As Introduced

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Representatives Carruthers, Sweeney

Cosponsors: Representatives Grim, Brennan, Brent, Robb Blasdel, Russo, Dell'Aquila

A BILL

To amend sections 3715.01, 3715.025, 3715.99, and 3717.01 and to enact section 3715.522 of the Revised Code to prohibit the sale of cosmetics tested on animals except under certain specified circumstances.

BE IT ENACTED BY THE GENERAL ASSEMBLY OF THE STATE OF OHIO:

Section 1. That sections 3715.01, 3715.025, 3715.99, and 3717.01 be amended and section 3715.522 of the Revised Code be enacted to read as follows:

Sec. 3715.01. (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) "Cosmetic ingredient" means a chemical or mixture used as a component in the manufacture of a cosmetic product, as described in 21 C.F.R. 700.3(e).

(7) "Cosmetic product" means a finished cosmetic, the manufacture of which has been completed.

(8) "Cosmetic animal testing" means the internal or external application or exposure of any cosmetic product or cosmetic ingredient to the skin, eyes, or any other organ or extremity of a live, nonhuman vertebrate for the purpose of evaluating the safety or efficacy of a cosmetic product or a cosmetic ingredient or nonfunctional constituent for use in a cosmetic product.

(9) "Cosmetic manufacturer" means any person whose name appears on the label of a cosmetic product pursuant to the requirements of 21 C.F.R. 701.12.

(10) "Cosmetic supplier" means any person that provides, directly or through a third party, a cosmetic ingredient used by a cosmetic manufacturer in the formulation of a cosmetic product.

(11) "Nonfunctional constituent" means any incidental ingredient, as defined in 21 C.F.R. 701.3.

(12) "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)~~ (13) "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)~~ (14) "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)~~ (15) "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)~~ (16) "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)~~ (17) "Honey" means the nectar and saccharine exudation of plants that has been gathered, modified, and stored in a honeycomb by honeybees.

~~(12)~~ (18) "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)~~ (19)(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)~~ (20) "Dangerous drug" has the same meaning as in section 4729.01 of the Revised Code.

~~(15)~~ (21) "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)~~ (22) "Licensed health professional authorized to prescribe drugs" and "prescriber" have the same meanings as in section 4729.01 of the Revised Code.

~~(17)~~ (23) "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)~~ (24) "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)~~ (25) "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)~~ (26) "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~~ March 21, 2017, in subsection (i) of section 351 of the "Public Health Service Act," 42 U.S.C. 262(i).

~~(21)~~ (27) "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~~ March 21, 2017, 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~~ March 21, 2017, 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.

Sec. 3715.025. (A) A cottage food production operation shall not process acidified foods, low acid canned foods, or potentially hazardous foods.

(B) The director of agriculture shall adopt rules in accordance with Chapter 119. of the Revised Code specifying the

food items a cottage food production operation may produce that are in addition to the food items identified by name in division ~~(A)(19)~~ (A)(25) of section 3715.01 of the Revised Code. The director shall not adopt rules that permit a cottage food production operation to produce any food that is a potentially hazardous food.

Sec. 3715.522. (A) Subject to division (B) of this section, no cosmetic manufacturer shall knowingly sell, offer for sale, or deliver at retail or to a consumer, a cosmetic product developed or manufactured using cosmetic animal testing that was conducted or contracted for by the cosmetic manufacturer, or any cosmetic supplier of the cosmetic manufacturer.

(B) Division (A) of this section does not apply to any of the following:

(1) Animal testing conducted outside of the United States in order to comply with a requirement of a foreign regulatory authority, provided that no evidence derived from such testing was relied upon by the cosmetic manufacturer or cosmetic supplier to substantiate the safety of the cosmetic product sold, offered, or delivered in this state;

(2) Animal testing conducted for any cosmetic or cosmetic ingredient subject to regulation under Chapter V of the "Federal Food, Drug, and Cosmetic Act," 21 U.S.C. 351, et seq.;

(3) Animal testing conducted for an ingredient intended to be used in a product other than a cosmetic and conducted pursuant to a requirement of the department of agriculture, state board of pharmacy, or a federal, state, or foreign regulatory authority, provided that no evidence derived from

such testing was relied upon to substantiate the safety of the cosmetic product sold, offered, or delivered in this state, unless all of the following apply:

(a) There is no non-animal method or strategy recognized by the department of agriculture, state board of pharmacy, a federal agency, or the organization for economic co-operation and development for the relevant safety endpoints for the cosmetic ingredient;

(b) There is documented evidence that animal testing was conducted with the intent to use the ingredient in a product other than a cosmetic;

(c) The ingredient has been used in a product other than cosmetics at least twelve months before the cosmetic manufacturer or cosmetic supplier relied on the results of animal testing.

