201 KAR 2:116. Substitution of drugs, biologics and biosimilar products.

RELATES TO: KRS 217.819

STATUTORY AUTHORITY: KRS 217.814(5), (6), (7), (8), 217.819(1)

NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.819(1) requires the Kentucky Board of Pharmacy to prepare by administrative regulation a drug product formulary of drugs which should not be interchanged by pharmacists. This administrative regulation references drug products with active ingredients or dosage forms that are interchangeable. All other products not referenced as interchangeable are non-interchangeable.

Section 1. The following have been determined by the board to be interchangeable:

(1) Drugs, drug products, or dosage formulations considered by the United States Food and Drug Administration to be therapeutically equivalent as published in the Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book); and

(2) Biologics drugs, biologics drug products, or biologics dosage formulations considered by the United States Food and Drug Administration to be therapeutically equivalent as published in the Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book).

Section 2. Incorporation by Reference.

(1) The following material is incorporated by reference:

(a) "Approved Drug Products with Therapeutic Equivalence Evaluations," (Orange Book), U.S. Food and Drug Administration, 39th Edition, 2019; and

(b) "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations" (Purple Book), United States Food and Drug Administration, June 2019.

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(16 Ky.R. 1720; 2154; eff. 5-13-1990; 17 Ky.R. 2212; 2725; eff. 4-5-1991; 45 Ky.R. 3453, 46 Ky.R. 412; eff. 8-19-2019.)