CHAPTER 19-02.1
NORTH DAKOTA FOOD, DRUG, AND COSMETIC ACT

19-02.1-01. Definitions.

For the purpose of this chapter:

1. "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.
2. "Color" includes black, white, and intermediate grays.
3. "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, except that such term does not include any material which has been or hereafter is exempted under the Federal Act.
4. "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.
5. "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; or
   b. Articles intended for use as a component of any such articles, except that such term does not include soap.
6. "Department" means the department of health and human services.
7. "Device", except when used in the first paragraph following subsection 21 of this section and in subsection 10 of section 19-02.1-02, subsection 6 of section 19-02.1-10, subsections 3 and 16 of section 19-02.1-14, and subsection 3 of section 19-02.1-18, 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.
8. "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;
   b. Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;
   c. Articles, other than food, intended to affect the structure or any function of the body of man or other animals; or
   d. Articles intended for use as a component of any article specified in subdivision a, b, or c, but does not include devices or their components, parts, or accessories. Provided, however, that "drug", for the purpose of this chapter, and as defined by this subsection, does not include those controlled substances or drugs regulated by or under the authority of the Uniform Controlled Substances Act, with respect to such drugs, the Uniform Controlled Substances Act takes precedence over and supplants the provisions of this chapter only so far as its authority and control is synonymous with the provisions of this chapter.
9. "Federal Act" means the Federal Food, Drug, and Cosmetic Act, as amended [21 U.S.C. 301 et seq.].
10. "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.

11. "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;
    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;
    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.].
12. "Immediate container" does not include package liners.
13. "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 chapter that any word, statement, or other information appearing on the label may 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.
14. "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.
15. "Manufacture, compound, or process" includes repackaging or otherwise changing the container, wrapper, or labeling of any drug package in the furtherance of the distribution of the drug from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer, and the term "manufacturers, compounders, and processors" must be deemed to refer to persons engaged in such defined activities.
16. "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 investigations, been used to a material extent or for a material time under such conditions.
17. "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.
18. "Person" includes individual, partnership, corporation, limited liability company, and association.
19. "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

chapter 4.1-34, and which is used in the production, storage, or transportation of raw agricultural commodities.

20. "Practitioner" means an individual licensed, registered, or otherwise authorized by the jurisdiction in which the individual is practicing to prescribe drugs in the course of professional practice which are subject to this chapter.
21. "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.

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 must be taken into account, among other things, not only representations made or suggested by statement, word, design, device, sound, or in any combination thereof, but also the extent to which the 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.

The representation of a drug, in its labeling or advertisement, as an antiseptic must 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.

The provisions of this chapter regarding the selling of food, drugs, devices, or cosmetics must 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 articles in the conduct of any food, drug, or cosmetic establishment.

Nothing in subsection 21 may be construed to 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.

19-02.1-02. Prohibited acts.

The following acts and the causing thereof within the state of North Dakota 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 section 19-02.1-11 or 19-02.1-16.
5. The dissemination of any false advertisement.
6. The refusal to permit entry or inspection, or to permit the taking of a sample, as authorized by section 19-02.1-21.
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 Dakota from whom the person received in good faith the food, drug, device, or cosmetic.
8. The removal or disposal of a detained or embargoed article in violation of section 19-02.1-05.
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 adulterated or misbranded.

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 chapter or of the federal act.
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 section 19-02.1-16 or that such drug complies with the provisions of such section.
12. 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 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 subsection may be construed to exempt any person from any labeling requirement imposed by or under other provisions of this chapter.
13. 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; 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 this subsection; or making, selling, disposing of, or causing to be made, sold, or disposed of, or keeping in possession, control, or custody, or concealing, with intent to defraud, any punch, die, plate, or other thing designed to print, imprint, or reproduce that trade name or other identifying mark or imprint of another or any likeness of any of the foregoing upon any drug, device, or container thereof.
14. Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the express permission in each case of the person ordering or prescribing.
15. The manufacture of drugs, or the supplying of drugs at wholesale or retail, unless a license or permit to do so has first been obtained from the state board of pharmacy after application to the state board of pharmacy and the payment of a fee set by the state board of pharmacy.
16. The filling or refilling of any prescription in violation of subsection 1 of section 19-02.1-15.

19-02.1-03. Injunction proceedings.

In addition to the remedies hereinafter provided, the department is hereby authorized to apply to the district court of Burleigh County 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 section 19-02.1-02, irrespective of whether or not there exists an adequate remedy at law.

19-02.1-04. Penalties and guaranty.

1. Any person who violates any of the provisions of subsections 1 through 16 of section 19-02.1-02 is guilty of a class B misdemeanor.
2. No person shall be subject to the penalties of subsection 1, for having violated subsection 1 or 3 of section 19-02.1-02 if the person established a guaranty or undertaking signed by, and containing the name and address of, the person residing in the state of North Dakota from whom the person received in good faith the article, to the effect that such article is not adulterated or misbranded within the meaning of this chapter, designating this chapter.
3. 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 the person of such false advertisement, unless the person has refused, on the request of the department, to furnish the department the name and post-office address of the manufacturer, packer, distributor, seller, or advertising agency residing in the state of North Dakota who caused the person to disseminate such advertisement.

4. Repealed by S.L. 1971, ch. 235, § 49.

19-02.1-05. Seizure.

1. Whenever a duly authorized agent of the department finds or has probable cause to believe that any food, drug, device, or cosmetic is adulterated or so misbranded as to be dangerous or fraudulent, within the meaning of this chapter, the authorized agent 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 is unlawful for any person to remove or dispose of such detained or embargoed article by sale or otherwise without such permission.
2. When an article detained or embargoed under subsection 1 has been found by such agent to be adulterated or misbranded, the authorized agent shall petition the judge of the district court in the county in which the article is detained or embargoed for a libel for condemnation of such article. When such agent has found that an article so detained or embargoed is not adulterated or misbranded, the authorized agent shall remove the tag or other marking.
3. If the court finds that a detained or embargoed article is adulterated or misbranded, such article must, 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, must be taxed against the claimant of such article or the claimant's 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 decrees and after such costs, fees, and expenses have been paid and a good and sufficient bond, conditioned that such article must 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. The expense of such supervision must be paid by the claimant. Such must be returned to the claimant of the article on the representation to the court by the department that the article is no longer in violation of this chapter, and that the expenses of such supervision have been paid.
4. Whenever an authorized agent of the department finds 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 department's authorized agent shall forthwith condemn or destroy the same, or in any other manner render the same unsalable as human food.
5. Any person, firm, corporation, or limited liability company having an interest in the alleged article, equipment, or other thing proceeded against, or any person, firm, corporation, or limited liability company against whom a civil or criminal liability would exist if said merchandise is in violation of section 19-02.1-02 may, within twenty days following the seizure, appear and file answer to the complaint. The answer must allege the interest or liability of the party filing it. In all other respects, the issue must be made up as in other civil actions.
6. Any article, equipment, conveyance, or other thing condemned under this section must, after entry of the decree, be disposed of by destruction or sale as the court may, in accordance with the provisions of this section, direct and the proceeds thereof, if sold, less the legal costs and charges, must be paid to the treasurer of the state; but

such article, equipment, or other thing may not be sold under such decree contrary to provisions of this chapter.

