§ 6815. Adulterating, misbranding and substituting. 1. Adultered drugs. A drug or device shall be deemed to be adulterated:

a. (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been 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 (3) 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 (4) 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 that has been certified in accordance with regulations provided in this article.

b. 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 or inadequacy of such tests or methods of assay, then in accordance with tests or methods of assay prescribed by regulations of the board of pharmacy as promulgated under this article. Deviations from the official assays may be made in the quantities of samples and reagents employed, provided they are in proportion to the quantities stated in the official compendium. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because (1) it exceeds the standard of strength therefor set forth in such compendium, if such difference is plainly stated on its label; or (2) it falls below the standard of strength, quality, or purity therefor set forth in such compendium if such difference is plainly stated on its label, except that this clause shall apply only to such drugs, or classes of drugs, as are specified in regulations which the board shall promulgate when, as applied to any drug, or class of drugs, the prohibition of such difference is not necessary for the protection of the public health. 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.

c. If it is not subject to the provisions of paragraph b of this subdivision and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

d. If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

e. If it is sold under or by a name not recognized in or according to a formula not given in the United States pharmacopoeia or the national formulary but that is found in some other standard work on pharmacology recognized by the board, and it differs in strength, quality or purity from the strength, quality or purity required, or the formula prescribed in, the standard work.

2. Misbranded and substituted drugs and devices. A drug or device shall be deemed to be misbranded:

a. If its labeling is false or misleading in any particular.

b. If in package form, unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: Provided, that under clause (2) of this paragraph the board may establish reasonable variations as to quantity and exemptions as to small packages.

c. If any word, statement, or other information required by or under authority of this article to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the

ordinary individual under customary conditions of purchase and use.

d. If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha eucaine, barbituric acid, beta eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substance, which derivative has been by the secretary, after investigation, found to be, and by regulations under this article, or by regulations promulgated by the board, designated as, habit forming; unless its label bears the name and quantity, or proportion, of such substance or derivative and in juxtaposition therewith the statement "Warning--May be habit forming."

e. If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2) in case it is fabricated from two or more ingredients, the common or usual name of each active ingredient, including the kind and quantity by percentage or amount of any alcohol, and also including, whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: Provided, that, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the board.

f. Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: Provided, that, where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the board shall promulgate regulations exempting such drug or device from such requirement.

g. If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: Provided, that, the method of packing may be modified with the consent of the secretary in accordance with regulations promulgated by the board. 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 with respect to packaging and labeling 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.

h. (1) If it is a drug and its container is so made, formed or filled as to be misleading; (2) if it is an imitation of another drug; (3) if it is offered for sale under the name of another drug; or (4) if it bears a copy, counterfeit, or colorable imitation of the trademark, label, container or identifying name or design of another drug.

i. If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended or suggested in the labeling thereof.

j. Except as required by article thirty-three of the public health law, the labeling provisions of this article shall not apply to the compounding and dispensing of drugs on the written prescription of a physician, a dentist, a podiatrist or a veterinarian, which prescription when filled shall be kept on file for at least five years by the pharmacist or druggist. Such drug shall bear a label containing the name and place of business of the dispenser, the serial number and date of the prescription, directions for use as may be stated in the prescription, name and address of the patient and the name of the physician or other practitioner authorized by law to issue the prescription. In addition, such label shall contain the proprietary or brand name of the drug and, if applicable, the strength of the contents, unless the person issuing the prescription explicitly states on the prescription, in his own handwriting, that the name of the drug and the

strength thereof should not appear on the label.