

10A NCAC 26F .0112 APPLICATION FOR EXCEPTION OF A STIMULANT OR DEPRESSANT

(a) Any person seeking to have any compound, mixture or preparation containing any depressant or stimulant substance listed in Paragraph .0204(b) or (c) or in Rule .0205 or in .0206 of this Section excepted from the application of all or any part of the act, pursuant to G.S. 90-91(i) and 90-92(b), may apply to the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services.

(b) An application for an exception under this Rule shall contain the following information:

- (1) the complete quantitative composition of the dosage form,
- (2) description of the unit dosage form together with complete labeling,
- (3) a summary of the pharmacology of the product including animal investigations and clinical evaluations and studies with emphasis on the psychic or physiological dependence liability, (This must be done for each of the active ingredients separately and for the combination product.)
- (4) details of dynergisms and antagonisms among ingredients,
- (5) deterrent effects of the noncontrolled ingredients,
- (6) complete copies of all literature in support of claims,
- (7) reported instances of abuse,
- (8) reported and anticipated adverse effects,
- (9) number of dosage units produced for the past two years.

(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 on 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 Director shall issue and publish its final order on the application in three newspapers of statewide circulation qualified for legal advertising in accordance with Rule 4 of the North Carolina Rules of Civil Procedure. 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 Director finds that conditions of public health or safety necessitate an earlier effective date in which event the Director shall specify in the order its findings as to such conditions.

(e) The Director may at any time revoke any exception granted pursuant to G.S. 90-91 or G.S. 90-92(b) by following the procedures set forth in Paragraphs (c) and (d) of this Rule for handling an application for an exception which has been accepted for filing.

*History Note: Authority G.S. 90-88;
Eff. June 30, 1978;
Amended Eff. May 1, 1990; May 15, 1979;
Pursuant to G.S. 150B-21.3A, rule is necessary without substantive public interest Eff. February 2, 2016.*