Article 12.

Food, Drugs and Cosmetics.

§ 106-120. Title of Article.

This Article may be cited as the North Carolina Food, Drug and Cosmetic Act. (1939, c. 320, s. 1.)

§ 106-121. Definitions and general consideration.

For the purpose of this Article:

(1) The term "advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purposes of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices or cosmetics.

(1a) The term "color" includes black, white, and intermediate grays.

(1b) The term "color additive" means a material which:

a. Is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source; or

b. When added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

Provided, that such term does not apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological process of produce of the soil and thereby affecting its color, whether before or after harvest.

(2) The term "Commissioner" means the Commissioner of Agriculture; the term "Department" means the Department of Agriculture and Consumer Services, and the term "Board" means the Board of Agriculture.

(2a) The term "consumer commodity" except as otherwise specifically provided by this subdivision means any food, drug, device, or cosmetic as those terms are defined by this Article. Such term does not include:

a. Any tobacco or tobacco product; or

b. Any commodity subject to packaging or labeling requirements imposed under the North Carolina Pesticide Law of 1971, Article 52, Chapter 143, of the General Statutes of North Carolina, or the provisions of the eighth paragraph under the heading "Bureau of Animal Industry" of the act of March 4, 1913 (37 Stat. 832-833; 21 U.S.C. 151-157) commonly known as the Virus-Serum Toxin Act; or

c. Any drug subject to the provisions of G.S. 106-134(13) or 106-134.1 of this Article or section 503(b)(1) or 506 of the federal act; or

d. Any beverage subject to or complying with packaging or labeling requirements imposed under the Federal Alcohol Administration Act (27 U.S.C., et seq.); or

e. Any commodity subject to the provisions of the North Carolina Seed Law, Article 31, Chapter 106 of the General Statutes of North Carolina.

(3) The term "contaminated with filth" applies to any food, drug, device or cosmetic not securely protected from dust, dirt, and as far as may be necessary by all reasonable means, from all foreign or injurious contaminations.

(4) The term "cosmetic" means

a. Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and

b. Articles intended for use as a component of any such articles, except that such terms shall not include soap.

(4a) The term "counterfeit drug" means a drug which, or the container or labeling of which, without authorization, bears the trademark, trade name or other identifying mark, imprint, or device, or any likeness thereof, of a drug manufacturer, processor, packer or distributor other than the person or persons who in fact manufactured, processed, packed or distributed such drug and which thereby falsely purports or is represented to be the product of, or to have been packed or distributed by, such other drug manufacturer, processor, packer or distributor.

(5) The term "device," except when used in subdivision (15) of this section and in G.S. 106-122, subdivision (10), 106-130, subdivision (6), 106-134, subdivision (3) and 106-137, subdivision (3) means instruments, apparatus and contrivances, including their components, parts and accessories, intended

a. For use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or

b. To affect the structure or any function of the body of man or other animals.

(6) The term "drug" means

a. Articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and

b. Articles intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals; and

c. Articles (other than food) intended to affect the structure or any function of the body of man or other animals; and

d. Articles intended for use as a component of any article specified in paragraphs a, b or c; but does not include devices or their components, parts, or accessories.

(7) The term "federal act" means the Federal Food, Drug and Cosmetic Act (Title 21 U.S.C. 301 et seq.; 52 Stat. 1040 et seq.).

(8) The term "food" means

a. Articles used for food or drink for man or other animals,

b. Chewing gum, and

c. Articles used for components of any such article.

(8a) The term "food additive" means any substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food

(including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting or holding food; and including any source of radiation intended for any such use) if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in a food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include:

a. A pesticide chemical in or on a raw agricultural commodity; or
b. A pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or
c. A color additive; or
d. Any substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958, pursuant to the federal act; the Poultry Products Inspection Act (21 U.S.C. 451 et seq.) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 et seq.).

(9) The term "immediate container" does not include package liners.

(10) The term "label" means a display of written, printed or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Article that any word, statement, or other information appearing on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(11) The term "labeling" means all labels and other written, printed, or graphic matter

a. Upon an article or any of its containers or wrappers, or
b. Accompanying such article.

(11a) Repealed by Session Laws 1989, c. 226, s. 1.

(12) The term "new drug" means

a. Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, as safe and effective for use under the conditions prescribed, recommended, or suggested in the labeling thereof; or
b. Any drug the composition of which is such that such drug, as a result of investigations to determine its safety and effectiveness for use under such conditions, has become so recognized, but which has not, otherwise than in such investigation, been used to a material extent or for a material time under such conditions.

(12a) Repealed by Session Laws 1989, c. 226, s. 1.

(13) The term "official compendium" means the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

(13a) The term "package" means any container or wrapping in which any consumer commodity is enclosed for use in the delivery or display of that consumer commodity to retail purchasers, but does not include:

a. Shipping containers or wrappings used solely for the transportation of any consumer commodity in bulk or in quantity to manufacturers, packers, or processors, or to wholesale or retail distributors thereof; or

b. Shipping containers or outer wrappings used by retailers to ship or deliver any commodity to retail customers if such containers and wrappings bear no printed matter pertaining to any particular commodity.

(14) The term "person" includes individual, partnership, corporation, and association.

(14a) The term "pesticide chemical" means any substance which, alone, in chemical combination, or in formulation with one or more other substances is a "pesticide" within the meaning of the North Carolina Pesticide Law of 1971, Article 52, Chapter 143, of the General Statutes of North Carolina, or the Federal Insecticide, Fungicide and Rodenticide Act (7 U.S.C. 135 et seq.), and which is used in the production, storage, or transportation of raw agricultural commodities.

(14b) The term "practitioner" means a physician, dentist, veterinarian or other person licensed, registered or otherwise permitted to distribute, dispense, conduct research with respect to or to administer a drug so long as such activity is within the normal course of professional practice or research.

(14c) The term "principal display panel" means that part of a label that is most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale.

(14d) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(14e), (14f) Repealed by Session Laws 1989, c. 226, s. 1.

(15) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is misleading, there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, sound, or any combination thereof, but also the extent to which labeling or advertisement fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling or advertisement relates under the conditions of use prescribed in the labeling or advertisement thereof or under such conditions of use as are customary or usual.

(16) The representation of a drug, in its labeling or advertisement, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use

as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(17) The provisions of this Article regarding the selling of food, drugs, devices, or cosmetics, shall be considered to include the manufacture, production, processing, packing, exposure, offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving of any such article; and the supplying or applying of any such article in the conduct of any food, drug or cosmetic establishment. (1939, c. 320, s. 2; 1975, c. 614, ss. 1, 2; 1987, c. 737, s. 1; 1989, c. 226, s. 1; 1997-261, s. 32.)

