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Circular Letter: DCP 22-01-112

TO: Massachusetts Pharmacies and Pharmacists

FROM: David Johnson, Director, Drug Control Program

DATE: January 14, 2022

SUBJECT: Dispensing Authorized Generics

The term “authorized generic” is defined in [21 CFR 314.3](#) and is most commonly used to describe an approved brand name drug that is marketed without the brand name on its label. Other than the fact that it does not have the brand name on its label, it is the exact same drug product as the branded product. An authorized generic drug is marketed under the brand name drug company, or another company with the brand name company’s permission.

Because the authorized generic is identical to the brand name drug, it is not specifically listed in the [Orange Book](#), however, it is considered to be therapeutically equivalent to its brand name drug.

Therefore, a pharmacist may interchange a prescription written for a brand name drug with its authorized generic version provided that the prescriber did not indicate “no substitution” on the prescription.

If a pharmacist is not able to determine if drug products are interchangeable using the [FDA listing of authorized generics](#), the pharmacist should contact the manufacturers, distributors, or re-packagers.

Contact Information:

Please direct questions or concerns to the Drug Control Program: dcp.dph@mass.gov