## SUBCHAPTER 52G - BIOLOGICS

## SECTION .0100 - DEFINITIONS

### 02 NCAC 52G .0101 DEFINITIONS

The following definitions are applicable throughout this Subchapter:

(1) "Person" means and includes an individual corporation, partnership, or other legal entity.

(2) "Expiration Date" means the end of the period in which the biological product properly stored and handled, can with reasonable certainty, yield the result expected.

(3) "Commissioner" means the North Carolina Commissioner of Agriculture.

*History Note:* *Authority G.S. 106-712;*
*Eff. April 1, 1984;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 26, 2017.*

### 02 NCAC 52G .0102 DEFINITION ADOPTED BY REFERENCE

The definitions contained in 9 CFR 101.4 (labeling terminology) are hereby adopted by reference, except that reference to Veterinary Services shall be interpreted to mean the N.C. Department of Agriculture. Copies of these definitions are available in the office of the State Veterinarian.

*History Note:* *Authority G.S. 106-712;*
*Eff. April 1, 1984;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 26, 2017.*

## SECTION .0200 - LICENSES

### 02 NCAC 52G .0201 BIOLOGICS PRODUCTION LICENSE APPLICATION AND FEES

(a) An application for an initial license to produce biologics shall be accompanied by an application fee of one hundred dollars ($100.00) and a license fee of one hundred dollars ($100.00).

(b) Applications for a license to produce biologics shall contain all of the following:

(1) the name and address of the person who owns the establishment proposed to produce biologics;

(2) the name and address of the person in charge of biologics production;

(3) the type(s) of biologics to be produced;

(4) a full description of the building, including its location, facilities, equipment, and apparatus to be used in biologics production; and

(5) such other information as may be required by the Commissioner.

*History Note:* *Authority G.S. 106-710; 106-712; 106-713;*
*Eff. April 1, 1984;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 26, 2017.*

### 02 NCAC 52G .0202 LICENSING CRITERIA FOR PRODUCTION ESTABLISHMENTS

(a) All establishments producing biologics shall be located in a facility that is a permanent fixture.

(b) All establishments shall be properly equipped to produce the product(s) for which they are registered.

*History Note:* *Authority G.S. 106-712; 106-713;*
*Eff. April 1, 1984;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 26, 2017.*

### 02 NCAC 52G .0203 LICENSES

A license is not transferable as to location or ownership. Change in equity ownership, directly or by sale or transfer of a controlling stock interest or change in location, requires a new license and fee. An annual license renewal fee of one hundred dollars ($100.00) is payable to the N.C. Department of Agriculture on or before July 1 of each year.

*History Note:* *Authority G.S. 106-710; 106-712; 106-713;*
*Eff. April 1, 1984;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 26, 2017.*

## SECTION .0300 - INSPECTION AND RECORD KEEPING

### 02 NCAC 52G .0301 INSPECTIONS

(a) Upon receipt of an application for a license to produce biologics and the appropriate application fee, the director or his authorized agent shall inspect the establishment.
(b) An authorized representative of the Commissioner shall be permitted to enter an establishment producing registered biologics at any reasonable hour and inspect without previous notification the entire premises of such establishment and all records maintained relative to the condition of animals maintained, biologic production, spoilage, and distribution, as well as any other premises where the registrant may have placed any such products, records, or animals.
(c) The licensed manufacturer shall provide upon request and without cost to the Commissioner samples of stock cultures, other material, or finished product from his establishment and all firms or persons storing or selling the manufacturer's registered biologics; and shall also provide in contracts with distributors that the Commissioner may take such samples without charge to the Commissioner.

*History Note:* *Authority G.S. 106-712; 106-713;*
*Eff. April 1, 1984;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 26, 2017.*

### 02 NCAC 52G .0302 RECORDS AND SAMPLES

Each establishment licensed by the Commissioner shall maintain, as to each registered biologic, records of the source of stock cultures, methods of preparation, results of tests for purity and safety of each serial of biologics produced and the sale, shipment, or other disposition of the above.

*History Note:* *Authority G.S. 106-712; 106-713;*
*Eff. April 1, 1984;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 26, 2017.*

### 02 NCAC 52G .0303 PROTECTION OF CONFIDENTIAL INFORMATION

Information submitted by users of biologics shall be treated as confidential information to the extent that the release thereof will divulge the contents or formulation of such product.

*History Note:* *Authority G.S. 106-24.1; 106-709; 106-712;*
*Eff. April 1, 1984;*
*Readopted Eff. July 1, 2019.*

## SECTION .0400 - REGISTRATION OF BIOLOGICS

### 02 NCAC 52G .0401 BIOLOGICS REQUIRING REGISTRATION

(a) Each biologic produced in an establishment licensed by the Commissioner shall be separately registered, except as provided in (b) and (c) of this Rule.
(b) Biologics produced by a licensed veterinarian for prevention or treatment of disease in animals which are under his care and are administered only by him or under his supervision to such animals need not be registered.
(c) Biologics which are produced pursuant to 9 CFR 102.5 (U.S. Veterinary Biological Product License) need not be registered with the Commissioner.

(d) The Commissioner may require registration of any biologic when he determines it necessary to prevent the spread or introduction of infection or disease and to assure its safe and effective use.

*History Note:* *Authority G.S. 106-709; 106-712;*
*Eff. April 1, 1984;*
*Amended Eff. April 1, 1985;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 26, 2017.*

**02 NCAC 52G .0402 APPLICATIONS FOR REGISTRATION**

(a) Each application for registration of a biologic shall include a detailed protocol of methods of production which shall specify, as a minimum, the source and type of biologic material used to produce the product and methods used to determine purity and safety of the product during manufacture and distribution.
(b) Each application for registration of a biologic shall include a sample of the label to be used, which shall specify, as a minimum:

(1) the name of the product;
(2) the name of the person producing the biologic as it appears on the license;
(3) the date the product was manufactured;
(4) the expiration date;
(5) the lot number; and
(6) conditions of use.

(c) Each application for registration of a biologic shall include such other information as required by the Commissioner to determine if a product may be hazardous to human or animal health.

*History Note:* *Authority G.S. 106-709; 106-712;*
*Eff. April 1, 1984;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 26, 2017.*

**02 NCAC 52G .0403 REGISTRATION**

(a) Registration of a biologic shall be approved when the applicant provides such information concerning protocols, source of biologic agents, purity and safety as may be required by these Rules.
(b) Upon approval, a biologic shall be registered upon receipt of a fifty dollar ($50.00) fee.
(c) The registration of a biologic shall specify the conditions of use and period for which the registration is granted.
(d) No change in composition, protocol of production or labeling of a biologic registered by the Commissioner shall be made without prior approval of the Commissioner.

*History Note:* *Authority G.S. 106-709; 106-710; 106-712; 106-713; 106-715;*
*Eff. April 1, 1984;*
*Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. March 26, 2017.*