

NORTH CAROLINA GENERAL ASSEMBLY
1981 SESSION

CHAPTER 552
HOUSE BILL 868

AN ACT TO PROVIDE FOR THE PRODUCTION AND SALE OF BIOLOGICS FOR THE
TREATMENT OF ANIMALS IN NORTH CAROLINA.

The General Assembly of North Carolina enacts:

Section 1. Chapter 106 of the General Statutes is amended by adding a new Article to the end to read:

"ARTICLE 58.

"North Carolina Biologics Law of 1981.

"§ 106-710. Short title and purpose. — This Article shall be known as 'The North Carolina Biologics Law of 1981'. The purpose of the law is to provide for the production and sale of biologics for the prevention or treatment of disease in animals other than man and to establish controls for the sale and use of biologics in North Carolina.

"§ 106-711. Definitions. — For purposes of this Article, the following words, terms and phrases are defined as follows:

- (1) 'Animal' means all birds and mammals, other than man, to which biologics may be administered.
- (2) 'Biologics' means preparations made from living organisms and their products, including serums, vaccines, antigens and antitoxins which are used for the treatment or prevention of diseases in animals other than humans, or in the diagnosis of diseases.
- (3) 'Board' means the North Carolina Board of Agriculture.
- (4) 'Commissioner' means the Commissioner of Agriculture.
- (5) 'Department' means the Department of Agriculture.

"§ 106-712. Rules and regulations. — The Board of Agriculture shall adopt rules and regulations necessary for the implementation and administration of this Article.

"§ 106-713. Biologics production license. — (a) No person shall engage in the production of biologics except in:

- (1) An establishment licensed by the Department;
- (2) An establishment licensed by the United States Department of Agriculture; or
- (3) An establishment producing biologics only for use by the owner or operator of the establishment for animals owned by him, if the biologics are registered with the Commissioner.

(b) Any establishment applying for a license to produce biologics shall be inspected by the Commissioner. Approval shall be based on compliance with the rules and regulations adopted by the board.

(c) Application for a license to produce biologics shall be made on forms provided by the Commissioner and shall be accompanied by a reasonable fee as established by the board.

(d) Upon approval, a license shall be granted upon payment of the annual license fee of one hundred dollars (\$100.00) for each establishment licensed, and an additional fee of fifty dollars (\$50.00) for each product produced at any time during the year. This license shall be

renewed annually. The annual renewal fee shall be paid on or before the first day of July of each year.

"§ 106-714. License revocation or suspension. — The Commissioner, upon a finding that a licensed establishment producing biologics is not in compliance with this Article or any rules or regulations promulgated thereunder, may revoke or suspend the license in accordance with Chapter 150A of the General Statutes.

"§ 106-715. Registration of biologics. — (a) No person shall offer for sale or use any biologic in North Carolina unless it is registered with the Commissioner. The registration shall be made on forms provided by the Commissioner. The forms shall require the applicant to provide information showing that the biologic:

- (1) is produced under procedures approved by the Commissioner;
- (2) is safe and noninjurious to animals when used as directed;
- (3) is labeled for proper handling, use and contents;
- (4) is produced in an establishment licensed under this Article; and
- (5) is not in violation of this Article or any rule or regulation promulgated thereunder.

(b) The application for registration shall also include a protocol of methods of production in detail which is followed in the production of the biologic, a sample of the label to be placed on the biologic, and any other information prescribed by the board as necessary for the implementation of this Article.

"§ 106-716. Revocation or suspension of registration. — The Commissioner, upon a finding that a registered biologic is being produced, sold or distributed in violation of this Article or any rules and regulations promulgated thereunder, may revoke or suspend the regulation in accordance with Chapter 150A of the General Statutes.

"§ 106-717. Penalties for violation. — (a) Any person adjudged to have violated any provision of this Article or the rules and regulations promulgated thereunder is guilty of a misdemeanor punishable by a fine of no less than one hundred dollars (\$100.00) per violation and no more than one thousand dollars (\$1,000), or imprisonment for no less than 60 days and no more than six months, or both. The Attorney General or his representative has concurrent jurisdiction with the district attorneys of this State to prosecute violations under this section.

(b) The Commissioner may apply to the Superior Court for an injunction to restrain and prevent violations of this Article or the rules and regulations promulgated thereunder irrespective of whether there exists an adequate remedy elsewhere at law."

Sec. 2. This act is effective upon ratification.

In the General Assembly read three times and ratified, this the 12th day of June, 1981.