151.35 DRUGS, ADULTERATION.

A drug shall be deemed to be adulterated:

(1) if it consists in whole or in part of any filthy, putrid or decomposed substance; or if it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been rendered injurious to health, or whereby it may have been contaminated with filth; or if the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice as required under the federal act to assure that such drug is safe and has the identity, strength, quality, and purity characteristics, which it purports or is represented to possess; or the facility in which it was produced was not registered by the United States Food and Drug Administration or licensed by the board; or, its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the federal act, or it is a color additive, the intended use of which in or on drugs is for the purposes of coloring only, and is unsafe within the meaning of the federal act;

(2) if it purports to be or is represented as a drug the name of which is recognized in the United States Pharmacopoeia or the National Formulary, and its strength differs from, or its quality or purity falls below, the standard set forth therein. 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 the United States Pharmacopoeia or the National Formulary shall be deemed to be adulterated under this paragraph 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;

(3) if it is not subject to the provisions of paragraph (2) of this section and its strength differs from, or its purity or quality differs from that which it purports or is represented to possess;

(4) if any substance has been mixed or packed therewith so as to reduce its quality or strength, or substituted wholly or in part therefor.

History: *1969 c 933 s 16; 2014 c 285 s 6*