BOARDS AND COMMISSIONS

Board of Pharmacy

(Amendment)

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)

CERTIFICATION STATEMENT: This is to certify that this administrative regulation complies with the requirements of 2025 RS HB6, Section 8.

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, 45th Edition, 2025; 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 27, 2025.

(c) "Approved Animal Drug Products," (Green Book), U.S. Food and Drug Administration, 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 Friday, 8 a.m. to 4:30 p.m. and is available online at http://www.fda.gov.

CHRISTOPHER HARLOW, PharmD, Executive Director

APPROVED BY AGENCY: December 3, 2025

FILED WITH LRC: December 12, 2025 at 10:45 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on February 27, 2026, at 9:00 a.m. EST via a Zoom teleconference. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing was received by that date, the hearing may be cancelled. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through February 28, 2026. Send written notification of intent to be heard at the public

hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: Christopher Harlow, Executive Director, Kentucky Board of Pharmacy, 125 Holmes Street, Suite 300, State Office Building Annex, Frankfort, Kentucky 40601, phone (502) 564-7910, fax (502) 696-3806, email Christopher.harlow@ky.gov.