
By: **Chairman, Education, Health, and Environmental Affairs Committee**
(By Request - Departmental - Health and Mental Hygiene)

Introduced and read first time: February 4, 2005

Rules suspended

Assigned to: Education, Health, and Environmental Affairs

Committee Report: Favorable

Senate action: Adopted

Read second time: March 15, 2005

CHAPTER _____

1 AN ACT concerning

2 **Food, Drugs, and Cosmetics - Regulation**

3 FOR the purpose of defining the term "person" to include a unit of State or local
4 government if the State or local unit of government is the operator of a facility
5 and an operator of a facility owned by a unit of State or local government, as the
6 term is used in provisions of law regulating food, drugs, and cosmetics; and
7 generally relating to the regulation by the State of food, drugs, and cosmetics.

8 BY repealing and reenacting, with amendments,
9 Article - Health - General
10 Section 21-101
11 Annotated Code of Maryland
12 (2000 Replacement Volume and 2004 Supplement)

13 SECTION 1. BE IT ENACTED BY THE GENERAL ASSEMBLY OF
14 MARYLAND, That the Laws of Maryland reads as follows:

15 **Article - Health - General**

16 21-101.

17 (a) In this title the following words have the meanings indicated.

18 (b) "Advertisement" means any representation that:

1 (1) Is intended or is likely to induce, directly or indirectly, any person to
2 purchase any food, drug, device, or cosmetic; and

3 (2) Is published by any means other than labeling.

4 (c) (1) "Color additive" means any material that:

5 (i) Is a dye, pigment, or other substance made by a process of
6 synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or
7 without intermediate or final change of identity, from a vegetable, animal, mineral, or
8 other source; or

9 (ii) When added or applied to a food, drug, or cosmetic, or to any
10 part of the human body, is capable, alone or through reaction with any other
11 substance, of imparting color, including black, white, or intermediate grays, to the
12 food, drug, cosmetic, or body.

13 (2) "Color additive" does not include any material that is not a color
14 additive under the federal act.

15 (d) "Consumer commodity" means any food, drug, device, or cosmetic that is
16 not:

17 (1) Tobacco or a tobacco product;

18 (2) A commodity that is subject to packaging or labeling requirements
19 imposed under the Federal Insecticide, Fungicide, and Rodenticide Act or the federal
20 Animal Virus, Serum, Toxin, Antitoxin Act;

21 (3) A drug that is subject to the provisions of § 353(b)(1) or § 356 of the
22 federal act;

23 (4) A beverage that is subject to or complies with packaging or labeling
24 requirements imposed by the Federal Bureau of Alcohol, Tobacco and Firearms; or

25 (5) A seed or other commodity that is subject to the provisions of §§
26 9-206 through 9-213 of the Agriculture Article.

27 (e) (1) "Cosmetic" means any substance, or any component of a substance,
28 that is intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or
29 otherwise applied to the human body for cleansing, beautifying, promoting
30 attractiveness, or altering appearance.

31 (2) "Cosmetic" does not include soap.

32 (f) "Device" means any instrument, apparatus, or contrivance, or any part or
33 accessory of an instrument, apparatus, or contrivance, that is intended:

34 (1) For use in the diagnosis, cure, mitigation, treatment, or prevention of
35 human disease; or

1 (2) To affect the structure or any function of the human body for medical,
2 surgical, or therapeutic purposes.

3 (g) (1) "Drug" means any substance or component of a substance:

4 (i) That is recognized in an official compendium;

5 (ii) That is intended for use in the diagnosis, cure, mitigation,
6 treatment, or prevention of disease in human beings; or

7 (iii) Except for food, that is intended to affect the structure or any
8 function of the human body.

9 (2) "Drug" does not include a device.

10 (h) "Federal act" means the Federal Food, Drug, and Cosmetic Act as that act
11 appears at 21 U.S.C. § 301 et seq.

12 (i) "Food" means:

13 (1) Any substance that is used as food or drink for human beings or as a
14 component of food or drink for human beings; or

15 (2) Chewing gum or any substance that is used as a component of
16 chewing gum.

17 (j) (1) "Food additive" means any substance:

18 (i) The intended use of which results or reasonably may be
19 expected to result, directly or indirectly, in the substance becoming a component of
20 food or otherwise affecting the characteristics of food, including any substance used to
21 produce, manufacture, pack, process, prepare, treat, package, transport, or hold food,
22 or any source of radiation that is intended for any of these uses; and

23 (ii) That is not recognized generally by qualified scientific experts
24 as having been shown to be safe under the conditions of its intended use:

25 1. Through scientific procedures; or

26 2. Through either scientific procedures or experience based
27 on common use, if the substance was used in a food before January 1, 1958.

28 (2) "Food additive" does not include a color additive.

29 (k) "Label" means a display of written, printed, or graphic matter on the
30 container, other than the package liner, of a substance.

31 (l) "Labeling" means any label or other written or graphic material that:

32 (1) Is on a substance or its container or its wrapping; or

1 (2) Accompanies a substance.

2 (m) "Official compendium" means the most recent revision of the United States
3 Pharmacopoeia and National Formulary, the official Homeopathic Pharmacopoeia of
4 the United States, or any of their current supplements.

5 (n) (1) "Package" means any container or wrapping of a consumer
6 commodity that is used for delivery or display to retail consumers.

7 (2) "Package" does not include any container or wrapping that is used
8 only for:

9 (i) Transportation of a consumer commodity in bulk or quantity to
10 a manufacturer, packer, processor, or wholesale or retail distributor; or

11 (ii) Shipment or delivery of a consumer commodity to a retail
12 customer, if the container or wrapping bears no printed material that relates to a
13 particular consumer commodity.

14 (O) "PERSON" INCLUDES:

15 (1) AN OPERATOR OF A FACILITY THAT IS OWNED BY A STATE OR LOCAL
16 UNIT OF GOVERNMENT; OR

17 (2) A STATE OR LOCAL UNIT OF GOVERNMENT IF THE STATE OR LOCAL
18 UNIT OF GOVERNMENT IS THE OPERATOR OF THE FACILITY.

19 [(o)] (P) "Secretary" means for the purposes of Subtitles 1, 2, 3, 4, 8, and 11 of
20 this title, the Secretary of Health and Mental Hygiene or the Secretary's designee.

21 SECTION 2. AND BE IT FURTHER ENACTED, That this Act shall take effect
22 October 1, 2005.