§ 106-122. Certain acts prohibited.

The following acts and the causing thereof within the State of North Carolina are hereby prohibited:

(1) The manufacture, sale, or delivery, holding or offering for sale of any food, drug, device, or cosmetic that is adulterated or misbranded.

(2) The adulteration or misbranding of any food, drug, device, or cosmetic.

(3) The receipt in commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(4) The sale, delivery for sale, holding for sale, or offering for sale of any article in violation of G.S. 106-131 or 106-135.

(5) The dissemination of any false advertisement.

(6) The refusal to permit entry or inspection, or to permit the taking of a sample, or to permit access to or copying of any record as authorized by G.S. 106-140.

(7) The giving of a guaranty or undertaking which guaranty or undertaking is false, except by a person who relied on a guaranty or undertaking to the same effect signed by, and containing the name and address of the person residing in the State of North Carolina from whom he received in good faith the food, drug, device or cosmetic.

(8) The removal or disposal of a detained or embargoed article in violation of G.S. 106-125.

(9) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device or cosmetic, if such act is done while such article is held for sale and results in such article being misbranded or adulterated.

(10) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label or other identification device authorized or required by regulations promulgated under the provisions of this Article.

(11) The using, on the labeling of any drug or in any advertisement relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under G.S. 106-135, or that such drug complies with the provisions of such section.

(12) The sale at retail of any food for which a definition and standard of identity for enrichment with vitamins, minerals or other nutrients has been promulgated by

the Board, unless such food conforms to such definition and standard, or has been specifically exempted from same by the Board.

(13) The distribution in commerce of a consumer commodity, as defined in this Article, if such commodity is contained in a package, or if there is affixed to that commodity a label, which does not conform to the provisions of this Article and regulations promulgated under authority of this Article; provided, however, that this prohibition shall not apply to persons engaged in business as wholesale or retail distributors of consumer commodities except to the extent that such persons:
   a. Are engaged in the packaging or labeling of such commodities; or
   b. Prescribe or specify by any means the manner in which such commodities are packaged or labeled.

(14) The using by any person to his own advantage, or revealing, other than to the Commissioner or authorized officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Article, any information acquired under authority of this Article concerning any method or process which as a trade secret is entitled to protection.

(15) In the case of a prescription drug distributed or offered for sale in this State, the failure of the manufacturer, packer, or distributor thereof to maintain for transmittal, or to transmit, to any practitioner licensed by applicable law to administer such drug within the normal course of professional practice, who makes written request for information as to such drug, true and correct copies of all printed matter which is required to be included in any package in which that drug is distributed or sold, or such other printed matter as is approved under the federal act. Nothing in this paragraph shall be construed to exempt any person from any labeling requirement imposed by or under other provisions of this Article.

(16) a. Placing or causing to be placed upon any drug or device or container thereof, with intent to defraud, the trade name or other identifying mark, or imprint of another or any likeness of any of the foregoing; or
   b. Selling, dispensing, disposing of or causing to be sold, dispensed or disposed of, or concealing or keeping in possession, control or custody, with intent to sell, dispense or dispose of, any drug, device or any container thereof, with knowledge that the trade name or other identifying mark or imprint of another or any likeness of any of the foregoing has been placed thereon in a manner prohibited by subsection (a) of this section; or
   c. Making, selling, or disposing of; causing to be made, sold or disposed of; keeping in possession, control or custody; or concealing any punch, die, plate, stone, or other thing designed to print, imprint, or reproduce the trademark, trade name, or other identifying mark, imprint, or device of another or any likeness of any of the foregoing upon any drug or container or labeling thereof so as to render such drug a counterfeit drug.

(17) The doing of any act which causes a drug to be a counterfeit drug, or the sale or dispensing, or the holding for sale or dispensing of a counterfeit drug.

(18) Dispensing or causing to be dispensed a different drug in place of the drug ordered or prescribed without the express permission of the person ordering or prescribing.

(19) The acquiring or obtaining or attempting to acquire or obtain any drug subject to the provisions of G.S. 106-134.1(a)(3) or (4) by fraud, deceit, misrepresentation, or subterfuge, or by forgery or alteration of a prescription, or by the use of a false name, or the giving of a false address. (1939, c. 320, s. 3; 1975, c. 614, ss. 3-5.)

§ 106-123. Injunctions restraining violations.

In addition to the remedies hereinafter provided, the Commissioner of Agriculture is hereby authorized to apply to the superior court for, and such court shall have jurisdiction upon hearing and for cause shown to grant, a temporary or permanent injunction restraining any person from violating any provision of G.S. 106-122, irrespective of whether or not there exists an adequate remedy at law. (1939, c. 320, s. 4.)

§ 106-124. Violations made misdemeanor.

(a) Any person, firm or corporation violating any provision of this Article, or any regulation of the Board adopted pursuant to this Article, shall be guilty of a Class 2 misdemeanor. In addition, if any person continues to violate or further violates any provision of this Article after written notice from the Commissioner, or his duly designated agent, the court may determine that each day during which the violation continued or is repeated constitutes a separate violation subject to the foregoing penalties.

(b) No person shall be subject to the penalties of subsection (a) of this section, for having violated G.S. 106-122, subdivision (1) or (3) if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the State of North Carolina from whom he received in good faith the article, to the effect that such article is not adulterated or misbranded within the meaning of this Article, designating this article.

(c) No publisher, radio-broadcast licensee, or agency or medium for the dissemination of an advertisement, except the manufacturer, packer, distributor, or seller of the article to which a false advertisement relates, shall be liable under this section by reason of the dissemination by him of such false advertisement, unless he has refused on the request of the Commissioner of Agriculture to furnish the Commissioner the name and post-office address of the manufacturer, packer, distributor, seller or advertising agency residing in the State of North Carolina who caused him to disseminate such advertisement. (1939, c. 320, s. 5; 1975, c. 614, s. 6; 1993, c. 539, s. 744; 1994, Ex. Sess., c. 24, s. 14(c).)

§ 106-124.1. Civil penalties.

(a) The Commissioner may assess a civil penalty of not more than two thousand dollars ($2,000) against any person who violates a provision of this Article or any rule adopted pursuant to this Article. In determining the amount of the penalty, the Commissioner shall consider the degree and extent of harm caused by the violation.

(b) Prior to assessing a civil penalty, the Commissioner shall give the person written notice of the violation and a reasonable period of time in which to correct the violation. However, the Commissioner shall not be required to give a person time to correct a violation before assessing a

penalty if the Commissioner determines the violation is likely to cause future physical injury or illness.

