Virginia Board of Pharmacy

Dispensing with an Authorized Generic

The term "authorized generic" is defined in 21 CFR § 314.3 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 the 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 and share 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, "[a]ny 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 affirms 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 "brand medically necessary" on the prescription; 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:

Va. Code § 54.1-3401 (*see* definition of "therapeutically equivalent drug products")

Va. Code § 54.1-3408.03