GENERAL ASSEMBLY OF NORTH CAROLINA
SESSION 2021

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HOUSE BILL 95

Committee Substitute Favorable 3/2/21
Senate Agriculture, Energy, and Environment Committee Substitute Adopted 8/18/21

Short Title: Wholesale Rx Distribution Licensee Change. (Public)

Sponsors:

Referred to:

February 17, 2021

A BILL TO BE ENTITLED

AN ACT TO AUTHORIZE THE COMMISSIONER OF AGRICULTURE TO REVIEW AN APPLICATION AND ISSUE OR DENY A LICENSE FOR WHOLESALE DISTRIBUTION OF PRESCRIPTION DRUGS THAT IS CONDITIONED UPON APPROVAL OF A PRESCRIPTION DRUG UNDER FEDERAL LAW WHILE THE FEDERAL APPROVAL PROCESS IS PENDING.

The General Assembly of North Carolina enacts:

SECTION 1. G.S. 106-145.5 reads as rewritten:

"**§ 106-145.5. Review of application and qualifications of applicant.**

The Commissioner shall determine whether to issue or deny a wholesale distributor license within 90 days after an applicant files an application for a license with the Commissioner. The Commissioner shall have authority to review an application and issue or deny a license that is conditioned upon approval of a prescription drug under section 505 of the Federal Food, Drug, and Cosmetic Act (Title 21 U.S.C. § 301 et seq.; 52 Stat. 1040 et seq.) while the federal approval process is pending. In reviewing an application, the Commissioner shall consider the factors listed in this subsection. In the case of a partnership or corporation, the Commissioner shall consider the factors as applied to each individual whose name is required to be included in the license application.

The factors to be considered are:

(1) Any convictions of the applicant under any federal, state, or local law relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances.

(2) Any felony convictions of the applicant under federal, state, or local law.

(3) The applicant's past experience in the manufacture or distribution of controlled substances and other prescription drugs.

(4) Whether the applicant has previously given any false or fraudulent information in an application made in connection with drug manufacturing or distribution.

(5) Suspension or revocation by the federal government or a state or local government of any license currently or previously held by the applicant for the manufacture or distribution of any controlled substances or other prescription drugs.

(6) Compliance with the licensing requirements under any previously granted license.

(7) Compliance with the requirements to maintain or make available to the Commissioner or to a federal, state, or local law enforcement official those records required under G.S. 106-145.8.

(8) Whether the applicant requires employees of the applicant who are involved in any prescription drug wholesale distribution activity to have education, training, experience, or any combination of these factors sufficient to enable the employee to perform assigned functions in a manner that ensures that prescription drug quality, safety, and security will be maintained at all times as required by law.

(9) Any other factors or qualifications the Commissioner considers relevant to and consistent with the public health and safety.

The Commissioner shall inspect the facility of an applicant at which prescription drugs will be stored, handled, or distributed before issuing the applicant a license."

SECTION 2. This act is effective when it becomes law and applies to applications for licenses submitted on or after that date.