

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.