GENERAL ASSEMBLY OF NORTH CAROLINA
1987 SESSION

CHAPTER 737
HOUSE BILL 1166

AN ACT TO AMEND THE LAW REGARDING FOOD, DRUGS, AND COSMETICS.

The General Assembly of North Carolina enacts:

Section 1. G.S. 106-121 is amended by inserting the following new subdivisions to read:

"(11a) The term 'manufacturer' means a person who prepares, derives, or produces a prescription drug. Pharmacists are specifically excluded from this definition if they are acting in the course of their professional practice as defined in Chapter 90 and rules adopted pursuant to it.

(12a) The term 'prescription drug' means a drug that under federal law is required, prior to being dispensed or delivered, to be labeled with the following statement: 'Caution: Federal law prohibits dispensing without a prescription.'

(14e) The term 'repackager' means a person who repacks, relabels, or manipulates a prescription drug which was in a unit packaged and sealed by a manufacturer. Pharmacies are specifically exempted from this definition if they are acting in the course of their professional practice as defined in Chapter 90 and rules adopted pursuant to it.

(14f) The term 'wholesaler' means a person acting, as a jobber, wholesale merchant, salvager, or broker, or agent thereof, who sells or distributes for resale a prescription drug. Pharmacists are specifically exempted from this definition if they are acting in the course of their professional practice as defined in Chapter 90 and rules adopted pursuant to it."

Sec. 2. Chapter 106 is amended by adding a new section to read:

"**§ 106-140.1. Registration of producers of prescription drugs and devices.–**(a)On or before December 31 of each year, every person doing business in North Carolina and operating as a wholesaler as defined in G.S. 106-121(14f) or manufacturer as defined in G.S. 106-121(11a) or repackager as defined in G.S. 106-121(14e) shall register with the Commissioner his name and business location(s) in North Carolina. If said person has no business locations in North Carolina, he shall register his name and location of his corporate offices.

(b) Every person, upon first operating as a wholesaler, manufacturer or repackager in North Carolina shall immediately register with the Commissioner his name, place of business, and such establishment. If said person has no business locations in North Carolina, he shall register his name and location of his corporate offices.

(c) Every person duly registered in accordance with subsections (a) and (b) of this section shall register with the Commissioner any additional establishment that he owns or operates in the State of North Carolina prior to doing business as a manufacturer, wholesaler or repackager.

(d) The Commissioner may assign a registration number to any person or any establishment registered in accordance with this section.

(e) The Commissioner shall make available for inspection to any person so requesting any registration filed pursuant to this section.

(f) The foregoing subsections of this section shall not apply:

(1) To pharmacists as defined in G. S. 90-85.3 (q) holding a valid permit as defined in G. S. 90-85.3(m).

(2) To practitioners licensed or registered by law to prescribe or administer drugs and who manufacture, prepare, compound, or process drugs or devices solely for use in the course of their professional practice;

(3) To persons who manufacture, prepare, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale; or

(4) To such other classes of persons as the Commissioner may by regulation exempt from the application of this section upon a finding that registration by these classes of persons in accordance with this section is not necessary for the protection of the public health.

(g) Every establishment in the State of North Carolina registered with the Commissioner pursuant to this section shall be subject to inspection pursuant to G.S. 106-140.

(h) The Commissioner shall issue regulations to implement the registration requirements of this section. These regulations may provide for an annual registration fee of up to one hundred dollars ($100.00) for companies operating as manufacturers, wholesalers, or repackagers. The Department of Agriculture shall use these funds for the implementation of the North Carolina Food, Drug and Cosmetic Act.

(i) For the purposes of this act, name means the name of the partnership if a partnership and the name of the corporation if a corporation."

Sec. 3. This act shall become effective July 1, 1988.

In the General Assembly read three times and ratified this the 6th day of August, 1987.