7. Whenever in any proceedings under this section the condemnation of any equipment or conveyance or other thing, other than a drug, is decreed, the court shall allow the claim of any claimant, to the extent of such claimant's interest, for remission or mitigation of such forfeiture if such claimant proves to the satisfaction of the court all of the following:
   a. The claimant has not committed or caused to be committed any prohibited act referred to in chapter 19-03.1 and has no interest in any drug or controlled substance referred to therein.
   b. The claimant has an interest in such equipment, or other thing as owner or lienor or otherwise, acquired by the claimant in good faith.
   c. The claimant at no time had any knowledge or reason to believe that such equipment, conveyance, or other thing was being or would be used in, or to facilitate, the violation of the laws of this state relating to depressant, stimulant, or hallucinogenic drugs or counterfeit drugs.
8. When a decree of condemnation is entered against the article, equipment, conveyance, or other thing, court costs and fees and storage and other proper expenses must be awarded against the person, if any, intervening as claimant of the article.

19-02.1-06. Prosecutions - State's attorney.

It is the duty of each state's attorney, to whom the department or state board of pharmacy reports any violation of this chapter occurring in the state's attorney's county, to cause appropriate proceedings to be instituted in the proper courts without delay and to be prosecuted in the manner required by law.

19-02.1-07. Minor violations.

Nothing in this chapter may be construed as requiring the department or the state board of pharmacy to report minor violations of this chapter for the institution of proceedings under this chapter whenever the department or the state board of pharmacy believes that the public interest will be adequately served in the circumstances by a suitable written notice or warning.

19-02.1-08. Food - Definitions and standards.

Whenever in the judgment of the department such action will promote honesty and fair dealing in the interest of consumers, the department shall promulgate regulations fixing and establishing for any food or class of food a reasonable definition and standard of identity or reasonable standard of quality 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 department shall, for the purpose of promoting honesty and fair dealing in the interest of consumers, designate the optional ingredients which must be named on the label. The definitions and standards so promulgated must conform so far as practicable to the definitions and standards promulgated under authority of the federal act.

19-02.1-09. Food - Adulteration defined.

A food must be deemed to be adulterated for any of the following reasons:

1. 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 may not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health.
2. If it bears or contains any added poisonous or added deleterious substance, other than one which is:
   a. A pesticide chemical in or on a raw agricultural commodity;
   b. A food additive; or

c. A color additive which is unsafe within the meaning of subsection 1 of section 19-02.1-12.

3. If it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of subsection 1 of section 19-02.1-12.
4. If it is or bears or contains, any food additive which is unsafe within the meaning of subsection 1 of section 19-02.1-12. Provided, that when a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or tolerance prescribed under subsection 1 of section 19-02.1-12, 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 may not, notwithstanding the provisions of section 19-02.1-12 and this subsection, 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.
5. 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.
6. If it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth or whereby it may have been rendered diseased, unwholesome, or injurious to health.
7. 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.
8. If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.
9. If any valuable constituent has been in whole or in part omitted or abstracted therefrom.
10. If any substance has been substituted wholly or in part therefor.
11. If damage or inferiority has been concealed in any manner.
12. 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.
13. If it is confectionery and has partially or completely imbedded therein any non-nutritive object. This subsection does not apply in the case of any non-nutritive object if, in the judgment of the department as provided by rules, the object is of practical functional value to the confectionery product and would not render the product injurious or hazardous to health. This subsection does not apply to any confectionery, by reason of its containing less than one-half of one percent by volume of alcohol derived solely from the use of flavoring extracts. This subsection does not apply to a non-nutritive substance that is in or on confectionery by reason of its use for some practical functional purpose in the manufacture, packaging, or storage 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 chapter. To avoid or resolve uncertainty as to the application of this subsection, the department may issue rules allowing or prohibiting use of particular non-nutritive substances.
14. If it is or bears or contains any color additive which is unsafe within the meaning of subsection 1 of section 19-02.1-12.
15. 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 federal law.

19-02.1-10. Food - Misbranding defined.

A food must be deemed to be misbranded:

1. If its labeling is false or misleading in any particular.
2. If it is offered for sale under the name of another food.
3. If it is an imitation of another food for which a definition and standard of identity has been prescribed by regulations as provided by section 19-02.1-08 or if it is an imitation of another food that is not subject to subsection 7, 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;
   b. An accurate statement of the quantity of the contents in terms of weight, measure, or numerical count; and
   c. In the case of beverages that are manufactured, distributed, and sold under a franchise or trademark name indicated thereon, whereby the person, firm, corporation, or limited liability company owning the franchise or trademark has control over the distribution, such beverages may be exempt from this subsection, if a certified statement is filed with the department, stating the name and address of the manufacturer or distributor, and a statement signed by the manufacturer or distributor that they assume all responsibility and liability for the product named, which is being sold, or offered for sale, under such name within the area of the state designated, which certificate must be in the following form:

      NORTH DAKOTA DEPARTMENT OF HEALTH AND HUMAN SERVICES
      BISMARCK, NORTH DAKOTA
      BEVERAGE LABELING EXEMPTIONS CERTIFICATE
      I, _____, the undersigned, an agent of and having authority to sign, do hereby certify that the following information is correct:
      Name and address of company requesting exemption
      _____
      Name _____
      Street Address _____
      City or Town _____
      State _____
      Name of Product _____
      Brand Name _____

      In order to be exempt from subdivisions a and b of subsection 5 of section 19-02.1-10 of the North Dakota Century Code, relating to misbranding of food, which requires the name and address of the real manufacturer or other persons responsible for placing the product upon the market, I, the undersigned, do bind the company listed above by agreeing to assume all responsibility for the product named in this certificate which is being sold, or offered for sale under such name and brand name within the area consisting of _____ in the State of North Dakota.

      Note: The area must be designated by counties or other legal subdivisions of the city, county, or state.

      Firm _____
      Signed _____
      Title _____
      Address _____

      Note: If signed by a person other than an officer of the company, authorization for signature must accompany this form. This certificate must be acknowledged.

   Provided, that under subdivision b reasonable variations must be permitted, and exemptions as to small packages must be established, by regulations prescribed by the department.
6. If any word, statement, or other information required by or under authority of this chapter 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 section 19-02.1-08 unless it conforms to such definition and standard, 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 section 19-02.1-08 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 section 19-02.1-08, 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 subsection 7, unless it bears labeling clearly giving:
   a. The common or usual name of the food, if any there be; and
   b. The common or usual name of each such ingredient, in case it is fabricated from two or more ingredients, 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 this subdivision is impracticable or results in deception or unfair competition, exemptions must be established by regulations promulgated by the department and, provided further, that the requirements of this subdivision do not apply to food products which are packaged at the direction of purchasers at retail at the time of sale, the ingredients of which are disclosed to the purchasers by other means in accordance with regulations promulgated by the department.
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 department 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 preservative, unless it bears labeling stating that fact; provided, that the extent that compliance with the requirements of this subsection is impracticable, exemptions must be established by regulations promulgated by the department.
12. 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.
13. 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 the federal act.
14. If it is a raw agricultural commodity that is the produce of the soil, bearing or containing a pesticide chemical applied after harvest, unless the shipping container of the commodity bears labeling that declares the presence of the chemical in or on the commodity and the common or usual name and the function of the chemical. No such declaration is required while the commodity, having been removed from the shipping container, is being held or displayed for sale at retail out of the container in accordance with the custom of the trade.
15. If its packaging or labeling is in violation of an applicable regulation issued under section 3 or 4 of the Poison Prevention Packaging Act of 1970.

