Ohio Revised Code

Section 3715.01 Pure food and drug law definitions.

Effective: March 21, 2017
Legislation: House Bill 505 - 131st General Assembly

(A) As used in this chapter:

(1) "Person" means an individual, partnership, corporation, or association.

(2) "Food" means:

(a) Articles used for food or drink for humans or animals;

(b) Chewing gum;

(c) Articles used for components of any such articles.

(3) "Drug" means:

(a) Articles recognized in the United States pharmacopoeia and national formulary, or any supplement to them;

(b) Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals;

(c) Articles, other than food, intended to affect the structure or any function of the body of humans or other animals;

(d) Articles intended for use as a component of any of the foregoing articles, other than devices or their components, parts, or accessories.

(4) "Device," except when used in division (B)(1) of this section and in division (A)(10) of section 3715.52, division (F) of section 3715.60, division (A)(5) of section 3715.64, and division (C) of

section 3715.67 of the Revised Code, means any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is any of the following:

(a) Recognized in the United States pharmacopoeia and national formulary, or any supplement to them;

(b) Intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in humans or animals;

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

(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;

(b) Articles intended for use as a component of any such article, except that "cosmetic" does not include soap.

(6) "Label" means a display of written, printed, or graphic matter upon the immediate container, exclusive of package liners, of any article.

Any word, statement, or other information required by this chapter to appear on the label must appear on the outside container or wrapper, if any, of the retail package of the article, or the label must be easily legible through the outside container or wrapper.

(7) "Labeling" means all labels and other written, printed, or graphic matter:

(a) Upon an article or any of its containers or wrappers;

(b) Accompanying such article.

(8) "Advertisement" means all representations disseminated in any manner or by any means, other than by labeling, for the purpose of inducing, or that are likely to induce, directly or indirectly, the purchase of food, drugs, devices, or cosmetics.

(9) "New drug" means:

(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 of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof;

(b) Any drug the composition of which is such that the drug, as a result of investigation to determine its safety for use under such conditions, has become so recognized, but that has not, other than in an investigation, been used to a material extent or for a material time under such conditions.

(10) "Contaminated with filth" applies to any food, drug, device, or cosmetic that has not been protected as far as may be necessary by all reasonable means from dust, dirt, and all foreign or injurious substances.

(11) "Honey" means the nectar and saccharine exudation of plants that has been gathered, modified, and stored in a honeycomb by honeybees.

(12) "Finished dosage form" means the form of a drug that is, or is intended to be, dispensed or administered to humans or animals and requires no further manufacturing or processing other than packaging, reconstituting, or labeling.

(13)(a) "Manufacture" means the planting, cultivating, harvesting, processing, making, preparing, or otherwise engaging in any part of the production of a drug by propagating, compounding, converting, or processing, either directly or indirectly by extracting from substances of natural origin, or independently by means of chemical synthesis, or by a combination of extraction and

chemical synthesis, and includes the following:

(i) Any packaging or repackaging of the drug or labeling or relabeling of its container, the promotion and marketing of the drug, and other activities incident to production;

(ii) The preparation and promotion of commercially available products from bulk compounds for resale by pharmacies, licensed health professionals authorized to prescribe drugs, or other persons.

(b) "Manufacture" does not include the preparation, compounding, packaging, or labeling of a drug by a pharmacist as an incident to either of the following:

(i) Dispensing a drug in the usual course of professional practice;

(ii) Providing a licensed health professional authorized to prescribe drugs with a drug for the purpose of administering to patients or for using the drug in treating patients in the professional's office.

(14) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

(15) "Generically equivalent drug" means a drug that contains identical amounts of the identical active ingredients, but not necessarily containing the same inactive ingredients, that meets the identical compendial or other applicable standard of identity, strength, quality, and purity, including potency, and where applicable, content uniformity, disintegration times, or dissolution rates, as the prescribed brand name drug and the manufacturer or distributor holds, if applicable, either an approved new drug application or an approved abbreviated new drug application unless other approval by law or from the federal food and drug administration is required.

No drug shall be considered a generically equivalent drug for the purposes of this chapter if it has been listed by the federal food and drug administration as having proven bioequivalence problems.

(16) "Licensed health professional authorized to prescribe drugs" and "prescriber" have the same meanings as in section 4729.01 of the Revised Code.

(17) "Home" means the primary residence occupied by the residence's owner, on the condition that

the residence contains only one stove or oven used for cooking, which may be a double oven, designed for common residence usage and not for commercial usage, and that the stove or oven be operated in an ordinary kitchen within the residence.

(18) "Potentially hazardous food" means a food that is natural or synthetic, to which any of the following apply:

(a) It has a pH level greater than 4.6 when measured at seventy-five degrees fahrenheit or twenty-four degrees celsius.

(b) It has a water activity value greater than 0.85.

(c) It requires temperature control because it is in a form capable of supporting the rapid and progressive growth of infectious or toxigenic microorganisms, the growth and toxin production of clostridium botulinium, or in the case of raw shell eggs, the growth of salmonella enteritidis.

(19) "Cottage food production operation" means a person who, in the person's home, produces food items that are not potentially hazardous foods, including bakery products, jams, jellies, candy, fruit butter, and similar products specified in rules adopted pursuant to section 3715.025 of the Revised Code.

(20) "Biological product" means, except as provided in section 3715.011 of the Revised Code, a drug that is a biological product, as defined on the effective date of this amendment, in subsection (i) of section 351 of the "Public Health Service Act," 42 U.S.C. 262(i).

(21) "Interchangeable biological product" means, except as provided in section 3715.011 of the Revised Code, both of the following:

(a) A biological product that, on the effective date of this amendment, has been determined by the United States food and drug administration to meet the standards for interchangeability set forth in subsection (k) of section 351 of the "Public Health Service Act," 42 U.S.C. 262(k), as amended, and has been licensed under that subsection;

(b) A biological product that, prior to the effective date of this amendment, was determined by the United States food and drug administration to be therapeutically equivalent as set forth in its publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations."

(B) For the purposes of sections 3715.52 to 3715.72 of the Revised Code:

(1) If an article is alleged to be misbranded because the labeling is misleading, or if an advertisement is alleged to be false because it is misleading, then in determining whether the labeling or advertisement is misleading, there shall be taken into account, among other things, not only representations made or suggested by statement, word, design, device, sound, or 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 consequence 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.

(2) The provisions regarding the selling of food, drugs, devices, or cosmetics 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. The provisions do not prohibit a licensed health professional authorized to prescribe drugs from administering or personally furnishing a drug or device to a patient.

(3) The representation of a drug, in its labeling or advertisement, as an antiseptic is 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 other use that involves prolonged contact with the body.

(4) Whenever jurisdiction is vested in the director of agriculture or the state board of pharmacy, the jurisdiction of the board shall be limited to the sale, offering for sale, giving away, delivery, or dispensing in any manner of drugs at the wholesale and retail levels or to the consumer and shall be exclusive in the case of such sale, offering for sale, giving away, delivery, or dispensing in any manner of drugs at the wholesale and retail levels or to the consumer in any place where prescriptions are dispensed or compounded.

(5) To assist in effectuating the provisions of those sections, the director of agriculture or state board of pharmacy may request assistance or data from any government or private agency or individual.