BOARDS AND COMMISSIONS
Board of Pharmacy
(Amended at ARRS Committee)

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

RELATES TO: KRS 217.819***, 217.822***
STATUTORY AUTHORITY: KRS 217.814(5), (6), (7), (8), 217.819(1)***, 315.191***
CERTIFICATION STATEMENT: This is to certify that this administrative regulation complies with the requirements of 2025 RS HB 6, Section 8.
NECESSITY, FUNCTION, AND CONFORMITY: KRS 217.819(1) requires the Kentucky Board of Pharmacy to prepare by administrative regulation a ***nonequivalent*** drug product formulary of drugs which should not be interchanged by pharmacists. ***KRS 217.822 authorizes pharmacists to dispense interchangeable drug products and biological products.*** This administrative regulation references drug products with active ingredients or dosage forms that are interchangeable***, and[.]*** 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 ***Database[Lists]*** of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book) ***available at https://purplebooksearch.fda.gov/; and***
(3) Animal drug products considered by the United States Food and Drug Administration to be therapeutically equivalent as published in the Approved Animal Drug Products (Green Book) updated monthly, and available at https://animaldrugsatfda.fda.gov/adafda/views/#/search.

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, ***46th[45][th]*** Edition, ***2026[2025]***[39th Edition, 2019];***[and]***
(b) "***Database[Lists]*** of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations" (Purple Book), United States Food and Drug Administration, ***2026[June 27, 2025]; and***[June 2019]***[.]***
(c) "Approved Animal Drug Products," (Green Book), U.S. Food and Drug Administration, ***2026 [2025]*** .
(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, Frankfort, Kentucky 40601-8204, Monday through[throught] Friday, 8 a.m. to 4:30 p.m. and is available online at http://www.fda.gov.
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