19-02.1-10.1. Eggs - Labeling and temperature rules.

The department may adopt appropriate rules under chapter 28-32 to establish standards for proper labeling and temperature during the retail storage and sale of shell eggs. As used in this section, "eggs" means eggs in the shell which are the product of a domesticated chicken.

19-02.1-11. Emergency permit control.

Whenever the department finds after investigation that the distribution in the state of North Dakota of any class of food may, by reason of contamination with micro-organisms during manufacture, processing, or packing thereof in any locality, be injurious to health and that such injurious nature cannot be adequately determined after such articles have entered commerce, it 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 must be attached such conditions governing the manufacture, processing, or packaging, 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 may 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 department as provided by such regulations.

The department 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 is privileged at any time to apply for the reinstatement of such permit, and the department shall, immediately after prompt hearing and 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.

Any officer or employee duly designated by the department shall have access to any factory or establishment, the operator of which holds a permit from the department for the purpose of ascertaining whether or not the conditions of the permit are being complied with, and denial of access for such inspection is grounds for suspension of the permit until such access is freely given by the operator.

19-02.1-12. Food - Tolerances for added poisonous ingredients.

1. Any added poisonous or 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 subsection 2 of section 19-02.1-09 with respect to any food, subsection 1 of section 19-02.1-13 with respect to any drug or device, or subsection 1 of section 19-02.1-17 with respect to any cosmetic, unless there is in effect a regulation pursuant to subsection 2 limiting the quantity of such substance, and the use or intended use of such substance conforms to the terms prescribed by such regulation. While such regulation relating to such substance is in effect, a food, drug, or cosmetic may not, by reason of bearing or containing such substance in accordance with the regulation, be considered adulterated within the meaning of subsection 1 of section 19-02.1-09, subsection 1 of section 19-02.1-13, or subsection 1 of section 19-02.1-17.
2. The department, whenever public health or other considerations in the state so require, is authorized to adopt, amend, or repeal regulations whether or not in accordance with regulations promulgated under the federal act prescribing therein tolerances for any added poisonous or deleterious substances, for food additives, for pesticide chemicals in or on raw agricultural commodities, or for color additives, including zero tolerances, and exemptions from tolerances in the case of pesticide chemicals in or on raw agricultural commodities, and prescribing the conditions under which a food additive or a color additive may be safely used and exemptions when such food additive or color additive is to be used solely for investigational or experimental purposes, upon its own motion or upon the petition of any interested party requesting that such a regulation be established, and it is incumbent upon such petitioner to establish by data submitted to the department that a necessity exists for such regulation, and that its effect will not be detrimental to the public health. If the data furnished by the petitioner is not sufficient to allow the department to determine whether such regulation should be promulgated, the department may require additional data to be submitted and failure to comply with the request is sufficient grounds to deny the request. In adopting, amending, or repealing regulations relating

to such substances, the department shall consider among other relevant factors the following which the petitioner, if any, shall furnish:

a. The name and all pertinent information concerning such substance, including where available, its chemical identity and composition, a statement of the conditions of the proposed use, including directions, recommendations, and suggestions and including specimens of proposed labeling, and all relevant data bearing on the physical or other technical effect and the quantity required to produce such effect;
b. The probable composition of any substance formed in or on a food, drug, or cosmetic resulting from the use of such substance;
c. The probable consumption of such substance in the diet of man and animals taking into account any chemically or pharmacologically related substance in such diet;
d. Safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of such substances for the use or uses for which they are proposed to be used, are generally recognized as appropriate for the use of animal experimentation data;
e. The availability of any needed practicable methods of analysis for determining the identity and quantity of such substance in or on an article, any substance formed in or on such article because of the use of such substance, and the pure substance and all intermediates and impurities; and
f. Facts supporting a contention that the proposed use of such substance will serve a useful purpose.

19-02.1-12.1. Misrepresentation of cell-cultured protein as meat food product prohibited.

1. A person may not advertise, offer for sale, sell, or misrepresent cell-cultured protein as a meat food product. A cell-cultured food product:
   a. May not be packaged in the same, or deceptively similar, packaging as a meat food product; and
   b. Must be labeled as a cell-cultured food product.
2. For purposes of this section, "deceptively similar" means packaging that could mislead a reasonable person to believe the product is a meat food product.

19-02.1-13. Drugs and devices - Adulteration defined.

A drug or device must be deemed to be adulterated:

1. If it consists in whole or in part of any filthy, putrid, or decomposed substance.
2. If it has been produced, prepared, packed, or held under unsanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health.
3. 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 chapter as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.
4. 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.
5. If it is a drug and it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of subsection 1 of section 19-02.1-12 or 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 subsection 1 of section 19-02.1-12.
6. 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 must 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 prescribed under authority of the federal act. No drug defined in an official compendium may be deemed to be adulterated under this subsection 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 is 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 is subject to the provisions of the homeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia.

7. If it is not subject to the provisions of subsection 6 and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.
8. If it is a drug and any substance has been mixed or packed therewith so as to reduce its quality or strength or substituted wholly or in part therefor.

19-02.1-14. Drugs and devices - Misbranding defined.

A drug or device must be deemed to be misbranded:

1. If its labeling is false or misleading in any particular.
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; provided, that under this subdivision reasonable variations must be permitted, and exemptions as to small packages must be allowed, in accordance with regulations prescribed by the department or issued under the federal act.
3. If any word, statement, or other information required by or under authority of this chapter 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 alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marijuana, morphine, opium, paraldehyde, peyote, or sulfonmethane, or any chemical derivative of such substance, which derivative, after investigation, has been found to be and designated as, habit-forming, by regulations issued by the department under this chapter, or by regulations issued pursuant to section 502(d) of the federal act, 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. If it is a drug, unless its label bears, to the exclusion of any other nonproprietary name, except the applicable systematic chemical name or the chemical formula:
   a. The established name, as defined in subsection 6, of the drug, if such there be; and
   b. The established name and quantity of each active ingredient, in case it is fabricated from two or more ingredients, 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, acetophenetidin, 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 subsection applies only to prescription drugs; provided, further, that to the extent that compliance with the

requirements of subdivision b of subsection 6 is impracticable, exemptions must be allowed under regulations promulgated by the department, or under the federal act.

6. As used in subsections 5 and 6, the term "established name", with respect to a drug or ingredient thereof, means:
   a. The applicable official name designated pursuant to section 508 of the federal act;
   b. 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
   c. If neither subdivision a nor b applies, then the common or usual name, if any, of such drug or of such ingredient.

