Ohio Revised Code

Section 3715.64 Misbranded drug or device.

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

(A) A drug or device is misbranded within the meaning of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code, if:

(1) Its labeling is false or misleading in any particular.

(2) It is in package form and does not bear a label containing both of the following:

(a) In clearly legible form, 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; but reasonable variations shall be permitted, and exemptions as to small packages shall apply as established by rules adopted by the director of agriculture or state board of pharmacy.

(3) It is a dangerous drug and does not bear a label containing in clearly legible form the name and place of business of the manufacturer of the finished dosage form and, if different, the packer or distributor.

(4) It is a dangerous drug in finished solid oral dosage form and it does not have clearly and prominently marked or imprinted on it an individual symbol, company name, national drug code number or other number, words, letters, or any combination thereof, identifying the drug and its manufacturer or distributor. This requirement does not apply to drugs that are compounded by a licensed pharmacist. The manufacturer or distributor of each such drug shall make available to the state board of pharmacy descriptive material identifying the mark or imprint used by the manufacturer or distributor. The board shall provide this information to all poison control centers in this state. Upon application by a manufacturer or distributor, the board may exempt a drug from the requirements of this division on the grounds that marking or imprinting the drug is not feasible because of its size, texture, or other unique characteristic.

(5) Any word, statement, or other information that is required by or under authority of sections 3715.01 and 3715.52 to 3715.72 of the Revised Code to appear on the label or labeling is not prominently placed on the label or labeling in a conspicuous manner, as compared with other words, statements, designs, or devices on the label or labeling, and in terms that render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(6) It is a drug and it is not designated solely by a name recognized in the United States pharmacopoeia and national formulary, or any supplement to them, unless its label bears:

(a) The common or usual name of the drug, if any;

(b) In case it is fabricated from two or more ingredients, the common or usual name of each active ingredient the drug contains, including the kind and quantity or proportion of any alcohol, and also including whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanalid, acetophenetidin, aminopyrine, atropine, hyoscine, hyoscyamine, arsenic, digitalis, digitalis glycosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances; but to the extent that compliance with these requirements is impracticable, exemptions shall apply as established by rules adopted by the director of agriculture or state board of pharmacy.

(7) Its labeling does not bear the following:

(a) Adequate directions for use of the drug or device, except that when compliance with this requirement is not necessary for a particular drug or device to protect the public health, the director shall adopt rules exempting the drug or device from the requirement;

(b) 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, presented in a manner and form as necessary for the protection of users.

(8) It purports to be a drug the name of which is recognized in the United States pharmacopoeia and national formulary, or any supplement to them, and it is not packaged and labeled as prescribed in those compendiums, except that the method of packing may be modified with the consent of the

director of agriculture. Whenever a drug is recognized in both the homoeopathic pharmacopoeia of the United States and in the United States pharmacopoeia and national formulary, including their supplements, it shall be subject to the requirements of the United States pharmacopoeia and national formulary with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the homoeopathic pharmacopoeia of the United States and not to those of the United States pharmacopoeia and national formulary.

(9) It has been found by the director of agriculture to be a drug liable to deterioration, unless it is packaged in the form and manner, and its label bears a statement of precautions, as required by rules adopted by the director as necessary for the protection of public health. No rule shall be established for any drug recognized in the United States pharmacopoeia and national formulary, or any supplements to them, until the director has informed the appropriate bodies charged with the revision of those compendiums of the need for packaging or labeling requirements and those bodies have failed within a reasonable time to prescribe such requirements.

(10)(a) It is a drug and its container is so made, formed, or filled as to be misleading.

(b) It is an imitation of another drug.

(c) It is offered for sale under the name of another drug.

(d) The drug sold or dispensed is not the brand or drug specifically prescribed or ordered or, when dispensed by a pharmacist upon prescription, the drug is neither the brand or drug prescribed nor a generically equivalent drug or, in the case of a drug that is a biological product, is neither the brand or biological product prescribed nor an interchangeable biological product.

(11) It is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling.

(12) It is a drug intended for human use to which the following apply:

(a) Because of its toxicity or other potentiality for harmful effect, the method of its use, or the

collateral measures necessary to its use, the drug is not safe for use except under the supervision of a licensed health professional authorized to prescribe drugs;

(b) The drug is limited by an effective application under section 505 of the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040 (1938), 21 U.S.C.A. 301, as amended, to use under professional supervision by a licensed health professional authorized to prescribe drugs, unless it is dispensed only:

(i) Upon a written or electronic prescription;

(ii) Upon an oral prescription, which is reduced promptly to writing by the pharmacist;

(iii) By refilling a prescription if refilling is authorized by the prescriber either in the original prescription or by oral order, which is promptly reduced to writing by the pharmacist.

(B)(1) Any drug dispensed pursuant to a written, electronic, or oral prescription of a licensed health professional authorized to prescribe drugs shall be exempt from the requirements of division (A) of this section, except divisions (A)(1) and (10) of this section, if the drug bears a label containing the name and address of the dispenser, the serial number and the date the prescription is dispensed, the name of the prescriber, the name of the patient, and, if stated in the prescription, the directions for use and cautionary statements.

(2) Unless the prescriber instructs otherwise, the label for the dispensed drug shall include information that meets the following requirements, using abbreviations as necessary:

(a) Except as provided in divisions (B)(2)(b) and (c) of this section, the label shall include the dispensed drug's brand name.

(b) If the drug dispensed has no brand name and is a generically equivalent drug, the label shall include the generic name of the drug and the distributor of the finished dosage form.

(c) If the drug dispensed has no brand name and is an interchangeable biological product, the label shall include the name of the interchangeable biological product, the manufacturer, and if the

distributor is not the same as the manufacturer, the distributor of the finished dosage form.