

## CHAPTER 73

AN ACT concerning drug manufacturing business registration and amending P.L.1961, c.52.

**BE IT ENACTED** by the Senate and General Assembly of the State of New Jersey:

1. Section 1 of P.L.1961, c.52 (C.24:6B-1) is amended to read as follows:

C.24:6B-1 Registration statement, issuance of registration.

1. No person shall hereafter engage or continue to engage in a drug manufacturing business or a wholesale non-prescription drug business in this State without first filing a completed registration statement with the department. The department shall promptly review completed registration statements. Within 30 days after receipt of a registration statement, the department shall either issue registration, or shall advise the registrant, in writing, of the specific deficiencies in the registration statement. Any supplemental materials, which are submitted in response to a notice of deficiency, shall be reviewed by the department within 30 days after receipt thereof.

2. Section 2 of P.L.1961, c.52 (C.24:6B-2) is amended to read as follows:

C.24:6B-2 Registration statement, signature, verification; form and contents.

2. The registration statement shall be signed and verified by the individuals specified in subsection (c) hereof, shall be made on forms prescribed and furnished by the commissioner, and shall state such information necessary and proper to the enforcement of this act as the commissioner may require, consistent with the provisions of this section, including:

(a) The name under which the business is conducted.

(b) The address of each location in New Jersey at which the business is to be conducted. If a wholesale non-prescription drug business is not to be conducted from a location within the State, the statement shall give the name and address of an agent resident in this State on whom process against the registrant may be served.

(c) If the registrant is a proprietorship, the name and address of the proprietor; if a partnership, the names and addresses of all partners; if a corporation, the date and place of incorporation, the names and addresses of the president and secretary thereof, and the name and address of the designated registered agent in this State; or if any other type of business association, the names and addresses of the principals of such association.

(d) The names and addresses of those individuals having actual administrative responsibility, which, in the case of a proprietorship, shall be the managing proprietor; in the case of a partnership, shall be the managing partners; in the case of a corporation, shall be the officers and directors; or in the case of any other type of association, shall be those having similar administrative responsibilities.

(e) If the business will be conducted at more than one location in this State, the name and address of the individual in charge of each such location.

(f) A description of the business the registrant will be engaged in, and the drug products intended to be manufactured for sale or wholesale. If the registrant's products have not yet been approved by the federal Food and Drug Administration, the registrant shall submit a statement confirming that an application for approval has been submitted to the federal Food and Drug Administration, or that the registrant intends to file such an application within 12 months. Approval by the federal Food and Drug Administration shall not be a condition of registration.

(g) The name and address of the individual or individuals on whom orders of the commissioner may be served.

(h) A statement as to whether the registrant will be engaged in manufacturing, compounding, processing, wholesaling, jobbing, or distribution of depressant or stimulant drugs as defined pursuant to law.

3. This act shall take effect immediately.

Approved December 5, 2016.