   Provided, further, that when subdivision b applies to an article recognized in the United States pharmacopeia and in the homeopathic pharmacopeia under different official titles, the official title used in the United States pharmacopeia applies unless it is labeled and offered for sale as a homeopathic drug, in which case the official title used in the homeopathic pharmacopeia applies.
7. Unless its labeling bears:
   a. Adequate directions for use; and
   b. Such adequate warnings against use in those pathological conditions or by children when 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 if any requirement of subdivision a, as applied to any drug or device, is not necessary for the protection of the public health, the department shall promulgate regulations exempting such drug or device from such requirements; provided, further, that articles exempted under regulations issued under section 502(f) of the federal act may also be exempt.
8. 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 department, or if consent is obtained under the federal act. Whenever a drug is recognized in both the United States pharmacopeia and the homeopathic pharmacopeia of the United States, it is subject to the requirements of the United States pharmacopeia with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it is subject to the provisions of the homeopathic pharmacopeia of the United States and not to those of the United States pharmacopeia; provided, further, that in the event of inconsistency between the requirements of this subsection and those of subsections 5 and 6 as to the name by which the drug or its ingredients must be designated, the requirements of subsections 5 and 6 must prevail.
9. If it has been found by the department or under the federal act 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 regulations issued by the department or under the federal act require as necessary for the protection of public health. No such regulation may be established for any drug recognized in an official compendium until the department 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.
10. If it is a drug and:
    a. Its container is so made, formed, or filled as to be misleading;
    b. If it is an imitation of another drug; or
    c. If it is offered for sale under the name of another drug.
11. 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.
12. If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless 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 such certificate or release is in effect with respect to such drug.

13. 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 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 such certificate or release is in effect with respect to such drug; provided, that this subsection does 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 a micro-organism and which has the capacity to inhibit or destroy micro-organisms in dilute solution, including the chemically synthesized equivalent of any such substance.
14. 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 subsection 2 of section 19-02.1-12 or of the federal act.
15. 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 the established name as defined in subsection 6, the formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e) of the federal act, and such other information in brief summary relating to side effects, contraindications, and effectiveness as are required in regulations issued under the federal act.
16. 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.
17. Drugs and devices 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 are exempt from any labeling or packaging requirements of this chapter; provided, that such drugs and devices are being delivered, manufactured, processed, labeled, repacked, or otherwise held in compliance with regulations issued by the department, or under the federal act.
18. If it is a device and it has an established name, unless its label bears, to the exclusion of any other nonproprietary name, its established name, as defined in subsection 6, prominently printed in type at least half as large as that used thereon for any proprietary name or designation for the device, except that to the extent compliance with the requirements of this subsection is impracticable, exemptions will be established by rules adopted by the department. As used in this subsection, the term "established name" with respect to a device means:
    a. The applicable official name of the device designated pursuant to federal law.
    b. If there is no official name of the device designated pursuant to federal law and the device is an article recognized in an official compendium, then the official title of the device in the compendium.
    c. If neither subdivision a nor subdivision b applies, then any common or usual name of the device.
19. If it is a device subject to a performance standard established under federal law, unless it bears labeling prescribed in the performance standard.

19-02.1-14.1. Definitions - Label of prescription drugs - Selecting and dispensing generic name drugs - Identification of prescription drugs.

1. As used in this section, unless the subject matter or context otherwise requires:
    a. "Brand name" means the registered trademark name given to a drug or medicine by its manufacturer, labeler, or distributor.

b. "Code imprint" means a series of letters or numbers assigned by the manufacturer or distributor to a specific drug, or marks or monograms unique to the manufacturer or distributor of the drug, or both.
c. "Distributor" means a person who distributes for resale a drug in solid dosage form under that person's own label even though that person is not the actual manufacturer of the drug.
d. "Generic name" means the established name or official chemical name of the drug, drug product, or medicine.
e. "Prescription drug" means a drug defined by section 503(b) of the federal Act and under which definition its label is required to bear the statement "Caution: Federal law prohibits dispensing without prescription" or "Rx Only".
f. "Solid dosage form" means capsules or tablets intended for oral use.
g. "Therapeutically equivalent" means a generic name drug product that would elicit the same therapeutic response from the same person as a brand name drug product.

2. Drugs or medicines dispensed pursuant to a prescription must bear a label permanently affixed to the immediate container in which the drug or medicine is dispensed or delivered and which is received by the purchaser or patient. The label must bear the brand name or the generic name, strength, quantity, serial number, date of dispensing, patient name, and directions for use of the drug or medicine, except when the physician or other health care provider authorized by law to prescribe drugs or medicine has notified the pharmacist that the appearance of the name on the label would be alarming to or detrimental to the well-being of the purchaser of the prescription.
3. If a practitioner prescribes a drug by its brand name, the pharmacist may exercise professional judgment in the economic interest of the patient by selecting a drug product with the same generic name and demonstrated therapeutical equivalency as the one prescribed for dispensing and sale to the patient unless the practitioner specifically indicates in the practitioner's own handwriting "brand medically necessary" on a written prescription or expressly indicates that an oral prescription is to be dispensed as communicated. If the prescription is created electronically by the prescriber, the required legend must appear on the practitioner's screen. The practitioner must take a specific overt action to include the "brand medically necessary" language with the electronic transmission. The pharmacist shall note the instructions on the file copy of the prescription, or maintain the digital record as transmitted if it is an electronic prescription. A reminder legend must be placed on all prescription forms or appear on the computer screen of the electronic prescribing system. The legend must state "In order to require that a brand name product be dispensed, the practitioner must handwrite the words 'brand medically necessary'.". The legend printed on the prescription form or appearing on the prescriber's computer screen must be in at least six-point uppercase print or font. The pharmacist may not substitute a generic name drug product unless its price to the purchaser is less than the price of the prescribed drug product. In addition, a pharmacist may not substitute drug products in the following dosage forms: enteric coated tablets, controlled release products, injectable suspensions other than antibiotics, suppositories containing active ingredients for which systemic absorption is necessary for therapeutic activity, and different delivery systems for aerosol and nebulizer drugs. In the event that any drug listed above is, subsequent to January 1, 1982, determined to be therapeutically equivalent, then the previously mentioned substitution ban is automatically removed for that drug. The pharmacist shall inform the person receiving the drug when a prescription for a brand name drug product does not require that the prescribed drug be dispensed and of the person's right to refuse a generic name drug product selected by the pharmacist. The pharmacy file copy of every prescription must include the brand name, if any, or the name of the manufacturer, packer, or distributor of the generic name drug dispensed. A pharmacist who selects and dispenses a therapeutically equivalent generic name drug product shall assume no greater liability

for selecting the dispensed drug product than would be incurred in filling a prescription for a drug product prescribed by its generic name. The practitioner is not liable for the substitution made by a pharmacist.