(c) The Commissioner shall consider the training and management practices implemented by the person for the purpose of complying with this Article as a mitigating factor when determining the amount of the civil penalty.

(d) The Commissioner shall remit the clear proceeds of civil penalties assessed pursuant to this section to the Civil Penalty and Forfeiture Fund in accordance with G.S. 115C-457.2. (2003-389, s. 1.)

§ 106-125. Detention of product or article suspected of being adulterated or misbranded.

(a) Whenever a duly authorized agent of the Department of Agriculture and Consumer Services finds or has probable cause to believe, that any food, drug, device, cosmetic or consumer commodity is adulterated, or so misbranded as to be dangerous or fraudulent within the meaning of this Article or is in violation of G.S. 106-131 or 106-135 of this Article, he shall affix to such article a tag or other appropriate marking giving notice that such article is, or is suspected of being, adulterated or misbranded and has been detained or embargoed, and warning all persons not to remove or dispose of such article by sale or otherwise until permission for removal or disposal is given by such agent or the court. It shall be unlawful for any person to remove or dispose of such detained or embargoed article by sale or otherwise without such permission.

(b) When an article detained or embargoed under subsection (a) has been found by such agent to be adulterated, or misbranded or to be in violation of G.S. 106-131 or 106-135 of this Article, he shall petition a judge of the district, or superior court in whose jurisdiction the article is detained or embargoed for an order for condemnation of such article. When such agent has found that an article so detained or embargoed is not adulterated or misbranded, he shall remove the tag or other marking.

(c) If the court finds that a detained or embargoed article is adulterated or misbranded, such article shall, after entry of the decree, be destroyed at the expense of the claimant thereof, under the supervision of such agent; and all court costs and fees, and storage and other proper expenses, shall be taxed against the claimant of such article or his agent: Provided, that when the adulteration or misbranding can be corrected by proper labeling or processing of the article, the court, after entry of the decree and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that such article shall be so labeled or processed, has been executed, may by order direct that such article be delivered to the claimant thereof for such labeling or processing under the supervision of an agent of the Department of Agriculture and Consumer Services. The expense of such supervision shall be paid by the claimant. Such bond shall be returned to the claimant of the article on representation to the court by the Department of Agriculture and Consumer Services that the article is no longer in violation of this Article, and that the expenses of such supervision have been paid.

(d) Whenever any duly authorized agent of the Department of Agriculture and Consumer Services shall find in any room, building, vehicle of transportation or other structure, any meat, seafood, poultry, vegetable, fruit or other perishable articles which are unsound, or contain any filthy, decomposed or putrid substance, or that may be poisonous or deleterious to health or otherwise unsafe, the same being hereby declared to be a nuisance, the agent shall forthwith condemn or destroy the same, or in any other manner render the same unsalable as human food. (1939, c. 320, s. 6; 1973, c. 108, s. 53; 1975, c. 614, ss. 7-9; 1997-261, s. 109.)

§ 106-126. Prosecutions of violations.

It shall be the duty of the solicitors and district attorneys of this State to promptly prosecute all violations of this Article. (1939, c. 320, s. 7; 1973, c. 47, s. 2; c. 108, s. 54; 1975, c. 614, s. 10.)

§ 106-127. Report of minor violations in discretion of Commissioner.

Nothing in this Article shall be construed as requiring the Commissioner of Agriculture to report for the institution of proceedings under this Article, minor violations of this Article, whenever the Commissioner believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning. (1939, c. 320, s. 8.)

§ 106-128. Establishment of reasonable standards of quality by Board of Agriculture.

Whenever in the judgment of the Board of Agriculture such action will promote honesty and fair dealing in the interest of consumers, the Board shall promulgate regulations fixing and establishing for any food or class of food a reasonable definition and standard of identity, and/or reasonable standard of quality and/or fill of container. In prescribing a definition and standard of identity for any food or class of food in which optional ingredients are permitted, the Board shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which shall be named on the label. The definitions and standards so promulgated shall conform so far as practicable to the definitions and standards promulgated by the Commissioner of the Federal Food and Drug Administration under authority conferred by section 401 of the federal act.

Temporary permits now or hereafter granted for interstate shipment of experimental packs of food varying from the requirements of federal definitions and standards of identity are automatically effective in this State under the conditions provided in such permits. In addition, the Board of Agriculture may cause to be issued additional permits where they are necessary to the completion or conclusiveness of an otherwise adequate investigation and where the interests of consumers are safeguarded. Such permits are subject to the terms and conditions the Board of Agriculture may prescribe by regulation. (1939, c. 320, s. 9; 1975, c. 614, ss. 11, 12.)

§ 106-129. Foods deemed to be adulterated.

A food shall be deemed to be adulterated:

(1) a. If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this paragraph if the quantity of such substance in such food does not ordinarily render it injurious to health; or

b. 1. If it bears or contains any added poisonous or added deleterious substance, other than one which is

I. A pesticide chemical in or on a raw agricultural commodity;

II. A food additive; or

III. A color additive, which is unsafe within the meaning of G.S. 106-132; or

2. If it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of G.S. 106-132; or

3. If it is or it bears or contains any food additive which is unsafe within the meaning of G.S. 106-132;

provided, that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or tolerance prescribed under G.S. 106-132 of this Article, and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of G.S. 106-132 and clause 3 of this section, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of such residue in the processed food when ready-to-eat, is not greater than the tolerance prescribed for the raw agricultural commodity; or

c. If it consists in whole or in part of a diseased, contaminated, filthy, putrid or decomposed substance, or if it is otherwise unfit for food; or

d. If it has been produced, prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered diseased, unwholesome or injurious to health; or

e. If it is the product of a diseased animal or an animal which has died otherwise than by slaughter, or that has been fed upon the uncooked offal from a slaughterhouse; or

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

g. If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to G.S. 106-132 of this Article; or

h. If a retail or wholesale establishment has added sulfiting agents, including sulfur dioxide, sodium sulfite, sodium or potassium bisulfite, and sodium or potassium metabisulfite, separately or in combination, to fresh fruits and fresh vegetables intended for retail sale as fresh food products.

(2) a. If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or

b. If any substance has been substituted wholly or in part therefor; or

c. If damage or inferiority has been concealed in any manner; or

d. If any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength or make it appear better or of greater value than it is.

