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§21–201.

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

(b) “Counterfeit drug” means a drug that:

(1) Bears, or the container or labeling of which bears, without authorization, the trademark, trade name, imprint, symbol, or any other identifying mark, or any likeness of any of these markings, of a manufacturer, processor, packer, or distributor other than the one who, in fact, manufactured, processed, packed, or distributed the drug; and

(2) By use of these markings falsely purports or is represented to be the product of, or to have been packed or distributed by, the other drug manufacturer, processor, packer, or distributor.

(c) (1) “Established name” means, in regard to a drug or an ingredient of a drug:

(i) The name designated under the federal act;

(ii) If a name has not been designated under the federal act, but the drug or ingredient has been recognized in an official compendium, then the title used in the compendium; or

(iii) If a name cannot be determined under item (i) or (ii) of this paragraph, the common or usual name of the drug or ingredient.

(2) In applying the provisions of paragraph (1)(ii) of this subsection, if a drug or an ingredient of a drug is recognized in both the United States Pharmacopoeia and National Formulary and in the Homeopathic Pharmacopoeia of the United States under different official titles, the title used in the United States Pharmacopoeia and National Formulary is the established name, unless the drug is labeled and offered for sale as a homeopathic drug, in which event the official title used in the Homeopathic Pharmacopoeia of the United States is the established name.

(d) “New drug” means any drug that:

(1) Among experts qualified by scientific training and experience to evaluate the safety and effectiveness of drugs, is not recognized generally as safe and effective for use under the conditions specified, recommended, or suggested in the labeling of the drug; or

(2) As a result of investigations to determine its safety and effectiveness for use, has become recognized by these experts as safe and effective under the

conditions, but that, other than in the investigations, has not been used to a material extent or for a material time under the conditions.

(e) “Prescription drug” means a drug that, under § 21-220 of this subtitle, may be dispensed only on the prescription of a health practitioner who is authorized by law to prescribe the drug.

(f) “State adopted federal rule or regulation” means any rule or regulation that is adopted by the federal government under the federal act and that becomes a rule or regulation by automatic adoption under the provisions of this subtitle.

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