4. In the case of a prescription for which a maximum allowable cost program for purposes of reimbursement has been established under title XIX of the federal Social Security Act, the following also apply:
   a. If the practitioner has instructed the pharmacist to dispense as written, the words "brand medically necessary" must also be written on the prescription in the practitioner's own handwriting, or appear as part of the electronic prescription as noted in subsection 3. The pharmacist may dispense a therapeutically equivalent generic name drug product if this handwritten or electronic instruction does not appear on the prescription.
   b. If the pharmacist is instructed orally to dispense a brand name drug as prescribed, the pharmacist shall reduce the prescription to writing and shall note the instructions on the file copy of the prescription.
   c. If the practitioner has not instructed the pharmacist to dispense a brand name drug or medicine and the patient specifically requests a brand name drug or medicine, the patient shall pay the difference between the price to the patient of the brand name drug or medicine and the therapeutically equivalent generic name drug or medicine if the price of the brand name drug or medicine is higher.
5. A pharmacist may not select and dispense a different drug product for a prescribed drug product unless it has been manufactured with the following minimum manufacturing standards and practices by a manufacturer who:
   a. Marks capsules and tablets with identification code or monogram.
   b. Labels products with their expiration date.
   c. Provides reasonable services to accept return goods that have reached their expiration date.
   d. Provides the pharmacist with information from which it can be determined whether a drug product is therapeutically equivalent.
   e. Maintains recall capabilities for unsafe or defective drugs.
6. No prescription drug in solid dosage form may be manufactured or distributed in this state unless it is clearly marked or imprinted with a code imprint identifying the drug and the manufacturer or distributor of the drug.
7. All manufacturers and distributors of prescription drugs in solid dosage form shall provide to the department or state board of pharmacy, upon request, a listing of all such prescription drugs identifying by code imprint the manufacturer and the specific type of drug. The listing must at all times be kept current by all manufacturers and distributors subject to the provisions of this section.
8. The state board of pharmacy may grant exemptions from the requirements of this section upon application by any drug manufacturer or distributor which shows size, physical characteristics, or other unique characteristics of a drug that render the use of a code imprint on the drug impracticable or impossible. Any exemption granted by the state board of pharmacy must be included by the manufacturer or distributor in the listing required by this section. The listing must describe the physical characteristics and type of drug to which the exemption relates.
9. All prescription drugs in solid dosage form that are possessed, distributed, sold, or offered for sale in violation of the provisions of this section must be deemed misbranded and must be seized by the department or state board of pharmacy.

19-02.1-14.2. Maximum allowable cost lists for pharmaceuticals - Pharmacy benefits managers - Penalty.

1. For the purposes of this section:
   a. "Determination" means a decision that settles and ends a controversy or the resolution of a question through appeal.

b. "Maximum allowable cost price" means a maximum reimbursement amount for a group of therapeutically equivalent and pharmaceutically equivalent multiple source drugs.
c. "Multiple source drug" means a therapeutically equivalent drug that is available from at least two manufacturers.
d. "Pharmacy benefits manager" has the same meaning as in section 19-03.6-01.

2. With respect to each contract between a pharmacy benefits manager and a pharmacy, each pharmacy benefits manager shall:
   a. Provide to the pharmacy, at the beginning of each contract and contract renewal, the sources utilized to determine the maximum allowable cost pricing of the pharmacy benefits manager.
   b. Update any maximum allowable cost price list at least every seven business days, and provide prompt notification of the pricing changes to network pharmacies.
   c. Disclose the sources utilized for setting maximum allowable cost price rates on each maximum allowable cost price list included under the contract and identify each maximum allowable cost price list that applies to the contracted pharmacy. A pharmacy benefits manager shall make the list of the maximum allowable costs available to a contracted pharmacy in a format that is readily accessible and usable to the contracted pharmacy.
   d. Ensure maximum allowable cost prices are not set below sources utilized by the pharmacy benefits manager.
   e. Provide a reasonable administrative appeals procedure to allow a dispensing pharmacy provider to contest a listed maximum allowable price rate. The pharmacy benefits manager shall provide a determination to a provider that has contested a maximum allowable price rate within seven business days. If an update to the maximum allowable price rate for an appealed drug is warranted, the pharmacy benefits manager shall make the change based on the date of the determination and make the adjustment effective for all similarly situated pharmacy providers in this state within the network.
   f. Ensure dispensing fees are not included in the calculation of maximum allowable cost price reimbursement to pharmacy providers.
3. A pharmacy benefits manager may not place a prescription drug on a maximum allowable price list unless:
   a. The drug has at least two nationally available, therapeutically equivalent, multiple source drugs or a generic drug is available only from one manufacturer;
   b. The drug is listed as therapeutically equivalent and pharmaceutically equivalent or "A" or "B" rated in the United States food and drug administration's most recent version of the "Orange Book" or the drug is "Z" rated; and
   c. The drug is generally available for purchase by pharmacies in the state from national or regional wholesalers and not obsolete.
4. This section does not apply to state Medicaid programs.
5. A pharmacy benefits manager that violates this section is guilty of a class B misdemeanor.

19-02.1-14.3. Biosimilar biological products.

1. In this section:
   a. "Biological product", "biosimilar", "interchangeable", "interchangeable biological product", "license", and "reference product" mean the same as these terms mean under section 351 of the federal Public Health Service Act [42 U.S.C. 262].
   b. "Prescription" means a product that is subject to section 503(b) of the Federal Food, Drug, and Cosmetic Act [21 U.S.C. 353(b)].
2. A pharmacy may not substitute a prescription biosimilar product for a prescribed product unless each of the following requirements is met:
   a. The biosimilar product has been determined by the United States food and drug administration to be interchangeable with the prescribed product.

b. The prescribing practitioner does not specifically indicate in the practitioner's own handwriting "brand medically necessary" on a written prescription, does not expressly indicate that an oral prescription is to be dispensed as communicated, or has not taken a specific overt action to include the "brand medically necessary" language with an electronically transmitted prescription.
c. The pharmacist or the pharmacist's designee informs the individual receiving the biological product that the biological product may be substituted with a biosimilar product and that the individual has a right to refuse the biosimilar product selected by the pharmacist and the individual chooses not to refuse.
d. Within two business days following the dispensing of the biosimilar product, the pharmacist or the pharmacist's designee notifies the prescribing practitioner of the substitution. Notification under this subdivision must include the name of the substitution product and the name of the manufacturer, and may be made using facsimile, telephone, electronic transmission, an entry into an interoperable electronic medical record accessible by the prescribing practitioner, or other prevailing means accessible by the prescribing practitioner.
e. The pharmacy and the prescribing practitioner retain a record of the interchangeable biosimilar substitution for a period of no less than five years.

3. Subsection 2 does not apply to a biologic product refill prescription that is not changed from the interchangeable biosimilar substitution dispensed on the previous filling of the prescription.
4. The board of pharmacy shall maintain on the board's public website a current list, or an internet link to a United States food and drug administration-approved list, of biosimilar biological products determined to be interchangeable under subdivision a of subsection 2.

19-02.1-15. Drugs limited to dispensing on prescription.

1. Except as authorized and provided in chapter 19-03.1, a depressant, stimulant, or hallucinogenic drug; or a drug intended for use by man which is a habit-forming drug to which subsection 4 of section 19-02.1-14 applies; or a drug that, 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; or a drug limited by an approved application under section 505 of the federal act or section 19-02.1-16 to use under the professional supervision of a practitioner, must be dispensed by prescription of a practitioner, and such prescription may not be filled or refilled after one year from the date on which such prescription was issued; except that nothing herein may be construed as preventing a practitioner from issuing a new prescription for the same drug either in writing or orally. Any oral prescription for such drug must be promptly reduced to writing and filed by the pharmacist.
2. Any drug dispensed by filling or refilling a written or oral prescription of a practitioner licensed by law to administer such drug is exempt from the requirements of section 19-02.1-14, except subsection 1, subdivisions b and c of subsection 10, subsections 12 and 13, and the packaging requirements of subsections 8 and 9 of section 19-02.1-14, if the drug bears a label containing the name and address of the dispenser, the serial number and date of the prescription or of its filling, the name of the prescriber and, if stated in the prescription, the name of the patient, and the directions for use and cautionary statements, if any, contained in such prescription. This exemption does not apply to any drug dispensed in the course of the conduct of a business of dispensing drugs pursuant to diagnosis by mail or electronic means, or to a drug dispensed in violation of subsection 1.
3. The department may, by regulation, remove drugs subject to subsection 4 of section 19-02.1-14 and section 19-02.1-16 from the requirements of subsection 1 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

may also, by regulations issued by the department, be removed from the requirements of subsection 1.

