GENERAL ASSEMBLY OF NORTH CAROLINA

SESSION 1989

H **2**

HOUSE BILL 695
Second Edition Engrossed 5/2/89

Short Title: Food, Drug Act/Tech. Change. (Public)

Sponsors: Representative Woodard.

Referred to: Human Resources.

March 20, 1989

A BILL TO BE ENTITLED

AN ACT TO MAKE TECHNICAL CORRECTIONS IN THE FOOD, DRUG, AND COSMETICS ACT.

The General Assembly of North Carolina enacts:

Section 1. G.S. 106-121 reads as rewritten:

"**§ 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 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 ~~appear~~ 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) 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.~~

(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) 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.'~~

(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) 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. Pharmacies 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.~~

~~(14f) 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.~~

(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."

Sec. 2. G.S. 106-140.1 is amended by adding a new subsection to read:

"(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.

(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."

Sec. 3. This act is effective upon ratification.