

Virginia Board of Pharmacy

Dispensing with an Authorized Generic

The term “authorized generic” is defined in 21CFR314.3 as a listed drug that has been approved under section 505(c) of the Federal Food, Drug, and Cosmetic Act and is marketed, sold, or distributed directly or indirectly to retail class of trade with labeling, packaging (other than repackaging as the listed drug in blister packs, unit doses, or similar packaging for use in institutions), product code, labeler code, trade name, or trademark that differs from that of the listed drug. Because authorized generics are identical to the branded drug product, sharing both the same active and inactive ingredients as the branded product, the FDA does not specifically list these drugs as a therapeutically equivalent drug product of the branded drug. However, according to the preface of the 38th edition of the FDA’s Orange Book, “Any drug product in the Orange Book repackaged and/or distributed by other than the applicant is considered to be therapeutically equivalent to the applicant’s drug product even if the applicant’s drug product is single source or coded as non-equivalent (e.g., BN).

Therefore, consistent with the provisions for dispensing therapeutically equivalent drug products as listed in 54.1-3408.03 the Board affirmed that a pharmacist may substitute an authorized generic when dispensing a prescription written for a branded drug product unless (i) the prescriber indicates such substitution is not authorized by specifying on the prescription, "brand medically necessary" or (ii) the patient insists on the dispensing of the brand-name drug product. A listing of authorized generics is provided by the FDA at: <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDER/ucm126391.htm>.

Related statutes:

§54.1-3401

"Therapeutically equivalent drug products" means drug products that contain the same active ingredients and are identical in strength or concentration, dosage form, and route of administration and that are classified as being therapeutically equivalent by the United States Food and Drug Administration pursuant to the definition of "therapeutically equivalent drug products" set forth in the most recent edition of the Approved Drug Products with Therapeutic Equivalence Evaluations, otherwise known as the "Orange Book."

§ 54.1-3408.03. Dispensing of therapeutically equivalent drug product permitted.

A. A pharmacist may dispense a therapeutically equivalent drug product for a prescription that is written for a brand-name drug product unless (i) the prescriber indicates such substitution is not authorized by specifying on the prescription, "brand medically necessary" or (ii) the patient insists on the dispensing of the brand-name drug product.

In the case of an oral prescription, the prescriber's oral dispensing instructions regarding substitution shall be followed.

B. Prescribers using prescription blanks printed in compliance with Virginia law in effect on June 30, 2003, having two check boxes and referencing the Virginia Voluntary Formulary, may indicate, until July 1, 2006, that substitution is not authorized by checking the "Dispense as Written" box. If the "Voluntary Formulary Permitted" box is checked on such prescription blanks or if neither box is checked, a pharmacist may dispense a therapeutically equivalent drug product pursuant to such prescriptions.

C. If the pharmacist dispenses a drug product other than the brand name prescribed, he shall so inform the purchaser and shall indicate, unless otherwise directed by the prescriber, on both his permanent record and the prescription label, the brand name or, in the case of a therapeutically equivalent drug product, the name of the manufacturer or the distributor. Whenever a pharmacist dispenses a therapeutically equivalent drug product pursuant to a prescription written for a brand-name product, the pharmacist shall label the drug with the name of the therapeutically equivalent drug product followed by the words "generic for" and the brand name of the drug for which the prescription was written.

D. When a pharmacist dispenses a drug product other than the drug product prescribed, the dispensed drug product shall be at a lower retail price than that of the drug product prescribed. Such retail price shall not exceed the usual and customary retail price charged by the pharmacist for the dispensed therapeutically equivalent drug product.