(3) If it is confectionery, and:

a. Has partially or completely imbedded therein any nonnutritive object: Provided, that this clause shall not apply in the case of any nonnutritive object if, in the judgment of the Board of Agriculture as provided by regulations, such object is of practical functional value to the

confectionery product and would not render the product injurious or hazardous to health; or

b. Bears or contains more than five percent (5%) alcohol by volume. Confectionery that contains more than five-tenths of one percent (0.5%) alcohol by volume shall conspicuously bear a label indicating alcohol content; or

c. Bears or contains any nonnutritive substance: Provided, that this clause shall not apply to a safe nonnutritive substance which is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storing of such confectionery if the use of the substance does not promote deception of the consumer or otherwise result in adulteration or misbranding in violation of any provision of this Article; and provided further, that the Board may, for the purpose of avoiding or resolving uncertainty as to the application of this clause, issue regulations allowing or prohibiting the use of particular nonnutritive substances.

(4) If it is or bears or contains any color additive which is unsafe within the meaning of G.S. 106-132. (1939, c. 320, s. 10; 1975, c. 614, ss. 13-16; 1985, c. 399; 2011-26, s. 1.)

§ 106-130. Foods deemed misbranded.

A food shall be deemed to be misbranded:

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

b. If its labeling or packaging fails to conform with the requirements of G.S. 106-139 and 106-139.1 of this Article.

(2) If it is offered for sale under the name of another food.

(3) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(4) If its container is so made, formed or filled as to be misleading.

(5) 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:

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.

(6) 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.

(7) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by G.S. 106-128, unless
   a. It conforms to such definition and standard, and
   b. Its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(8) If it purports to be or is represented as
   a. A food for which a standard of quality has been prescribed by regulations as provided by G.S. 106-128 and its quality falls below such standard unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or
   b. A food for which a standard or standards of fill of container have been prescribed by regulation as provided by G.S. 106-128, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(9) If it is not subject to the provisions of subdivision (7) of this section, unless its label bears
   a. The common or usual name of the food, if any there be, and
   b. In case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each:

   Provided, that, to the extent that compliance with the requirements of paragraph b of this subdivision is impracticable or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Board of Agriculture.

(10) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Board of Agriculture determines to be, and by regulations prescribes as, necessary in order to fully inform purchasers as to its value for such uses.

(11) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservatives, unless it bears labeling stating that fact: Provided, that to the extent that compliance with the requirements of this subdivision are impracticable, exemptions shall be established by regulations promulgated by the Board of Agriculture. The provisions of this subdivision and subdivisions (7) and (9) with respect to artificial coloring do not apply to butter, cheese, or ice cream. The provisions of this subdivision with respect to chemical preservatives do not apply to a pesticide chemical when used in or on a raw agricultural commodity which is the product of the soil.

(12) If it is a raw agricultural commodity which is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of such commodity bears labeling which declares the presence of such chemical in or on such commodity and the common or usual name and the

function of such chemical: Provided, however, that no such declaration shall be required while such commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of such container in accordance with the custom of the trade.

(13) If it is a product intended as an ingredient of another food and when used according to the directions of the purveyor will result in the final food product being adulterated or misbranded.

(14) If it is a color additive 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.

(15) If the labeling provided by the manufacturer, packer, distributor, or retailer on meat, meat products, poultry, or seafood includes a "sell-by" date or other indicator of a last recommended day of sale, and the date has been removed, obscured, or altered by any person other than the customer. This subdivision does not prohibit the removal of a label for the purpose of repackaging and relabeling a food item so long as the new package or new label does not bear a "sell-by" date or other indicator of a last recommended day of sale later than the original package. This subdivision does not prohibit relabeling of meat, meat products, poultry, or seafood that has had its shelf life extended through freezing, cooking, or other additional processing that extends the shelf life of the product. (1939, c. 320, s. 11; 1975, c. 614, ss. 17-20; 2000-67, s. 7.10.)

§ 106-131. Permits governing manufacture of foods subject to contamination with microorganisms.

(a) Whenever the Commissioner of Agriculture finds after investigation by himself or his duly authorized agents, that the distribution in North Carolina of any class of food may, by reason of contamination with microorganisms during manufacture, processing, or packing thereof in any locality in this State, be injurious to health, and that such injurious nature cannot be adequately determined after such articles have entered commerce, the Commissioner, then, and in such case only, shall promulgate regulations providing for the issuance, to manufacturers, processors, or packers of such class of food in such locality, of permits to which shall be attached such conditions governing the manufacture, processing, or packing of such class of food, for such temporary period of time, as may be necessary to protect the public health; and after the effective date of such regulations, and during such temporary period, no person shall introduce or deliver for introduction into commerce any such food manufactured, processed, or packed by any such manufacturer, processor, or packer unless such manufacturer, processor, or packer holds a permit issued by the Commissioner as provided by such regulations.

(b) The Commissioner of Agriculture is authorized to suspend immediately upon notice any permit issued under authority of this section if it is found that any of the conditions of the permit have been violated. The holder of a permit so suspended shall be privileged at any time to apply for the reinstatement of such permit, and the Commissioner shall immediately after prompt hearing and an inspection of the establishment, reinstate such permit if it is found that adequate measures have been taken to comply with and maintain the conditions of the permit, as originally issued, or as amended.

(c) Any officer or employee duly designated by the Commissioner of Agriculture shall have access to any factory or establishment, the operator of which holds a permit from the

Commissioner of Agriculture for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection shall be ground for suspension of the permit until such access is freely given by the operator. (1939, c. 320, s. 12.)

§ 106-132. Additives, etc., deemed unsafe.

Any added poisonous or added deleterious substance, any food additive, any pesticide chemical in or on a raw agricultural commodity or any color additive, shall with respect to any particular use or intended use be deemed unsafe for the purpose of application of G.S. 106-129(1), paragraphs b and g and 106-129(4) with respect to any food, 106-133(1) with respect to any drug or device, or 106-136(1) and (5) with respect to any cosmetic, unless there is in effect a regulation pursuant to G.S. 106-139 of this Article limiting the quantity of substance, and the use or intended use of such substance conforms to the terms prescribed by such regulation. While such regulations relating to such substance are in effect, a food, drug, or cosmetic shall not, by reason of bearing or containing such substance in accordance with the regulations be considered adulterated within the meaning of G.S. 106-129(1)a, 106-133(1) and 106-136(1). (1939, c. 320, s. 13; 1975, c. 614, s. 21.)

§ 106-133. Drugs deemed to be adulterated.

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. 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

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

1. It is a drug and it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of G.S. 106-132, or

2. If 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 G.S. 106-132;

e. 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 such drug meets the requirements of this Article as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.

