GENERL GOVERNMENT CABINET

Kentucky 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 HB, 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.

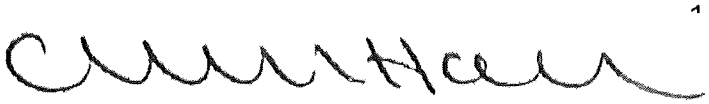
(1) The following material is incorporated by reference:

(a) "Approved Drug Products with Therapeutic Equivalence Evaluations," (Orange Book), U.S. Food and Drug Administration, 45th Edition, 2025 [~~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 27, 2025 [~~June 2019~~].

(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[~~t~~] Friday, 8 a.m. to 4:30 p.m. and is available online at http://www.fda.gov.



Christopher Harlow, PharmD
Executive Director, Kentucky Board of Pharmacy

12/3/2025
Date

PUBLIC HEARING AND PUBLIC 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.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

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

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.

Subject Headings: Pharmacy; Drugs and Medicines; Health and Medical Services

(1) Provide a brief summary of:

(a) What this administrative regulation does: This administrative regulation references drug products that are deemed interchangeable. All other products not referenced as interchangeable are deemed non-interchangeable.

(b) The necessity of this administrative regulation: KRS 217.819 directs the Kentucky Board of Pharmacy to prepare a drug product formulary of drugs which should not be interchanged by pharmacists. This administrative regulation references drug products that are deemed interchangeable. All other products not referenced as interchangeable are deemed non-interchangeable.

(c) How this administrative regulation conforms to the content of the authorizing statues: This administrative regulation references drug products that are deemed interchangeable. All other products not referenced as interchangeable are deemed non-interchangeable.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This amendment updates the references that are incorporated to the most recent version.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation: Updated reference information to the most recent edition for the "Approved Drug Products with Therapeutic

Equivalence Evaluations" published by the United States Food and Drug Administration (FDA); "Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimiarlity or Interchangeability Evaluations" or the "Purple Book" published by the FDA and adds the veterinary equivalent reference, "Approved Animal Drug Products," known as the "Green Book" published by the U.S. Food and Drug Administration.

(b) The necessity of the amendment to this administrative regulation: The incorporated references were out of date and the new editions were included in this amendment. In addition, because pharmacies also dispense drug products for animals the Board included the equivalent reference for veterinary practice.

(c) How the amendment conforms to the content of the authorizing statutes: KRS 315.002 and 315.005 authorize the board to regulate the practice of pharmacy. KRS 315.191 authorizes the board to promulgate administrative regulations pertaining to pharmacists and pharmacies. KRS 217.819 directs the Board of Pharmacy to promulgate administrative regulations regarding reference material and equipment suitable for pharmaceutical practice.

(d) How the amendment will assist in the effective administration of the statutes: The amendment will further promote, preserve, and protect public health through effective regulation of pharmacists and pharmacies by providing the most accurate and up to date information regarding the substitution of drugs, biologics and biosimilar products.

(3) Does this administrative regulation or amendment implement legislation from the previous five years? No.

(4) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: The board anticipates no one will be affected by the administrative regulation.

(5) Provide an analysis of how the entities identified in question (4) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (4) will have to take to comply with this administrative regulation or amendment: Pharmacies and pharmacists will have to familiarize themselves with new amended language in the regulation. However, there has been no significant changes beyond the updated references. These references are widely used in the practice of pharmacy.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4): There are no expected costs for the identities to comply with the amendment.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4): Pharmacists and the public can refer to the correct information for substitution of drugs for both humans and animals.

(6) Provide an estimate of how much it will cost to implement this administrative Regulation:

(a) Initially: No costs will be incurred.

(b) On a continuing basis: No costs will be incurred.

(7) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: Board revenues from pre-existing fees provide the funding to enforce the regulation.

(8) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: No increase in fees or funding will be required because of this new regulation.

(9) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees: This administrative regulation does not establish fees or directly or indirectly increase any fees.

(10) TIERING: Is tiering applied? (Explain why tiering was or was not used) Tiering is not applied because the regulation is applicable to all pharmacists and pharmacies.

FISCAL IMPACT STATEMENT

Regulation No. 201 KAR 2:116 Substitution of drugs, biologics and biosimilar products.

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.

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation: KRS 217.819

(2) State whether this administrative regulation is by an act of the General Assembly, and if so, identify the act: KRS 217.819

(3)(a) Identify the promulgating agency and any other affected state units, parts, or divisions: The Kentucky Board of Pharmacy will be impacted by this administrative regulation.

(b) Estimate the following for each affected state unit, part, or division identified in (3)(a):

1. Expenditures:
   For the first year: $0
   For subsequent years: $0
2. Revenues:
   For the first year: $0
   For subsequent years: $0
3. Cost Savings:
   For the first year: $0
   For subsequent years: $0

(4)(a) Identify affected local entities (for example: cities, counties, fire departments, school districts): Only the Kentucky Board of Pharmacy will be impacted by this administrative regulation.

(b) Estimate the following for each affected local entity identified in (4)(a):

1. Expenditures:
   For the first year: $0
   For subsequent years: $0
2. Revenues:
   For the first year: $0

For subsequent years: $0

3. Cost Savings:

For the first year: $0

For subsequent years: $0

(5)(a) Identify any affected regulated entities not listed in (3)(a) or (4)(a): None.

(b) Estimate the following for each regulated entity identified in (5)(a):

1. Expenditures:

For the first year: $0

For subsequent years: $0

2. Revenues:

For the first year: $0

For subsequent years: $0

3. Cost Savings:

For the first year: $0

For subsequent years: $0

(6) Provide a narrative to explain the following for each entity identified in (3)(a), (4)(a), and (5)(a):

(a) Fiscal impact of this administrative regulation: The regulation does not cost anything for regulated parties to implement nor does it have a cost to the Board to oversee.

(b) Methodology and resources used to reach this conclusion: None.

(7) Explain, as it relates to the entities identified in (3)(a), (4)(a), and (5)(a):

(a) Whether this administrative regulation will have a "major economic impact", as defined by KRS 13A.010(14): No, this administrative regulation does not have an overall negative or adverse major economic impact to regulated entities, or those entities identified in questions (2)-(4).

(b) The methodology and resources used to reach this conclusion: Analysis of the Board's expenditures as well as an assessment regarding cost of compliance for regulated entities.

SUMMARY OF CHANGES TO MATERIAL INCORPORATED BY REFERENCE

This administrative regulation amendment updates the edition of the material incorporated by reference to reflect the most current version published by the issuing organization which sets forth the standards for substitution of drugs, biologics and biosimilar products. No substantive changes have been made to the requirements set forth in this regulation other than replacing the previously incorporated editions with the most recent edition. In addition, the amendment also addresses the gap in guidance by including the "Green Book" which sets forth the standards for drug substitutions for drug products dispensed to animals.

(a) "Approved Drug Products with Therapeutic Equivalence Evaluations," (Orange Book), U.S. Food and Drug Administration, 45th Edition, 2025. https://www.fda.gov/media/71474/download?attachment

(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 https://purplebooksearch.fda.gov/ ; and

(c) "Approved Animal Drug Products," (Green Book), U.S. Food and Drug Administration, 2025. https://www.fda.gov/industry/structured-product-labeling-resources/electronic-animal-drug-product-listing-directory