217.814 Definitions for KRS 217.815 to 217.826.

The following words and phrases, as used in KRS 217.815 to 217.826, shall have the following meanings, unless the context requires otherwise:

(1) "Biological product" has the same meaning as in 42 U.S.C. sec. 262;

(2) "Board" means the Kentucky Board of Pharmacy;

(3) "Brand name" means the name that a manufacturer of a drug or pharmaceutical places on the container thereof at the time of packaging;

(4) "Dosage formulation" shall include but not be limited to those specific dosage forms which, by the nature of their physical manufacture, are deemed to be nonequivalent to other similar formulations such as controlled-release tablets, aerosol-nebulizer drug delivery systems, and enteric-coated oral dosage forms;

(5) "Equivalent drug product" means a product with the same generic name, active ingredients, strength, quantity, and dosage form as the drug product identified in a prescription;

(6) "Generic name" means the chemical or established name of a drug or pharmaceutical;

(7) "Interchangeable biological product" means:

(a) A biological product that the United States Food and Drug Administration has licensed and determined meets the standards for interchangeability pursuant to 42 U.S.C. sec. 262(k)(4); or

(b) A biological product that the United States Food and Drug Administration has determined is therapeutically equivalent as set forth in the latest edition or supplement to the federal Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations;

(8) "Nonequivalent drug product formulary" means a formulary of drugs, drug products, and dosage formulations for which there are no equivalent drugs, drug products, or dosage formulations and which have been determined to be noninterchangeable or to have actual or potential bioequivalency problems by the United States Food and Drug Administration and are contained in a drug bioequivalence problems list as published in the United States Food and Drug Administration publication entitled "Approved prescription drug products with therapeutic equivalence evaluations" with supplements;

(9) "Pharmacist" has the same meaning as in KRS 315.010; and

(10) "Practitioner" has the same meaning as in KRS 217.015.

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