

### **217.055 When drug deemed adulterated.**

A drug or device shall be deemed to be adulterated:

- (1)
  - (a) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or
  - (b) If it has been produced, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth or whereby it may have been rendered injurious to health; or
  - (c) If it is a drug and its container is composed in whole or in part of any poisonous or deleterious substance which may render the contents injurious to health; or
  - (d) If 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 the authority of the federal act;
- (2) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the federal act. No drug defined in an official compendium shall be deemed to be adulterated under this subsection because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia;
- (3) If it is not subject to the provisions of subsection (2) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess;
- (4) If it is a drug and any substance has been:
  - (a) Mixed or packed therewith so as to reduce its quality or strength; or
  - (b) Substituted wholly or in part therefor.

**Effective:**

**History:** Created 1960 Ky. Acts ch. 247, sec. 6.