4. A drug which is subject to subsection 1 must 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", "Rx Only", or "Caution: State Law Prohibits Dispensing Without Prescription". A drug to which subsection 1 does not apply must be deemed to be misbranded if at any time prior to dispensing its label bears the caution statement quoted in the preceding sentence.
5. Nothing in this section may 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 classifications of narcotic drugs or marijuana as defined in the applicable federal and state laws relating to narcotic drugs and marijuana.

19-02.1-15.1. Requirements for dispensing controlled substances and specified drugs - Penalty.

1. As used in this section:
   a. "Controlled substance" has the meaning set forth in section 19-03.1-01.
   b. "Deliver, distribute, or dispense by means of the internet" refers, respectively, to delivery, distribution, or dispensing of a controlled substance or specified drug that is caused or facilitated by means of the internet.
   c. "In-person medical evaluation" means a medical evaluation that is conducted with the patient in the physical presence of the practitioner, without regard to whether portions of the evaluation are conducted by other practitioners, and must include one of the following actions:
      (1) The prescribing practitioner examines the patient at the time the prescription or drug order is issued;
      (2) The prescribing practitioner has performed a prior examination of the patient within twelve months;
      (3) Another prescribing practitioner practicing within the same health system, group, or clinic as the prescribing practitioner has examined the patient within twelve months;
      (4) A consulting practitioner to whom the prescribing practitioner has referred the patient has examined the patient within twelve months; or
      (5) The referring practitioner has performed an examination in the case of a consultant practitioner issuing a prescription or drug order when providing services by means of telemedicine.
   d. "Internet" and "practice of telemedicine" have the meanings set forth in the Ryan Haight Online Pharmacy Consumer Protection Act of 2008 [Pub. L. 110-425; 21 U.S.C. 802-803].
   e. "Specified drugs" mean:
      (1) A skeletal muscle relaxant containing carisoprodol, chlorphenesin, chlorzoxazone, metaxalone, or methocarbamol;
      (2) A centrally acting analgesic with opioid activity such as tapentadol or tramadol;
      (3) A drug containing butalbital; and
      (4) Phosphodiesterase type 5 inhibitors when used to treat erectile dysfunction.
   f. "Valid prescription" means a prescription that is issued for a legitimate medical purpose in the usual course of professional practice by a practitioner who has conducted an in-person medical evaluation of the patient.
2. A controlled substance or specified drug may not be delivered, distributed, or dispensed without a valid prescription. It is also unlawful for a person to knowingly or intentionally aid or abet in these activities. An example of such an activity includes knowingly or intentionally serving as an agent, intermediary, or other entity that causes the internet to be used to bring together a buyer and seller to engage in the dispensing of a controlled substance or specified drug.

3. This section applies to the delivery, distribution, and dispensing of a controlled substance or specified drug by means of the internet or any other electronic means from a location whether within or outside this state to a person or an address in this state.
4. Nothing in this section may be construed:
   a. To apply to the delivery, distribution, or dispensing of a controlled substance or specified drug by a practitioner engaged in the practice of telemedicine in accordance with applicable federal and state laws;
   b. To prohibit or limit the use of electronic prescriptions for a controlled substance or any other drug;
   c. To prohibit a physician from prescribing a controlled substance or specified drug through the use of a guideline or protocol established with an allied health professional, resident, or medical student under the direction and supervision of the physician;
   d. To prohibit a practitioner from issuing a prescription or dispensing a controlled substance or specified drug in accordance with administrative rules adopted by a state agency authorizing expedited partner therapy in the management of a sexually transmitted disease; or
   e. To limit prescription, administration, or dispensing of a controlled substance or specified drug through a distribution mechanism approved by the state health officer in order to prevent, mitigate, or treat a pandemic illness, infectious disease outbreak, or intentional or accidental release of a biological, chemical, or radiological agent.
5. A person who violates this section is guilty of a class C felony.

19-02.1-16. New drugs.

1. No person may sell, deliver, offer for sale, hold for sale, or give away any new drug unless:
   a. An application with respect thereto has been approved and said approval has not been withdrawn under section 505 of the federal act; or
   b. When not subject to the federal act, 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 department an application setting forth:
      (1) 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.
      (2) A full list of the articles used as components of such drug.
      (3) A full statement of the composition of such drug.
      (4) A full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drugs.
      (5) Such samples of such drug and of the articles used as components thereof as the department may require.
      (6) Specimens of the labeling proposed to be used for such drug.
2. An application provided for in subdivision b of subsection 1 becomes effective on the one hundred eightieth day after the filing thereof, except that if the department finds, after due notice to the applicant and giving the applicant an opportunity for a hearing, that the drug is not safe or not effective for use under the conditions prescribed, recommended, or suggested in the proposed labeling thereof, the department shall, prior to the effective date of the application, issue an order refusing to permit the application to become effective.
3. An order refusing to permit an application under this section to become effective may be revoked by the department.
4. This section does not apply:
   a. To a drug intended solely for investigational use by experts qualified by scientific training and experience to investigate the safety and effectiveness of drugs,

provided the drug is plainly labeled in compliance with regulations issued by the department or pursuant to section 505(i) or 507(d) of the federal act;

b. To a drug sold in this state at any time prior to the enactment of this chapter or introduced into interstate commerce at any time prior to the enactment of the federal act;

c. To any drug which is licensed under the Virus, Serum, and Toxin Act of July 1, 1902, U.S.C. 1958 ed. Title 42 Chapter 6A Sec. 262; or

d. To any drug which is subject to subsection 5 of section 19-02.1-14.

5. The provisions of subsection 16 of section 19-02.1-01 do not apply to any drug which, on October 9, 1962, or on the date immediately preceding the enactment of this subsection:

a. Was commercially sold or used in this state or in the United States;

b. Was not a new drug as defined by subsection 16 of section 19-02.1-01 as then in force; and

c. Was not covered by an effective application under section 19-02.1-16 or under section 505 of the federal act, when such drug is intended solely for use under conditions prescribed, recommended, or suggested in labeling with respect to such drug.

19-02.1-16.1. Pharmacy claim fees and pharmacy rights - Pharmacy benefits managers - Penalty.

1. As used in this section:

a. "Pharmacy benefits manager" has the same meaning as in section 19-03.6-01.

b. "Plan sponsor" has the same meaning as in section 19-03.6-01.

c. "Third-party payer" has the same meaning as in section 19-03.6-01.

