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.