126.2 Definitions applicability.

As used in this chapter, unless the context otherwise requires:

1. *"Advertising"* means any representation disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase of drugs, devices, or cosmetics.

2. *"Anabolic steroid"* means any anabolic steroid, including, but not limited to oxymetholone, oxandrolone, ethylestrenol, methandrostenolone, stanozolol, nandrolone phenpropionate, nandrolone decanoate, and any other substance designated by the board as an anabolic steroid through the adoption of rules pursuant to chapter 17A.

3. *"Board"* means the board of pharmacy examiners.

4. *"Contaminated with filth"* means not securely protected from dust, dirt, and as far as is necessary by all reasonable means, from all foreign or injurious contaminations.

5. *"Cosmetic"* means any of the following, but does not include soap:

a. An article intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part of a human body for cleaning, beautifying, promoting attractiveness, or altering the appearance.

b. An article intended for use as a component of an article defined in paragraph *"a"*.

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

7. *"Device"* means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory of any of these, which is any of the following:

a. Recognized as a device in the official United States Pharmacopoeia National Formulary or any supplement to it.

b. Intended for use in the diagnosis of diseases or other conditions, or in the cure, mitigation, treatment, or prevention of diseases or other conditions in a human.

c. Intended to affect the structure or any function of the body of a human, and which does not achieve any of its principal intended purposes through chemical action within or on the body of a human and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

8. *"Drug"* means any of the following, but does not include a device:

a. An article recognized as a drug in the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to either document.

b. An article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases in a human.

c. An article, other than food, intended to affect the structure or any function of the body of a human.

d. An article intended for use as a component of any articles specified in paragraphs *"a"*, *"b"*, or *"c"*.

9. *"Electronic prescription"* means a prescription which is transmitted by a computer device in a secure manner, including computer-to-computer transmission and computer-to-facsimile transmission.

10. *"Facsimile prescription"* means a prescription which is transmitted by a device which sends an exact image to the receiver.

11. *"Federal Act"* means the federal Food, Drug, and Cosmetic Act, which is codified in 21 U.S.C. § 301 et seq.

12. *"Immediate container"* does not include a package liner.

13. *"Label"* means a display of written, printed, or graphic matter upon the immediate container of an article; and a requirement made by or under authority of this chapter that any word, statement, or other information appear on the label is not complied with unless the word, statement, or other information also appears on the outside container or wrapper of the retail package of the article, or is easily legible through the outside container or wrapper.

14. *"Labeling"* means all labels and other written, printed, or graphic matter upon an article or any of its containers or wrappers, or accompanying an article.

15. *"New drug"* means either of the following:

a. Any drug, the composition of which is such that the 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 its labeling, except that a drug not so recognized is not a new drug if at any time prior to the enactment of this chapter it was subject to the federal Act, and if at that time its labeling contained the same representations concerning the conditions of its use.

b. Any drug, the composition of which is such that the drug, as a result of investigations to determine its safety and effectiveness for use under the conditions prescribed, recommended, or suggested in its labeling, has become recognized as safe and effective, but which has not, other than in such investigations, been used to a material extent or for a material time under the conditions prescribed, recommended, or suggested in its labeling.

16. *"Official compendium"* means the official United States Pharmacopoeia National Formulary, official Homeopathic Pharmacopoeia of the United States, or any supplement to either document.

17. *"Person"* means an individual, partnership, corporation, or association.

18. *"Principal display panel"* means that part of a label that is most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale.

19. *"Safe"* as used in this chapter has reference to the health of a human.

20. *"Secretary"* means the secretary of the United States department of health and human services.

The provisions of this chapter regarding the selling of drugs, devices, or cosmetics are applicable to the

manufacture, production, processing, packaging, exposure, offer, possession, and holding of any such article for sale; and the sale, dispensing, and giving of any such article, and the supplying or applying of any such article, in the conduct of any drug, device, or cosmetic establishment.

89 Acts, ch 197, § 2

CS89, § 203B.2

90 Acts, ch 1078, § 1

C93, § 126.2

2004 Acts, ch 1036, §4