(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 so prescribed under

authority of the federal act. No drug defined in an official compendium shall be deemed to be adulterated under this subdivision because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such 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 subdivision (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. (1939, c. 320, s. 14; 1975, c. 614, ss. 22-24.)

§ 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.)

§ 106-134.1. Prescriptions required; label requirements; removal of certain drugs from requirements of this section.

(a) A drug intended for use by man which:

(1) Is a habit-forming drug to which G.S. 106-134(4) applies; or

(2) Because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug in the course of his normal practice; or

(3) Is limited by an approved application under section 505 of the federal act to use under the professional supervision of a practitioner licensed by law to administer such drug; or

(4) Is a drug the label of which bears the statement "Caution: Federal law prohibits dispensing without a prescription," shall be dispensed only

a. Upon a written prescription of a practitioner licensed by law to administer such drug, or authorized to issue orders pursuant to G.S. 90-87(23)(a), provided that the written prescription must bear the printed or stamped name, address, telephone number and DEA number of the prescriber in addition to his legal signature, or

b. Upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or

c. By refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. If any prescription for such drug does not indicate the times it may be refilled, if any, such prescription may not be refilled unless the pharmacist is subsequently authorized to do so by the practitioner.

The act of dispensing a drug contrary to the provisions of this subdivision shall be deemed to be an act which results in a drug being misbranded while held for sale.

(b) Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be exempt from the requirements of G.S. 106-134, except subsections (1), (9)b and c, (13) and (14), and the packaging requirements of subsections (7) and (8), if the drug bears an affixed label containing the name of the patient, the name and address of the pharmacy, the phrase "Filled by _____" or "Dispensed by_____," with the name of the practitioner who dispenses the prescription appearing in the blank, the serial number and date of the prescription or of its filling, the name of the prescriber, the directions for use, and unless otherwise directed by the prescriber of such drug, the name and strength of such drug. This exemption shall not apply to any drugs dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail, or to a drug dispensed in violation of subsection (a) of this section.

Any tranquilizer or sedative dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug shall be labelled by the pharmacist, if the prescriber so directs on the prescription, with a warning that: "The consumption of alcoholic beverages while on this medication can be harmful to your health."

(c) The Board may, by regulation, remove drugs subject to G.S. 106-134(4) and G.S. 106-135 from the requirements of subsection (a) of this section when such requirements are not necessary for the protection of the public health. Drugs removed from the prescription requirements of the federal act by regulations issued thereunder shall also, by regulations issued by the Board, be removed from the requirement of subsection (a).

(d) A drug which is subject to subsection (a) of this section shall be deemed to be misbranded if at any time prior to dispensing its label fails to bear the statement "Caution: Federal Law Prohibits Dispensing Without Prescription." A drug to which subsection (a) of this section does not apply shall be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.

(e) Nothing in this section shall be construed to relieve any person from any requirement prescribed by or under authority of law with respect to drugs now included or which may hereafter be included within the classification of "controlled substances" as this term is defined in applicable

federal and State controlled substance acts. (1975, c. 614, s. 29; 1977, c. 421; 1979, c. 626; 1981, c. 75, s. 2.)

§ 106-135. Regulations for sale of new drugs.

(a) No person shall sell, deliver, offer for sale, hold for sale or give away any new drug unless:

(1) An application with respect thereto has been approved and said approval has not been withdrawn under section 505 of the federal act, or

(2) When not subject to the federal act, by virtue of not being a drug in interstate commerce, unless such drug has been tested and has been found to be safe for use and effective in use under the conditions prescribed, recommended, or suggested in the labeling thereof, and prior to selling or offering for sale such drug, there has been filed with the Commissioner an application setting forth

a. Full reports of investigations which have been made to show whether or not such drug is safe for use and whether such drug is effective in use;

b. A full list of the articles used as components of such drug;

c. A full statement of the composition of such drug;

d. A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug;

e. Such samples of such drug and of the articles used as components thereof as the Commissioner may require; and

f. Specimens of the labeling proposed to be used for such drug.

(b) An application provided for in subdivision (a)(2) of this section shall become effective on the one hundred eightieth day after the filing thereof, except that if the Commissioner finds, after due notice to the applicant and giving him an opportunity for hearing,

(1) That the drug is not safe or not effective for use under the conditions prescribed, recommended or suggested in the proposed labeling thereof; or

(2) The methods used in, and the facilities and controls used for, the manufacture, processing and packing of such drug is inadequate to preserve its identity, strength, quality, and purity; or

(3) Based on a fair evaluation of all material facts, such labeling is false or misleading in any particular; he shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.

(c) An order refusing to permit an application under this section to become effective may be revoked by the Commissioner.

(d) The Commissioner shall promulgate regulations for exempting from the operation of the foregoing subsections and subdivisions of this section drugs intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs. Such regulations may, within the discretion of the Commissioner among other conditions relating to the protection of the public health, provide for conditioning such exemption upon

(1) The submission to the Commissioner, before any clinical testing of a new drug is undertaken, of reports, by the manufacturer or the sponsor of the investigation of such drug, of preclinical tests (including tests on animals) of such drug adequate to justify the proposed clinical testing;

(2) The manufacturer or the sponsor of the investigation of a new drug proposed to be distributed to investigators for clinical testing obtaining a signed agreement from each of such investigators that patients to whom the drug is administered will be under his personal supervision, or under the supervision of investigators responsible to him, and that he will not supply such drug to any other investigator, or to clinics, for administration to human beings; and

(3) The establishment and maintenance of such records, and the making of such reports to the Commissioner, by the manufacturer or the sponsor of the investigation of such drug, of data (including but not limited to analytical reports by investigators) obtained as the result of such investigational use of such drug, as the Commissioner finds will enable him to evaluate the safety and effectiveness of such drug in the event of the filing of an application pursuant to subsection (b).

Such regulations shall provide that such exemption shall be conditioned upon the manufacturer, or the sponsor of the investigation, requiring that experts using such drugs for investigational purposes certify to such manufacturer or sponsor that they will inform any human beings to whom such drugs, or any controls used in connection therewith, are being administered, or their representatives, that such drugs are being used for investigational purposes and will obtain the consent of such human beings or their representatives, except where they deem it not feasible, or, in their professional judgment, contrary to the best interests of such human beings. Nothing in this subsection shall be construed to require any clinical investigator to submit directly to the Commissioner reports on the investigational use of drugs; provided, that regulations adopted under section 505(i) of the federal act may be adopted by the Commissioner as the regulations in this State.