(4) Animal testing requested, required, or conducted by the department of agriculture, state board of pharmacy, or a federal or state regulatory authority, if all of the following apply:

(a) There is no non-animal method or strategy recognized by the department of agriculture, state board of pharmacy, a federal agency, or the organization for economic co-operation and development for the relevant safety endpoints for the cosmetic ingredient or nonfunctional constituent;

(b) There is a reasonable probability that the ingredient or nonfunctional constituent poses a specific and serious adverse human health risk and the need to conduct an animal test is justified and supported by a detailed research protocol proposed as the basis for the evaluation of the cosmetic

ingredient or nonfunctional constituent;

(c) The cosmetic ingredient is widely used and cannot be replaced by another cosmetic ingredient capable of performing a similar function.

(5) A cosmetic, if the cosmetic in its final form was tested on animals before the effective date of this enactment, even if the cosmetic is manufactured on or after that date, provided that no new animal testing in violation of this section is conducted on the cosmetic by, or on behalf of, the cosmetic manufacturer;

(6) A cosmetic ingredient, if the cosmetic ingredient was tested on animals before the effective date of this enactment, even if the cosmetic ingredient is manufactured on or after that date, provided that no new animal testing in violation of this section is conducted on the cosmetic ingredient by, or on behalf of, the cosmetic manufacturer;

(7) A cosmetic manufacturer or cosmetic supplier reviewing, assessing, or retaining evidence from animal testing.

(C) No county, township, or municipal corporation, including a county that has adopted a charter under Ohio Constitution, Article X, Section 3, and a township that adopts a limited home rule government, shall prohibit or enforce a prohibition relating to cosmetic animal testing other than the prohibitions set forth in this section or identical prohibitions, which may be adopted by ordinance or resolution of the board of county commissioners, board of township trustees, or legislative authority of the municipal corporation.

Sec. 3715.99. (A) Whoever violates section 3715.13 or 3715.38 of the Revised Code is guilty of a minor misdemeanor.

(B) Whoever violates section 3715.22, 3715.25, or 3715.27 of the Revised Code is guilty of a misdemeanor of the fourth degree.

(C) Whoever violates section 3715.23 or 3715.34 of the Revised Code is guilty of a misdemeanor of the second degree.

(D) Whoever violates section 3715.52 or 3715.65 of the Revised Code is guilty of a misdemeanor of the fourth degree on a first offense; on each subsequent offense, the person is guilty of a misdemeanor of the second degree.

(E) Whoever violates section 3715.521 of the Revised Code is guilty of a minor misdemeanor. A violation of that section occurs on a daily basis, not according to the number of times per day that an expired drug, baby food, or infant formula is sold, offered for sale, or delivered at retail or to the consumer. Each day of violation is a separate offense.

(F) The director of agriculture or the director's designee shall impose a civil penalty, in accordance with Chapter 119. of the Revised Code, not exceeding five thousand dollars on whoever violates section 3715.522 of the Revised Code. The director shall impose an additional penalty of one thousand dollars for each day the violation continues. The director shall deposit the penalty to the credit of the cosmetic animal testing prevention fund, which is hereby created in the state treasury. All money in the fund shall be used to offset the costs incurred by the department of agriculture in enforcing section 3715.522 of the Revised Code.

Sec. 3717.01. As used in this chapter:

(A) "Ohio uniform food safety code" means the food safety and related standards adopted under section 3717.05 of the

Revised Code.

(B) "Food" means any raw, cooked, or processed edible substance used or intended for use in whole or in part for human consumption. "Food" includes ice, water or any other beverage, food ingredients, and chewing gum.

