

**10A NCAC 26F .0110 APPLICATION FOR EXEMPT CHEMICAL PREPARATIONS**

(a) Any person seeking to have any preparation or mixture containing controlled substances and one or more noncontrolled substances exempted from the application of all or any part of the act pursuant to General Statute Chapter 90-88(g) may apply to the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services.

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

- (1) the name, address and registration number, if any, of the applicant;
- (2) the name, address and registration number, if any, of the manufacturer or importer of the preparation or mixture, if not the applicant;
- (3) the exact trade name or other designation of the preparation or mixture;
- (4) the complete quantitative composition of all the preparation or mixture (including all active ingredients and noncontrolled substances);
- (5) the form of the immediate container in which the preparation or mixture will be distributed with sufficient descriptive detail to identify the preparation or mixture (e.g., bottle, packet, vial, soft plastic pillow, agar gel plate, etc.);
- (6) the dimensions or capacity of the immediate container of the preparation or mixture;
- (7) the label and labeling, as defined in Rule .0201 of Subchapter 26E of this Chapter and of G.S. 90-106, the North Carolina Controlled Substances Act, as amended, of the immediate container and the commercial containers, if any, of the preparation or mixture;
- (8) a brief statement of the facts which the applicant believes justify the granting of an exemption under this Paragraph including information on the use to which the preparation or mixture will be put;
- (9) the date of application; and
- (10) which of the information submitted on the application, if any, is deemed by the applicant to be a trade secret or otherwise confidential and entitled to protection under any law restricting public disclosure of information.

(c) The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may require the applicant to submit such documents or written statements of fact relevant to the application as it deems necessary to determine whether the application should be granted.

(d) Within a reasonable period of time after the receipt of an application for an exemption under this Rule, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services shall notify the applicant of its acceptance or nonacceptance of his application and, if not accepted, the reason therefor. The Commission for Mental Health, Developmental Disabilities and Substance Abuse Services need not accept an application for filing if any of the requirements prescribed in Paragraph (b) of this Rule or requested pursuant to Paragraph (c) of this Rule is lacking or is not set forth as to be readily understood. If the applicant desires, he may amend the application to meet the requirements of Paragraphs (b) and (c) of this Rule. If the application is accepted, 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 shall specify in the order its findings as to such conditions.

(e) In the event a preparation or mixture containing controlled substance no longer meets the criteria in G.S. 90-88(e) for being excluded, the Commission for Mental Health, Developmental Disabilities and Substance Abuse Services may at any time revoke or modify any exemption granted pursuant to this Section by following the procedure set forth in Paragraph (d) of this Rule for handling an application for exemption.

*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.*