(e) (1) In the case of any drug for which an approval of an application filed pursuant to this section is in effect, the applicant shall establish and maintain such records, and make such reports to the Commissioner, of data relating to clinical experience and other data or information, received or otherwise obtained by such applicant with respect to such drug, as the Commissioner may by general regulation, or by order with respect to such application, prescribe: Provided, however, that regulations and orders issued under this subsection and under subsection (d) shall have due regard for the professional ethics of the medical profession and the interests of patients and shall provide, where the Commissioner deems it to be appropriate, for the examination, upon request, by the persons to whom such regulations or orders are applicable, of similar information received or otherwise obtained by the Commissioner.

(2) Every person required under this section to maintain records, and every person in charge or custody thereof, shall, upon request of an officer or employee designated by the Commissioner, permit such officer or employee at all reasonable times to have access to and copy and certify such records.

(f) The Commissioner may, after affording an opportunity for public hearing, revoke an application approved pursuant to this section if he finds that the drug, based on evidence acquired after such approval, may not be safe or effective for its intended use, or that the facilities or controls used in the manufacture, processing, or labeling of such drug may present a hazard to the public health.

(g) This section shall not apply:

(1) To a drug sold in this State or introduced into interstate commerce at any time prior to the enactment of the federal act, if its labeling contained the same representations concerning the conditions of its use; or

(2) To any drug which is licensed under the Public Health Service Act of July 1, 1944 (58 Stat. 682, as amended; 42 U.S.C. 201 et seq.) or under the Animal Virus-Serum-Toxin Act of March 4, 1913 (13 Stat. 832; 21 U.S.C. 151 et seq.); or

(3) To any drug which is subject to G.S. 106-134 (14) of this Article. (1939, c. 320, s. 16; 1975, c. 614, s. 31.)

§ 106-136. Cosmetics deemed adulterated.

A cosmetic shall be deemed to be adulterated:

(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling or advertisement thereof, or under such conditions of use as are customary or usual: Provided, that this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution – This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness," and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this subdivision and subdivision (5) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(2) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(3) If it has been produced, prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

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

(5) If it is not a hair dye and it is, or it bears or contains a color additive which is unsafe within the meaning of G.S. 106-132. (1939, c. 320, s. 17; 1975, c. 614, s. 32.)

§ 106-137. Cosmetics deemed misbranded.

A cosmetic shall be deemed to be misbranded:

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

b. If its labeling or packaging fails to conform with the requirements of G.S. 106-139 and 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: 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 its container is so made, formed, or filled as to be misleading.

(5) If it is a color additive, 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. This subdivision shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of G.S. 106-136(1)). (1939, c. 320, s. 18; 1975, c. 614, ss. 33-35.)

§ 106-138. False advertising.

(a) An advertisement of a food, drug, device or cosmetic shall be deemed to be false if it is false or misleading in any particular.

(b) For the purpose of this Article the advertisement of a drug or device representing it to have any effect in albuminuria, appendicitis, arteriosclerosis, blood poison, bone disease, Bright's disease, cancer, carbuncles, cholecystitis, diabetes, diphtheria, dropsy, erysipelas, gallstones, heart and vascular diseases, high blood pressure, mastoiditis, measles, meningitis, mumps, nephritis, otitis, media, paralysis, pneumonia, poliomyelitis, (infantile paralysis), prostate gland disorders, pyelitis, scarlet fever, sexual impotence, sinus infection, smallpox, tuberculosis, tumors, typhoid, uremia, or venereal diseases, shall also be deemed to be false; except that no advertisement not in violation of subsection (a) shall be deemed to be false under this subsection if it is disseminated only to members of the medical, dental, pharmaceutical, or veterinary professions, or appears only in the scientific periodicals of these professions, or is disseminated only for the purpose of public health education by persons not commercially interested, directly or indirectly, in the sale of such drugs or devices: Provided, that whenever the Department of Agriculture and Consumer Services determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the Board shall by regulation authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the Board may deem necessary in the interest of public health: Provided, that this subsection shall not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious. (1939, c. 320, s. 19; 1997-261, s. 109.)

§ 106-139. Regulations by Board of Agriculture.

(a) The authority to promulgate regulations for the efficient enforcement of this Article is hereby vested in the Board of Agriculture, except the Commissioner of Agriculture is hereby authorized to promulgate regulations under G.S. 106-131 and 106-135. The Board and Commissioner are hereby authorized to make the regulations promulgated under this Article conform, insofar as practicable, with those promulgated for foods, drugs, devices, cosmetics and

consumer commodities under the federal act, including but not limited to pesticide chemical residues on or in foods, food additives, color additives, special dietary foods, labeling of margarine for retail sale or distribution, nutritional labeling of foods, the fair packaging and labeling of consumer commodities and new drug clearance. Notwithstanding the provisions of subsection (e) of this section, a federal regulation adopted by the Board or Commissioner pursuant to this Article shall take effect in this State on the date it becomes effective as a federal regulation.

(b) The Board may promulgate regulations exempting from any affirmative labeling requirement of this Article consumer commodities which are, in accordance with the practice of the trade, to be processed, labeled or repacked in substantial quantities at establishments other than those where originally processed or packed, on condition that such consumer commodities are not adulterated or misbranded under the provisions of this Article upon removal from such processing, labeling or repacking establishment. The Board may additionally promulgate regulations exempting from any labeling requirement of this Article foods packaged or dispensed at the direction of the retail purchaser at the time of sale, whether or not for immediate consumption by the purchaser on the premises of the seller.

(c) Whenever the Board determines that regulations containing prohibitions or requirements other than those prescribed by G.S. 106-139.1(a) are necessary to prevent the deception of consumers or to facilitate value comparisons as to any consumer commodity, the Board shall promulgate with respect to that commodity regulations effective to:

(1) Establish and define standards for the characterization of the size of a package enclosing any consumer commodity, which may be used to supplement the label statement of net quantity of contents of packages containing such commodity, but this paragraph shall not be construed as authorizing any limitation of the size, shape, weight, dimensions, or number of packages which may be used to enclose any commodity;

(2) Regulate the placement upon any package containing any commodity or upon any label affixed to such commodity, of any printed matter stating or representing by implication that such commodity is offered for retail sale at a price lower than the ordinary and customary retail sale price or that a retail sale price advantage is accorded to purchasers thereof by reason of the size of that package or the quantity of its contents;

(3) Require that the label on each package of a consumer commodity bear
   a. The common or usual name of such consumer commodity, if any, and
   b. In case such consumer commodity consists of two or more ingredients, the common or usual name of each such ingredient listed in order of decreasing predominance, but nothing in this paragraph shall be deemed to require that any trade secret be divulged; or

(4) Prevent the nonfunctional slack-fill of packages containing consumer commodities.

