AUTHENTICATED,
OHIO LEGISLATIVE SERVICE
COMMISSION
DOCUMENT #250956

Ohio Revised Code

Section 3715.63 When drug or device is adulterated.

Effective: September 12, 2008
Legislation: House Bill 283 - 127th General Assembly

(A) A drug or device is adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if any of the following apply:

(1) It consists, in whole or in part, of any filthy, putrid, or decomposed substance.

(2) It has been produced, processed, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.

(3) It is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance that may render the contents injurious to health.

(4) It is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch certified under authority of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended.

(5) It purports to be or is represented as a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and its strength differs from or its quality or purity falls below the standard set forth in those compendiums. A determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendiums, or in the absence or inadequacy of such tests or methods of assay, those prescribed under the authority of the "Federal Food, Drug, and Cosmetic Act." A drug recognized in the compendiums is not adulterated under this division because it differs from the standard of strength, quality, or purity set forth for that drug in the compendiums, if the difference in strength, quality, or purity is plainly stated on its label. Whenever a drug is recognized in both the homoeopathic pharmacopoeia of the United States and in the United States pharmacopoeia and national formulary, including their supplements, it shall be subject to the requirements of the United States pharmacopoeia and national formulary unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the homoeopathic

pharmacopoeia of the United States and not to those of the United States pharmacopoeia and national formulary.

(6) It is not subject to the provisions of division (A)(5) of this section, and its strength differs from or its purity or quality falls below that which it purports or is represented to possess.

(7) It is a drug and any substance has been:

(a) Mixed or packed with the drug so as to reduce the drug's quality or strength;

(b) Substituted wholly or in part for the drug.

(B) An expired drug is not adulterated within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code if the drug is donated pursuant to sections 3715.88 to 3715.92 of the Revised Code.