(C) "Retail food establishment" means a premises or part of a premises where food is stored, processed, prepared, manufactured, or otherwise held or handled for retail sale. Except when expressly provided otherwise, "retail food establishment" includes a mobile retail food establishment, seasonal retail food establishment, and temporary retail food establishment.

As used in this division:

(1) "Retail" means the sale of food to a person who is the ultimate consumer.

(2) "Prepared" means any action that affects a food, including receiving and maintaining it at the temperature at which it was received.

(D) "Seasonal retail food establishment" means a retail food establishment, other than a mobile retail food establishment, that is operated for not more than six months in a licensing period.

(E) "Temporary retail food establishment" means a retail food establishment that is operated at an event for not more than five consecutive days, except when operated for more than five consecutive days pursuant to division (E)(2) of section 3717.23 of the Revised Code.

(F) "Food service operation" means a place, location,

site, or separate area where food intended to be served in individual portions is prepared or served for a charge or required donation. As used in this division, "served" means a response made to an order for one or more individual portions of food in a form that is edible without washing, cooking, or additional preparation and "prepared" means any action that affects a food other than receiving or maintaining it at the temperature at which it was received.

Except when expressly provided otherwise, "food service operation" includes a catering food service operation, food delivery sales operation, mobile food service operation, seasonal food service operation, temporary food service operation, and vending machine location.

(G) "Catering food service operation" means a food service operation where food is prepared for serving at a function or event held at an off-premises site, for a charge determined on a per-function or per-event basis.

(H) "Food delivery sales operation" means a food service operation from which individual portions of food are ordered by a customer, prepared at another food service operation or a retail food establishment, and delivered to the customer by a person other than an employee of the food service operation or retail food establishment that prepared the food.

(I) "Mobile food service operation" means a food service operation that is operated from a movable vehicle, portable structure, or watercraft and that routinely changes location, except that if the operation remains at any one location for more than forty consecutive days, the operation is no longer a mobile food service operation. "Mobile food service operation" includes a food service operation that does not remain at any

one location for more than forty consecutive days and serves, in a manner consistent with division (F) of this section, only frozen desserts; beverages, nuts, popcorn, candy, or similar confections; bakery products identified in section 911.01 of the Revised Code; or any combination of those items.

(J) "Seasonal food service operation" means a food service operation, other than a mobile food service operation, that is operated for not more than six months in a licensing period.

(K) "Temporary food service operation" means a food service operation that is operated at an event for not more than five consecutive days, except when operated for more than five consecutive days pursuant to division (E)(2) of section 3717.43 of the Revised Code.

(L) "Vending machine location" means an area or room where one or more vending machines are installed and operated, except that if the machines within an area are separated by more than one hundred fifty feet, each area separated by that distance constitutes a separate vending machine location. As used in this division, "vending machine" means a self-service device that automatically dispenses on the insertion of currency, tokens, or similar means a predetermined unit serving of food, either in bulk or in package, without having to be replenished after each use.

(M) "Board of health" means a board of health of a city or general health district or the authority having the duties of a board of health under section 3709.05 of the Revised Code.

(N) "Government entity" means this state, a political subdivision of this state, another state, or a political subdivision or other local government body of another state.

(O) "Licensor" means one of the following:

(1) A board of health approved under section 3717.11 of the Revised Code;

(2) The director of agriculture acting pursuant to section 3717.11 of the Revised Code with respect to the licensing of retail food establishments;

(3) The director of health acting pursuant to section 3717.11 of the Revised Code with respect to the licensing of food service operations.

(P) "Licensing period" means the first day of March to the last day of February of the next succeeding year.

(Q) "Mobile retail food establishment" means a retail food establishment that is operated from a movable vehicle or other portable structure, and that routinely changes location, except that if the establishment operates from any one location for more than forty consecutive days, the establishment is no longer a mobile retail food establishment.

(R) "Unprocessed," when used with respect to fruits and vegetables, means that the fruits and vegetables are not processed beyond merely rough trimming and rinsing.

(S) "Cottage food production operation" has the same meaning as in ~~division (A)(19) of~~ section 3715.01 of the Revised Code.

Section 2. That existing sections 3715.01, 3715.025, 3715.99, and 3717.01 of the Revised Code are hereby repealed.