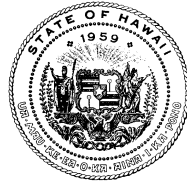


JOSH GREEN, M.D.
GOVERNOR OF HAWAII
KE KIA'AINA O KA MOKU'AINA 'O HAWAII



KENNETH S. FINK, MD, MGA, MPH
DIRECTOR OF HEALTH
KA LUNA HO'OKELE

STATE OF HAWAII
DEPARTMENT OF HEALTH
KA 'OIHANA OLAKINO
P. O. BOX 3378
HONOLULU, HI 96801-3378

In reply, please refer to:
File:

Hawai'i List of Equivalent Generic Drug Products and Interchangeable Biological Products

December 29, 2025

Dear Pharmacy Stakeholders:

The Hawai'i 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 [2025 Approved Drug Products with Therapeutic Equivalence Evaluations \(Orange Book\), 45th Edition](#), including [Cumulative Supplement 11 \(November 2025\)](#).

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 [December 2025](#) 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 Hawai'i pharmacists may substitute in accordance with Hawaii Revised Statutes (HRS) [§328-92](#) and [§328-96](#).

Hawai'i State Department of Health
Food and Drug Branch

Email: doh.fdbinfo@doh.hawaii.gov