tommy G. Thompson
Governor

Marlene A. Cummings
Secretary

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Bureau

CERTIFICATE

STATE OF WISCONSIN)
) SS
DEPARTMENT OF REGULATION AND LICENSING)

TO ALL TO WHOM THESE PRESENTS SHALL COME, GREETINGS:

I, John Young, director of the Bureau of Health Professions in the Department of Regulation and Licensing, and custodian of the official records of the Bureau, do hereby certify that the annexed rules, relating to manufacturer and distributor requirements were duly approved and adopted by the Pharmacy Examining Board on June 10, 1987.

I further certify that the attached copy has compared by me with the original on file in this department and that the same is a true copy thereof, and of the whole of the original.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the board at 1400 East Washington Avenue, Madison, Wisconsin, this 8th day of July, A.D. 1987.

John Young, Director
Bureau of Health Professions
Department of Regulation and Licensing

PRP:ma
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7/8/87

STATE OF WISCONSIN
BEFORE THE
PHARMACY EXAMINING BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE PHARMACY EXAMINING BOARD	:	ORDER OF THE PHARMACY EXAMINING BOARD REPEALING, AMENDING OR ADOPTING RULES

ORDER

Text of Rule

Under the authority vested in the Pharmacy Examining Board by sections 15.08(5)(b), 227.11(2)(a) and 450.07(4), Stats., the Pharmacy Examining Board hereby creates and adopts rules interpreting s. 450.07, Stats., as follows:

SECTION 1. Ch. Phar 12 is created to read:

Chapter Phar 12

MANUFACTURER REQUIREMENTS

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.

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 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.

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:

(a) Submit an application on a form provided by the Board;

(b) Pay the fee specified in s. 440.05(8), 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 C.F.R. ss. 200, 201, 202, 207, 210 and 211 (1985); and,

(e) If applicable, register with the Drug Enforcement Administration and comply with all appropriate requirements of 21 C.F.R. ss. 1301, 1302, 1303, 1304, 1305, 1307, 1311 and 1312 (1985).

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 license within 60 business days after receiving the completed application.

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 U.S.C. ss. 351 and 352 (1984) and 21 C.F.R. ss. 210 and 211 (1985).

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.

SECTION 2. Ch. Phar 13 is created to read:

Chapter Phar 13

DISTRIBUTOR REQUIREMENTS

Phar 13.01 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.

Phar 13.02 DEFINITIONS. In this chapter:

(1) "Controlled substance" has the meaning set forth in s. 161.01(4), Stats.

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

(3) "Distribute" has the meaning set forth in s. 450.01(8), Stats.

(4) "Distributor" means a person licensed by the Board under this chapter.

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

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

Phar 13.03 LICENSE; APPLICATION. (1) No person may sell or distribute at wholesale any prescription drug or device unless a license is granted to the person by the Board under this chapter.

(2) To obtain a license a person shall:

(a) Submit an application on a form provided by the Board;

(b) Pay the fee specified in s. 440.05(8), Stats.;

(c) Meet the inspection requirement under s. Phar 13.04;

(d) If applicable, register with the Drug Enforcement Administration and comply with all appropriate requirements in 21 C.F.R. ss. 1301, 1304, 1305 and 1307 (1985); and,

(e) Comply with all applicable requirements of 21 C.F.R. ss. 211.142(b), 211.150(a) and 211.96 (1985).

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 Drug Enforcement Administration, 500 Dirksen Federal Building, 219 Dearborn, Chicago, Illinois 60604.

(3) A distributor 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 license within 60 business days after receiving the completed application.

Phar 13.04 INSPECTION. 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 standards specified in 21 U.S.C. ss. 351 and 352 (1984) and 21 C.F.R. ss. 211.142(b) (1985).

Phar 13.04 DISTRIBUTION REQUIREMENTS. Any controlled substance or any prescription drug or device may be offered for sale, sold or distributed by distributors only to a person or firm which is required to be registered or exempt under 21 C.F.R. s. 1301 (1985), and s. 450.07(3), Stats.

Phar 13.06 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.

The rule created and adopted in this order shall take effect on the first day of the month following publication in the Wisconsin administrative register, pursuant to s. 227.22, Stats.

Dated this 8 day of July, 1987.

By: _____
Pharmacy Examining Board

PP:lml
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