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HONOLULU, HI 96801-3378

In reply, please refer to:
File:

Hawaiʻi List of Equivalent Generic Drug Products and Interchangeable Biological Products

April 30, 2024

Dear Pharmacy Stakeholders:

The Hawaiʻi State Department of Health Food and Drug Branch (FDB) has adopted the therapeutically equivalent generic drugs approved by the U.S. Food and Drug Administration (FDA) and listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), 44th Edition, which includes Cumulative Supplement 3 (March 2024).

FDB has also adopted FDA's List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book), which includes the April 2024 update to the Purple Book Database of Licensed Biological Products. The Purple Book database contains information on all FDA-licensed (approved) biological products regulated by the Center for Drug Evaluation and Research (CDER), including licensed biosimilar and interchangeable products, and their reference products. The Purple Book also contains information about all FDA-licensed allergenic, cellular, gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research (CBER).

By adopting the above, this letter serves as notification that Hawaiʻi pharmacists may substitute in accordance with Hawaii Revised Statutes (HRS) §328-92 and §328-96.

Hawaiʻi State Department of Health
Food and Drug Branch

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