ACT 6

H.B. NO. 1971

A Bill for an Act Relating to Adulteration of Drugs and Medical Devices.

Be It Enacted by the Legislature of the State of Hawaii:

SECTION 1. Section 328-14, Hawaii Revised Statutes, is amended to read as follows:

"**§328-14 Drugs or devices deemed adulterated when.** 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) (i) 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

(ii) 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 or device meets the requirements of this part 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

(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:

(i) It [is a drug that] bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of the Federal Act; or

(ii) 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;

(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 the compendium. Such a determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in the compendium, or in the absence of or inadequacy of [such] these 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 paragraph because it differs from the standard of strength, quality, or purity therefor set forth in the compendium, if its difference in strength, quality, or purity from [such] that 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 Homeopathic Pharmacopoeia of the United States and not those of the United States Pharmacopoeia;

(3) If it is not subject to 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 (A) mixed or packed therewith so as to reduce its quality or strength; or (B) substituted wholly or in part therefor.''

SECTION 2. Statutory material to be repealed is bracketed. New statutory material is underscored.

SECTION 3. This Act shall take effect upon its approval.

(Approved March 30, 1995.)