10A NCAC 26F .0108 APPLICATION FOR EXCLUSION OF NONNARCOTIC SUBSTANCE

(a) Any person seeking to have any nonnarcotic substance which may, under the Federal Food, Drug and Cosmetic Act (21 USC 301), as amended, be lawfully sold over the counter without a prescription, excluded from any schedule, pursuant to General Statute Chapter 90-88(e) may apply to the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services.

(b) An application for an exclusion under this Section shall contain the following information:

- (1) the name and address of the applicant,
- (2) the name and the substance for which exclusion is sought, and
- (3) the complete quantitative composition of the substance.

(c) The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may reject an application for filing, giving the reason therefor, if any of the requirements prescribed in Paragraph (b) of this Rule is lacking or is not set forth so as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of Paragraph (b) of this Rule. If accepted for filing, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall publish general notice in three newspapers of statewide circulation qualified for legal advertising in accordance with Rule 4 of the North Carolina Rules of Civil Procedure that it will make a determination on the application at its next regularly scheduled meeting. The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall permit any interested person to file written comments or objections to the proposal and shall designate in the notice the time during which such filings may be made.

(d) After consideration of the application and any comments on or objections to its proposed decision at its next regularly scheduled meeting, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall issue and publish in three newspapers of statewide circulation qualified for legal advertising in accordance with Rule 4 of the North Carolina Rules of Civil Procedure its final order on the application. This order shall specify the date on which it shall take effect, which shall not be less than 30 days from the date of publication unless the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services finds that conditions of public health or safety necessitate an earlier effective date in which event the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services finds that conditions of public health or safety necessitate an earlier effective date in which event the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services finds that conditions.

(e) In the event a nonnarcotic substance no longer meets the criteria in G.S. 90-88(e), the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may at any time revoke any exclusion granted pursuant to G.S. 90-88(e) by following the procedures set forth in Paragraphs (c) and (d) of this Rule for handling an application for an exclusion which has been accepted for filing.

History Note:

Authority G.S. 90-88; Eff. June 30, 1978; Amended Eff. May 1, 1990; Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.