

126.12 New drugs.

1. A person shall not sell, deliver, offer for sale, hold for sale, or give away a new drug unless both of the following apply:

a. An application with respect to the new drug has been approved and the approval has not been withdrawn under section 505 of the federal Act.

b. A copy of the letter of approval or approvability issued by the United States food and drug administration is on file with the secretary of the board, if the product is manufactured in this state.

2. A person shall not use in humans a new drug limited to investigational use unless the person has filed with the United States food and drug administration a completed and signed "Notice of Claimed Investigational Exemption for a New Drug" form in accordance with 21 C.F.R. §312.1 and the exemption has not been terminated. The drug shall be plainly labeled in compliance with section 505(i) or 507(d) of the federal Act.

3. [This section](#) does not apply to either of the following:

a. A drug which is not a new drug as defined in the federal Act.

b. A drug which is licensed under the federal Public Health Service Act of July 1, 1944, 42 U.S.C. §201 et seq. or under the Animal Virus-Serum-Toxin Act of March 4, 1913, 21 U.S.C. §151 et seq.

[89 Acts, ch 197, §12](#)

CS89, §203B.12

C93, §126.12

[2010 Acts, ch 1061, §24](#)

Referred to in [§126.3](#), [§126.6](#)