2. A pharmacy benefits manager or third-party payer may not directly or indirectly charge or hold a pharmacy responsible for a fee related to a claim:

a. That is not apparent at the time of claim processing;

b. That is not reported on the remittance advice of an adjudicated claim; or

c. After the initial claim is adjudicated at the point of sale.

3. Pharmacy performance measures or pay for performance pharmacy networks shall utilize the electronic quality improvement platform for plans and pharmacies or other unbiased nationally recognized entity aiding in improving pharmacy performance measures.

a. A pharmacy benefits manager or third-party payer may not collect a fee from a pharmacy if the pharmacy's performance scores or metrics fall within the criteria identified by the electronic quality improvement platform for plans and pharmacies or other unbiased nationally recognized entity aiding in improving pharmacy performance measures.

b. If a pharmacy benefits manager or third-party payer imposes a fee upon a pharmacy for scores or metrics or both scores and metrics that do not meet those established by the electronic quality improvement platform for plans and pharmacies or other nationally recognized entity aiding in improving pharmacy performance measures, a pharmacy benefits manager or third-party payer is limited to applying the fee to the professional dispensing fee outlined in the pharmacy contract.

c. A pharmacy benefits manager or third-party payer may not impose a fee relating to performance metrics on the cost of goods sold by a pharmacy.

4. A pharmacy benefits manager or third-party payer may not charge a patient a copayment that exceeds the cost of the medication. If a patient pays a copayment, the dispensing provider or pharmacy shall retain the adjudicated cost and the pharmacy benefits manager or third-party payer may not redact the adjudicated cost.

5. A pharmacy benefits manager or third-party payer may not prohibit a pharmacist or pharmacy from participating in a class action lawsuit. A pharmacy or pharmacist may disclose to the plan sponsor or to the patient information regarding the adjudicated reimbursement paid to the pharmacy which is compliant under the federal Health

Insurance Portability and Accountability Act of 1996 [Pub. L. 104-191; 110 Stat. 1936; 29 U.S.C. 1181 et seq.].

6. A pharmacist or pharmacy that belongs to a pharmacy service administration organization may receive a copy of a contract the pharmacy service administration organization entered with a pharmacy benefits manager or third-party payer on the pharmacy's or pharmacist's behalf.
7. A pharmacy or pharmacist may provide relevant information to a patient if the patient is acquiring prescription drugs. This information may include the cost and clinical efficacy of a more affordable alternative drug if one is available. Gag orders of such a nature placed on a pharmacy or pharmacist are prohibited.
8. A pharmacy or pharmacist may mail or deliver drugs to a patient as an ancillary service of a pharmacy.
9. A pharmacy benefits manager or third-party payer may not prohibit a pharmacist or pharmacy from charging a shipping and handling fee to a patient requesting a prescription be mailed or delivered.
10. Upon request, a pharmacy benefits manager or third-party payer shall provide a pharmacy or pharmacist with the processor control number, bank identification number, and group number for each pharmacy network established or administered by a pharmacy benefits manager to enable the pharmacy to make an informed contracting decision.
11. A pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or recertification requirements inconsistent with, more stringent than, or in addition to federal and state requirements for licensure as a pharmacy in this state.
12. A pharmacy benefits manager or other third-party payer that violates this section is guilty of a class B misdemeanor per violation occurrence.

19-02.1-16.2. Specialty pharmacy services and patient access to pharmaceuticals - Pharmacy benefits managers - Penalty.

1. As used in this section:
   a. "Pharmacy benefits manager" has the same meaning as in section 19-03.6-01.
   b. "Plan sponsor" has the same meaning as in section 19-03.6-01.
   c. "Specialty drug" means a prescription drug that:
      (1) Is not available for order or purchase by a retail community pharmacy and long-term care pharmacy, regardless of whether the drug is meant to be self-administered; and
      (2) Requires special storage and has distribution or inventory limitations not available at a retail community pharmacy or long-term care pharmacy.
   d. "Third-party payer" has the same meaning as in section 19-03.6-01.
2. If requested by a plan sponsor contracted payer, a pharmacy benefits manager or third-party payer that has an ownership interest, either directly or through an affiliate or subsidiary, in a pharmacy shall disclose to the plan sponsor contracted payer any difference between the amount paid to a pharmacy and the amount charged to the plan sponsor contracted payer.
3. A pharmacy benefits manager or a pharmacy benefits manager's affiliates or subsidiaries may not own or have an ownership interest in a patient assistance program and a mail order specialty pharmacy, unless the pharmacy benefits manager, affiliate, or subsidiary agrees to not participate in a transaction that benefits the pharmacy benefits manager, affiliate, or subsidiary instead of another person owed a fiduciary duty.
4. A pharmacy benefits manager or third-party payer may not require pharmacy accreditation standards or recertification requirements to participate in a network which are inconsistent with, more stringent than, or in addition to the federal and state requirements for licensure as a pharmacy in this state.
5. A licensed pharmacy or pharmacist may dispense any and all drugs allowed under that license.

6. A pharmacy benefits manager or other third-party payer that violates this section is guilty of a class B misdemeanor for each violation occurrence.

19-02.1-16.3. Pharmacy benefits managers - Step therapy protocols - Limitations.

1. As used in this section:
   a. "Metastatic cancer" means cancer that has spread from the primary or original site to lymph nodes, nearby tissues, or other parts of the body.
   b. "Pharmacy benefits manager" has the same meaning as in section 19-03.6-01.
   c. "Step therapy protocol" means a protocol requiring an individual use a drug, or sequence of drugs, other than the prescription drug, or sequence of prescription drugs, the individual's health care provider recommends for the individual's treatment, before the pharmacy benefits manager or health plan allows coverage for the recommended prescription drug, or sequence of prescription drugs.
2. A pharmacy benefits manager or a health plan may not require a step therapy protocol for coverage of a recommended prescription drug, or sequence of prescription drugs, approved by the United States food and drug administration if:
   a. The recommended prescription drug, or sequence of prescription drugs, is prescribed to treat the individual's diagnosis of metastatic cancer; and
   b. The use of the recommended prescription drug, or sequence of prescription drugs, is consistent with the United States food and drug administration-approved indications or is supported by peer-reviewed medical literature.
3. This section does not require coverage of a nonformulary prescription drug.

19-02.1-16.4. Mail order and home delivery - Prior consent - Refund.

1. If a pharmacy offers a prescription through home delivery or mail order delivery services, the pharmacy may not initiate delivery of a refill unless:
   a. The pharmacy obtains prior consent from the patient or the patient's authorized representative; or
   b. The pharmacy provides the patient with notice of the upcoming delivery through more than one communication attempt, by different means, and the patient or the patient's authorized representative does not respond indicating the patient does not want the refill.
2. If a pharmacy delivers a refill in violation of subsection 1:
   a. Within thirty days of the patient's or the patient's authorized representative's notification of the pharmacy of the unwanted refill, the pharmacy shall refund all payments received by the pharmacy relating to the unwanted refill.
   b. Within thirty days of the pharmacy's, patient's, or patient's authorized representative's notification of the health plan or the pharmacy benefits manager of the unwanted refill, the health plan and pharmacy benefits manager shall refund all payments received relating to the unwanted refill.

19-02.1-16.5. Pharmacy benefits managers - Prohibition on discrimination - Penalty.