   For the purposes of subdivision (4) of this subsection, a package shall be deemed to be nonfunctionally slack-filled if it is filled of substantially less than its capacity for reasons other than
   a. Protection of the contents of such package, or
   b. The requirements of machines used for enclosing the contents in such package;

provided, the Board may adopt any regulations promulgated pursuant to the Federal Fair Packaging and Labeling Act which shall have the force and effect of law in this State.

(d) Hearings authorized or required by G.S. 106-131 or G.S. 106-135 shall be conducted in accordance with Chapter 150B of the General Statutes.

(e) Repealed by Session Laws 1987, c. 827, s. 30 (1939, c. 320, s. 20; 1973, c. 476, s. 128; 1975, c. 614, s. 36; 1987, c. 827, s. 30.)

§ 106-139.1. Declaration of net quantity of contents.

(a) All labels of consumer commodities, as defined by this Article, shall conform with the requirement for the declaration of net quantity of contents of section 4 of the Federal Fair Packaging and Labeling Act (15 U.S.C. 1451, et seq.) and the regulations promulgated pursuant thereto: Provided, that consumer commodities exempted from such requirements of section 4 of the Federal Fair Packaging and Labeling Act shall also be exempt from this subsection.

(b) The label of any package of a consumer commodity which bears a representation as to the number of servings of such commodity contained in such package shall bear a statement of the net quantity (in terms of weight, measure, or numerical count) of each such serving.

(c) No person shall distribute or cause to be distributed in commerce any packaged consumer commodity if any qualifying words or phrases appear in conjunction with the separate statement of the net quantity of contents required by subsection (a) of this section, but nothing in this section shall prohibit supplemental statements, at other places on the package, describing in nondeceptive terms the net quantity of contents: Provided, that such supplemental statements of net quantity of contents shall not include any term qualifying a unit of weight, measure, or count that tends to exaggerate the amount of the commodity contained in the package. (1975, c. 614, s. 37.)

§ 106-140. Further powers of Commissioner of Agriculture for enforcement of Article; report by inspector to owner of establishment.

(a) For purposes of enforcement of this Article, the Commissioner or any of his authorized agents, are authorized upon presenting appropriate credentials and a written notice to the owner, operator or agent in charge,

(1) To enter at reasonable times any factory, warehouse or establishment in which food, drugs, devices or cosmetics are manufactured, processed, or packed or held for introduction into commerce or after such introduction or to enter any vehicle being used to transport or hold such food, drugs, devices or cosmetics in commerce; and

(2) To inspect at reasonable times and in a reasonable manner such factory, warehouse, establishment or vehicle and all pertinent equipment, finished or unfinished materials, containers and labeling therein, and to obtain samples necessary to the endorsement of this Article. In the case of any factory, warehouse, establishment, or consulting laboratory in which any food, drug, device or cosmetic is manufactured, processed, analyzed, packed or held, the inspection shall extend to all things therein (including records, files, papers, processes, controls and facilities) bearing on whether any food, drug, device or cosmetic which is adulterated or misbranded within the meaning of this Article or which may not be manufactured, introduced into commerce or sold or offered

for sale by reason of any provision of this Article, has been or is being manufactured, processed, packed, transported or held in any such place or otherwise bearing on violation of this Article. No inspection authorized by the preceding sentence shall extend to

a. Financial data,
b. Sales data other than shipment data,
c. Personnel data (other than data as to qualifications of technical and professional personnel performing functions subject to this Article),
d. Pricing data, and
e. Research data (other than data relating to new drugs and antibiotic drugs, subject to reporting and inspection under lawful regulations issued pursuant to section 505(i) or (j) or section 507 (d) or (g) of the federal act, and data, relating to other drugs, which in the case of a new drug would be subject to reporting or inspection under lawful regulations issued pursuant to section 505(j) of the federal act).

Such inspection shall be commenced and completed with reasonable promptness. The provisions of the second sentence of this subsection shall not apply to such classes of persons as the Board may by regulation exempt from the application of this section upon a finding that inspection as applied to such classes of persons in accordance with this section is not necessary for the protection of the public health.

(3) To have access to and to copy all records of carriers in commerce showing the movement in commerce of any food, drug, device, or cosmetic, or the holding thereof during or after such movement, and the quantity, shipper and consignee thereof: Provided, that evidence obtained under this subsection shall not be used in a criminal prosecution of the person from whom obtained; and provided further, that carriers shall not be subject to the other provisions of this Article by reason of their receipt, carriage, holding, or delivery of food, drugs, devices or cosmetics in the usual course of business as carriers.

(b) Upon completion of any such inspection of a factory, warehouse, consulting laboratory or other establishment and prior to leaving the premises, the authorized agent making the inspection shall give to the owner, operator, or agent-in-charge a report in writing setting forth any conditions or practices observed by him which in his judgment indicate that any food, drug, device or cosmetic in such establishment:

(1) Consists in whole or in part of any filthy, putrid, or decomposed substance; or
(2) Has been prepared, packed or held under insanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered injurious to health.

(c) If the authorized agent making any such inspection of a factory, warehouse or other establishment has obtained any salable product samples in the course of the inspection, upon completion of the inspection and prior to leaving the premises he shall offer reasonable payment for any such product samples.

(d) It shall be the duty of the Commissioner of Agriculture to make or cause to be made examination of samples secured under the provisions of this section to determine whether or not any provision of this Article is being violated. (1939, c. 320, s. 21; 1975, c. 614, s. 38.)

§ 106-140.1. Registration of producers of prescription drugs and devices.

(a) On or before December 31 of each year, every person doing business in North Carolina and operating as a wholesaler, manufacturer, outsourcing facility, or repackager, as those terms are defined in subsection (j) of this section, shall register with the Commissioner his name and business location(s) in North Carolina. If said person has no business locations in North Carolina, he shall register his name and location of his corporate offices.

(b) Every person, upon first operating as a wholesaler, manufacturer, outsourcing facility, or repackager in North Carolina shall immediately register with the Commissioner his name, place of business, and such establishment. If said person has no business locations in North Carolina, he shall register his name and location of his corporate offices.

(c) Every person duly registered in accordance with subsections (a) and (b) of this section shall register with the Commissioner any additional establishment that he owns or operates in the State of North Carolina prior to doing business as a manufacturer, wholesaler, outsourcing facility, or repackager.

(d) The Commissioner may assign a registration number to any person or any establishment registered in accordance with this section.

(e) The Commissioner shall make available for inspection to any person so requesting any registration filed pursuant to this section.

