**126.9 Drugs and devices — adulteration.**

A drug or device is adulterated under any of the following circumstances:

1. *a.* If it consists in whole or in part of any filthy, putrid, or decomposed substance.

*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.

*c.* If it is a drug and 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 to assure that the drug meets the requirements of this chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

*d.* If its container is composed, in whole or part, of any poisonous or deleterious substance which may render the contents injurious to health.

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 standards set forth in the official compendium. A determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the official compendium, or in the absence of or inadequacy of such tests or methods of assay, those prescribed under authority of the federal Act. A drug defined in an official compendium is not adulterated under this subsection because it differs from the standard of strength, quality, or purity set forth in the official compendium, if its difference in strength, quality, or purity from such standards is plainly stated on its label. If a drug is recognized in both the United States Pharmacopoeia National Formulary and the Homeopathic Pharmacopoeia of the United States it is subject to the United States Pharmacopoeia National Formulary unless it is labeled and offered for sale as a homeopathic drug, in which case it is subject to the Homeopathic Pharmacopoeia of the United States and not to the United States Pharmacopoeia National Formulary.

3. If it is not subject to subsection 2 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 mixed or packed with it so as to reduce its quality or strength, or any substance has been substituted for it wholly or in part.

5. If it is, or purports to be or is represented as, a device which is subject to a performance standard established under section 514 of the federal Act, unless the device is in all respects in conformity with such standard.

6. If it is a device banned by the board or by the United States food and drug administration.

7. If it is a device and the methods used in, or the facilities or controls used for its manufacture, packing, storage, or installation are not in conformity with applicable requirements under section 520(f)(1) of the federal Act or an applicable condition as prescribed by an order under section 520(f)(2) of the federal Act.

8. If it is a device for which an exemption has been granted under section 520(g) of the federal Act for investigational use and the person who was granted the exemption or any investigator who uses the device under the exemption fails to comply with a requirement prescribed by or under that section.

89 Acts, ch 197, §9
CS89, §203B.9
C93, §126.9