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In reply, please refer to:

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Guidance for Industry: Authorized Generics and Unbranded Biologics – Exclusion from The Hawaii List of Equivalent Generic Drug Products and Interchangeable Biological Products

June 1, 2022

This guidance represents the current thinking of the Department of Health (DOH) on this topic. It does not establish any rights for any person and is not binding on DOH or the public. You can use an alternative approach if it satisfies the requirements of Chapter 328, HRS.

Dear Pharmacist/other interested individuals:

The Department of Health is providing the following guidance on dispensing *authorized generic drugs* and *unbranded biologics* when a prescription order is received for a drug or biologic prescribed by its brand name.

Chapter 328, Part VI, Hawaii Revised Statutes (HRS) contains the requirements a pharmacist must follow when substituting an *equivalent generic drug product* or *interchangeable biologic product* for a prescribed branded product [section 328-92, HRS]. For substitution to occur a pharmacist must choose a generic drug or interchangeable biologic that is included in the "Hawaii List of Equivalent Generic Drug Products and Interchangeable Biological Products". The 'Hawaii List' is required by law to be informed by FDA published findings, including those found in the Orange Book or Purple Book, which provide evaluations on therapeutic equivalence of drug products and interchangeability evaluations for biologic products [section 328-96, HRS]. State law requires the 'Hawaii List' to only include products that are therapeutically equivalent or interchangeable [Id.].

However, there are a growing number of FDA approved drug and biologic products, referred to as "authorized generics" and "unbranded biologics", respectively, that FDA has decided not to include in the Orange Book or Purple Book. As such, these prescription only products are not included in the 'Hawaii List' and thus not to be considered for substitution by a pharmacist.

FDA currently considers evaluations to determine substitutability of "authorized generics"[1] and "unbranded biologics"[2] to be unnecessary as these products are made and marketed under the

1. FDA website: FDA List of Authorized Generic Drugs (last accessed May 16, 2022)
2. FDA website: Purple Book Database of Licensed Biological Products – FAQ see FAQ #9 (last accessed May 16, 2022)

same FDA approved New Drug Application (NDA) or Biologics Licensing Application (BLA), respectively, as the branded version but without the brand name on the label. FDA considers products made under the same approved application (NDA or BLA) to be equivalent to each other as they will not be different in strength, dosage form, or route of administration.

Based on FDA's explanation and rationale to exclude "authorized generics" and "unbranded biologics" from the Orange Book and Purple Book, and thus the 'Hawaii List', the Department would not consider the dispensing of an "authorized generic drug" or "unbranded biologic", made under the same NDA or BLA as the prescribed brand name product, to follow the substitution requirements found in Ch. 328, HRS, Part VI. Pharmacist should be able to demonstrate due diligence in the form of a record that documents product dispensed was made under the same approved NDA or BLA as the prescribed product.

The Department advises contacting the Department of Commerce and Consumer Affairs - Board of Pharmacy with any questions regarding compliance with drug substitution requirements found in their laws and rules.

Please contact the Department of Health, Food & Drug Branch at doh.fdbinfo@doh.hawaii.gov if you have any questions.