§ 106-134. Drugs deemed misbranded.

A drug or device shall be deemed to be misbranded:

(1) If its labeling is false or misleading in any particular, or if its labeling or packaging fails to conform with the requirements of G.S. 106-139 or 106-139.1 of this Article.

(2) If in package form unless it bears a label containing

a. The name and place of business of the manufacturer, packer, or distributor; and

b. An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count, which statement shall be separately and accurately stated in a uniform location upon the principal display panel of the label, except as exempted with respect to this clause by G.S. 106-121(2a)c of this Article; provided, that under paragraph b of this subdivision reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Board of Agriculture.

(3) 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.

(4) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alphaeucaine, barbituric acid, betaeucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulphonmethane; or any chemical derivative of such substances, which derivative has been by the Board after investigation, found to be, and by regulations under this Article, 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."

(5) a. If it is a drug, unless:

1. Its label bears, to the exclusion of any other nonproprietary name (except the applicable systematic chemical name or the chemical formula),

I. The established name (as defined in paragraph b of this subdivision) of the drug, if such there be, and

II. In case it is fabricated from two or more ingredients the established name and quantity of each active ingredient, including the kind and quantity or proportion of any alcohol and also including, whether active or not, the established 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 the requirement for stating the quantity of the active

ingredients, other than the quantity of those specifically named in this subdivision, shall apply only to prescription drugs; and

2. For any prescription drug the established name of such drug or ingredient, as the case may be, on such label (and on any labeling on which a name for such drug or ingredient is used) is printed prominently and in type at least half as large as that used thereon for any proprietary name or designation for such drug or ingredient; and provided, that to the extent that compliance with the requirements of 1 II or 2 of this subdivision is impracticable, exemptions shall be allowed under regulations promulgated by the Board.

b. As used in this subdivision (5), the term "established name," with respect to a drug or ingredient thereof, means:

1. The applicable official name designated pursuant to section 508 of the federal act, or
2. If there is no such name and such drug, or such ingredient, is an article recognized in an official compendium, then the official title thereof, in such compendium, or
3. If neither 1 nor 2 of this paragraph applies, then the common or usual name, if any, of such drug or of such ingredient:

Provided further, that where 2 of this sub-subdivision applies to an article recognized in the United States Pharmacopoeia and in the Homeopathic Pharmacopoeia under different official titles, the official title used in the United States Pharmacopoeia shall apply unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the Homeopathic Pharmacopoeia shall apply.

(6) Unless its labeling bears

a. Adequate directions for use; and

b. 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 paragraph a of this subdivision, as applied to any drug or device, is not necessary for the protection of the public health, the Board of Agriculture shall promulgate regulations exempting such drug or device from such requirements.

(7) 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 Board of Agriculture. 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.

(8) If it has been found by the Department of Agriculture and Consumer Services to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Board of Agriculture shall by regulations require as necessary for the protection of public health. No such regulation shall be established for any drug recognized in an official compendium until the Commissioner of Agriculture shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(9) a. If it is a drug and its container is so made, formed, or filled as to be misleading; or

b. If it is an imitation of another drug; or

c. If it is offered for sale under the name of another drug.

(10) 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.

(11), (12) Repealed by Session Laws 1975, c. 614, s. 28.

(13) If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless:

a. It is from a batch with respect to which a certificate or release has been issued pursuant to section 506 of the federal act, and

b. Such certificate or release is in effect with respect to such drug.

(14) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, bacitracin, or any other antibiotic drug, or any derivative thereof, unless

a. It is from a batch with respect to which a certificate or release has been issued pursuant to section 507 of the federal act, and

b. Such certificate or release is in effect with respect to such drug:

Provided, that this subsection shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507(c) or (d) of the federal act. For the purpose of this subsection the term "antibiotic drug" means any drug intended for use by man containing any quantity of any chemical substance which is produced by microorganisms and which has the capacity to inhibit or destroy microorganisms in dilute solution (including the chemically synthesized equivalent of any such substance).

(15) If it is a color additive, the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, prescribed under the provisions of G.S. 106-132 of this Article.

(16) In the case of any prescription drug distributed or offered for sale in this State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of

a. The established name, as defined in G.S. 106-134(5)b of this Article, printed prominently and in type at least half as large as that used for any trade or brand name thereof,

b. The formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e) of the federal act, and

c. Such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations issued under the federal act.

(17) If a trademark, trade name or other identifying mark, imprint or device of another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud.

(18) If it is a drug and its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Federal Poison Prevention Packaging Act of 1970. (1939, c. 320, s. 15; 1949, c. 370; 1973, c. 831, s. 1; 1975, c. 614, ss. 25-28, 30; 1997-261, s. 33.)