

Indiana Board of Pharmacy
Application for Conversion Resistant Products

Under authority of IC 35-48-4-14.3, the Indiana Board of Pharmacy adopted emergency rules to declare that a product is a conversion resistant form of ephedrine or pseudoephedrine if the board determines that the product does not pose a significant risk of being used in the manufacture of methamphetamine.

The Applicant must provide to the Board of Pharmacy the following information.

Manufacturer Information:

1. Business name of the drug manufacturer
2. Point of contact at the Business
3. Business address

Product Information:

1. Exact trade name of the product to be considered
2. Complete quantitative and qualitative composition of drug product
3. Brief statement of facts believed to justify granting conversion resistant recognition
4. Certification by applicant that the drug may be lawfully marketed or distributed under the Federal Food, Drug and Cosmetic Act
5. Empirical evidence demonstrating the product containing ephedrine or pseudoephedrine does not pose a significant risk of being used in the illicit manufacture of methamphetamine (This evidence may include but is not limited to underwriter laboratory analysis certifying the product can quantitatively yield low levels of ephedrine or pseudoephedrine when extracted or converted from the product)

If desired, the applicant may request to make a presentation before the board concerning the application

The board may require the applicant to submit additional documents or written statements of fact relevant to the application that the board deems necessary for determining if the application should be granted.

Pursuant to IC 5-14-3-4, the board will take necessary steps to protect information exempted from public disclosure, which includes “trade secrets,” defined by IC 24-3-2-3 as “information, including a formula, pattern, compilation, program, device, method, technique, or process, that:(1) derives independent economic value, actual or potential, from not being generally known to, and not being readily ascertainable by proper means by, other persons who can obtain economic value from its disclosure or use; and(2) is the subject of efforts that are reasonable under the circumstances to maintain its secrecy.

Applicants may send the above required information to the Indiana Board of Pharmacy for review by mail or electronically.

Indiana Professional Licensing Agency
Attn: Indiana Board of Pharmacy
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