1. As used in this section:
   a. "Pharmacy" means a pharmacy licensed under the laws of this state.
   b. "Pharmacy benefits manager" has the same meaning as in section 19-03.6-01.
2. A pharmacy benefits manager may not discriminate against or interfere with a covered entity participating under section 340B of the federal Public Health Service Act [42 U.S.C. 201 et seq.] or a pharmacy under contract with a covered entity under section 340B of the federal Public Health Service Act to provide pharmacy services on behalf of the covered entity. This includes refusing to contract with a pharmacy.
3. A pharmacy benefits manager may not modify, by contract, provider manual, or other means, the definition of pharmacy as defined in this section, reimburse a lower dollar amount for a drug purchased under section 340B than if the drug had been purchased outside section 340B, or interfere with any section 340B pharmacy service between the covered entity and the contracted pharmacy.

4. A pharmacy benefits manager may not directly or indirectly, on behalf of a pharmacy benefits manager, a carrier, or a health plan, charge or hold a pharmacy responsible for a fee for any step, component, or mechanism related to the claims adjudication processing network.
5. Contract and claim information between the covered entity and contracted pharmacy is confidential.
6. A pharmacy benefits manager that violates this section is guilty of a class B misdemeanor for each violation occurrence.

19-02.1-17. Cosmetics - Adulteration defined.

A cosmetic must 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 does 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 purpose of this subsection and subsection 5, the term "hair dye" does 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 subsection 1 of section 19-02.1-12.

19-02.1-18. Cosmetics - Misbranding defined.

A cosmetic must be deemed to be misbranded:

1. If its labeling is false or misleading in any particular.
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; provided, that under this subdivision reasonable variations must be permitted, and exemptions as to small packages must be established by regulations prescribed by the department.
3. If any word, statement, or other information required by or under authority of this chapter 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 the federal act. This subsection does 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 subsection 1 of section 19-02.1-17.
6. If its packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Poison Prevention Packaging Act of 1970.

19-02.1-19. False advertising.

1. An advertisement of a food, drug, device, or cosmetic is false if it is false or misleading in any particular.
2. For the purpose of this chapter, 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, sexually transmitted disease, sinus infection, smallpox, tuberculosis, tumors, typhoid, or uremia is also false, except that no advertisement not in violation of subsection 1 is 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 determines that an advance in medical science has made any type of self-medication safe as to any of the diseases named above, the department by rule shall authorize the advertisement of drugs having curative or therapeutic effect for such disease, subject to such conditions and restrictions as the department may deem necessary in the interests of public health; and provided, further, that this subsection may not be construed as indicating that self-medication for diseases other than those named herein is safe or efficacious.

19-02.1-20. Rules.

The authority to adopt rules for the efficient enforcement of this chapter is hereby vested in the department. The department is hereby authorized to make the rules adopted under this chapter conform, insofar as practicable, with those adopted under the federal act. Rules must conform and be consistent with the provisions of the Uniform Controlled Substances Act. When adopting any rules under this chapter, the department shall follow the procedures under chapter 28-32.

19-02.1-21. Inspections - Examinations.

The department has free access at all reasonable hours to any factory, warehouse, or establishment in which foods, drugs, devices, or cosmetics are manufactured, processed, packed, or held for introduction into commerce, or to enter any vehicle being used to transport or hold such foods, drugs, devices, or cosmetics in commerce, for the purpose of inspecting such factory, warehouse, establishment, or vehicle to determine if this chapter is being violated and to secure samples or specimens of any food, drug, device, or cosmetic after paying or offering to pay for such sample.

The department shall make or cause to be made examinations of samples secured under this section to determine whether or not this chapter is being violated.

Inspections of slaughterhouses, meatpacking, and meat processing plants where cattle, swine, sheep, goats, farmed elk, horses, or other equines are slaughtered for human food or where the carcass or the parts thereof, meat, or meat food products are salted, canned, packed, smoked, cured, rendered, or otherwise processed or prepared for human food may not be performed under this chapter if the slaughterhouses, meatpacking, or meat processing plants are inspected under the North Dakota Meat Inspection Act, or the Federal Meat Inspection Act, as amended [34 Stat. 1260-65; 21 U.S.C. 71-91].

19-02.1-22. Publicity.

The department may cause to be published from time to time reports summarizing all judgments, decrees, and court orders which have been rendered under this chapter, including the nature of the charge and the disposition thereof.

The department may also cause to be disseminated such information regarding food, drugs, devices, and cosmetics as the department deems necessary in the interest of public health and the protection of the consumer against fraud. Nothing in this section may be construed to prohibit the department from collecting, reporting, and illustrating the results of the investigations of the department.

19-02.1-23. Prohibition against manufacture of drugs - Exceptions.

Repealed by S.L. 1971, ch. 235, § 49.

19-02.1-24. Sale of prepackaged food from vending machines - License - Rules - Inspections.

1. An establishment may not sell any type of prepackaged food from a food vending machine without first obtaining a license from the department. The license expires on June thirtieth of each year. The department may adopt rules establishing the amount and the procedures for the collection of license fees. License fees collected pursuant to this section must be deposited in the department's operating fund in the state treasury and any expenditure from the fund is subject to appropriation by the legislative assembly.
2. The department may, in accordance with chapter 28-32, revoke an establishment's license if the establishment fails to comply with the rules adopted pursuant to subsection 3.
3. The department may adopt, in accordance with chapter 28-32, rules which define "food vending machine" for the purposes of this section and rules governing the sanitation, maintenance, and construction of such vending machines and exempting certain types of machines from this section, if it is deemed appropriate and not materially detrimental to public health.
4. The department may inspect any food vending machine for compliance with the rules and for the presence of a license required by this section.

19-02.1-25. Country of origin labels.

Each retailer shall indicate, by label, to customers the country of origin of fresh beef, lamb, and pork available for sale to customers. For purposes of this section, a label means a clearly visible printed or written indication that is placed in the immediate vicinity of the food product. This section does not apply to a restaurant, cafeteria, prepared food service establishment, or mobile food unit.

19-02.1-26. Limitation on exemplary damages.

1. Exemplary damages may not be awarded against the manufacturer or seller of a product or device that caused the harm claimed by the plaintiff if:
   a. The product or device was subject to approval under 21 U.S.C. 355 or premarket approval under 21 U.S.C. 360e by the food and drug administration with respect to the safety of formulation or performance of the aspect of the product or device that caused the harm, or by the adequacy of the packaging or labeling of the product or device; or
   b. The product or device was approved by the food and drug administration.
2. Subsection 1 does not apply in a case in which it is determined on the basis of clear and convincing evidence that the defendant:
   a. Withheld from or misrepresented to the food and drug administration information concerning the product or device which is required to be submitted under the federal act which is material and relevant to the harm suffered by the claimant;
   b. Made an illegal payment to an official of the food and drug administration for the purpose of securing approval of the product or device;
   c. Failed to use reasonable care to comply with the food and drug administration regulations concerning the manufacture of, or the investigation and correction of

defects in design or manufacture of, a medical device, and the failure to comply has caused the harm suffered by the plaintiff;

d. Made a significant or knowing departure from official food and drug administration requirements; or

e. Acted with conscious disregard for human safety.