(f) The following classes of people are exempt from the registration requirements of this section:

(1) Pharmacists as defined in G.S. 90-85.3(q) holding a valid permit as defined in G.S. 90-85.3(m).

(2) Practitioners licensed or registered by law to prescribe or administer drugs and who manufacture, prepare, compound, or process drugs or devices solely for use in the course of their professional practice.

(3) Persons who manufacture, prepare, compound, or process drugs solely for use in research, teaching, or chemical analysis and not for sale.

(4) Other classes of persons the Commissioner may by rule exempt from the application of this section upon a finding that registration by these classes of persons in accordance with this section is not necessary for the protection of the public health.

(5) Wholesale distributors of prescription drugs licensed under G.S. 106-145.3.

(g) Every establishment in the State of North Carolina registered with the Commissioner pursuant to this section shall be subject to inspection pursuant to G.S. 106-140.

(h) The Commissioner shall adopt rules to implement the registration requirements of this section. These rules shall provide for an annual registration fee of one thousand dollars ($1,000) for companies operating as manufacturers, outsourcing facilities, or repackagers and seven hundred dollars ($700.00) for companies operating as wholesalers. The Department of Agriculture and Consumer Services shall use these funds for the implementation of the North Carolina Food, Drug and Cosmetic Act.

(i) For the purposes of this act, name means the name of the partnership if a partnership and the name of the corporation if a corporation.

(j) As used in this section:

(1) The term "manufacturer" means a person who prepares, derives, or produces a prescription drug. Pharmacists are specifically excluded from this definition if

they are acting in the course of their professional practice as defined in Chapter 90 and rules adopted pursuant to it.

(1a) The term "outsourcing facility" means a manufacturer at a single geographic location or address that is engaged in the compounding of sterile drugs, has elected to register as an outsourcing facility with the Food and Drug Administration, and complies with the requirements as provided in 21 U.S.C. § 353b. Exemptions provided by 21 U.S.C. § 353b(a) with respect to labeling, new drug registration, and distribution supply chain requirements shall also apply to compounded drugs distributed in North Carolina by an outsourcing facility.

(2) The term "prescription drug" means a drug that under federal law is required, prior to being dispensed or delivered, to be labeled with the following statement: "Caution: Federal law prohibits dispensing without a prescription."

(3) The term "repackager" means a person who repacks, relabels, or manipulates a prescription drug which was in a unit packaged and sealed by a manufacturer. Pharmacists are specifically exempted from this definition if they are acting in the course of their professional practice as defined in Chapter 90 and rules adopted pursuant to it.

(4) The term "wholesaler" means a person acting as a jobber, wholesale merchant, salvager, or broker, or agent thereof, who sells or distributes for resale a prescription drug. Pharmacists are specifically exempted from this definition if they are acting in the course of their professional practice as defined in Chapter 90 and rules adopted pursuant to it. (1987, c. 737, s. 2; 1989, c. 226, s. 2; 1989 (Reg. Sess., 1990), c. 1024, s. 20; 1991, c. 699, ss. 3, 4; 1997-261, s. 109; 2015-241, s. 13.4(a); 2015-263, s. 32; 2015-268, s. 5.1.)

§ 106-141. Examinations and investigations.

(a) Repealed by Session Laws 1975, c. 614, s. 39.

(b) The Commissioner of Agriculture is authorized to conduct the examinations and investigations for the purposes of this Article through officers and employees of the Department or through any health, food or drug officer or employee of the State, or any political subdivision thereof: Provided, that when examinations and investigations are to be conducted through any officer or employee of any agency other than the Department of Agriculture and Consumer Services the arrangements for such examinations and investigations shall be approved by the directing head of such agency.

(c) The Commissioner of Agriculture is authorized to delegate embargo authority concerning food and drink pursuant to G.S. 106-125 to the Secretary of Health and Human Services and to local health directors. (1939, c. 320, s. 22; 1975, c. 614, s. 39; 1983, c. 891, s. 12; 1997-261, s. 109; 1997-443, s. 11A.118(a).)

§ 106-141.1. Inspections of donated food.

(a) The Department of Agriculture and Consumer Services is authorized to inspect for compliance with the provisions of Article 12 of Chapter 106 of the North Carolina General Statutes, food items donated for use or distribution by nonprofit organizations or nonprofit corporations, and may establish procedures for the handling of the food items, including reporting procedures concerning the donation of food.

(b) The Department of Agriculture and Consumer Services may apply to Superior Court for injunctive relief restraining the violation of this section.

(c) Nothing in this section shall limit the duties or responsibilities of the Commission for Public Health or the local boards of health. (1979, 2nd Sess., c. 1188, s. 3; 1997-261, s. 34; 2007-182, s. 2.)

§ 106-142. Publication of reports of judgments, decrees, etc.

(a) The Commissioner of Agriculture may cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this Article, including the nature of the charge and the disposition thereof.

(b) The Commissioner of Agriculture may also cause to be disseminated such information regarding food, drugs, devices, and cosmetics as he deems necessary in the interest of public health and the protection of the consumer against fraud. Nothing in this section shall be construed to prohibit the Commissioner of Agriculture from collecting, reporting, and illustrating the results of the investigations of the Department. (1939, c. 320, s. 23.)

§ 106-143. Article construed supplementary.

Nothing in this Article shall be construed as in any way amending, abridging, or otherwise affecting the validity of any law or ordinance relating to the Commission for Public Health or the Department of Environmental Quality or any local health department in their sanitary work in connection with public and private water supplies, sewerage, meat, or other foods, or food products, or the production, handling, or processing of these items. (1939, c. 320, s. 241/2; 1973, c. 476, s. 128; 1975, c. 19, s. 31; 1997-443, s. 11A.41; 2007-182, s. 2; 2011-145, s. 13.3(u); 2015-241, s. 14.30(u).)

§ 106-144. Exemptions.

Meats and meat products subject to the Federal Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 et seq.), and poultry and poultry products subject to the Federal Poultry Products Inspection Act (21 U.S.C. 451 et seq.) are exempted from the provisions of this Article so long as such meat, meat products, poultry, and poultry products remain in the possession of the processor. (1939, c. 320, s. 24 2/3; 1975, c. 614, s. 40.)

§ 106-145. Effective date.

This Article shall be in full force and effect from and after January 1, 1940: Provided, that the provisions of G.S. 106-139 shall become effective on April 3, 1939, and thereafter the Commissioner of Agriculture is authorized hereby to conduct hearings, and the Board is authorized to promulgate regulations which shall become effective on and after the effective date of this Article as the Board shall direct. (1939, c. 320, s. 25.)