

(6) *Facts supporting a contention that the proposed use of the substance will serve a useful purpose.*

189A.

*A drug or device shall be deemed to be adulterated:*

(1) (i) *If it consists in whole or in part of any filthy, putrid or decomposed substance; or (ii) (A) if it has been produced, prepared, packed, or held under insanitary conditions whereby it would reasonably be expected to have been contaminated with filth, or whereby it would reasonably be expected to have been rendered injurious to health; or (B) 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 subheading as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess, or (iii) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which would reasonably be expected to render the contents injurious to health; or (iv) if (A) it is a drug and it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the Federal Act or of Section 188F (a), or (B) it is a color additive, the intended use of which in or on drugs is for purposes of coloring only, and is unsafe within the meaning of the Federal Act or of Section 188F(a).*

(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, purity therefor set forth in the compendium, if its difference in strength, quality, or purity from the 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 paragraph (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 (i) mixed or packed therewith so as to reduce its quality or strength; or (ii) substituted wholly or in part therefor.*

189B.

*A drug or device shall be deemed to be misbranded:*

(1) (a) *If its labeling is false or misleading in any particular.*