



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

In reply, please refer to:
File:

Hawaii List of Equivalent Generic Drug Products and Interchangeable Biological Products

January 6, 2023

Dear Pharmacists and Stakeholders:

The Department of Health has adopted the therapeutically equivalent generic drugs approved by FDA, which are listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book), 42nd Edition, which includes Cumulative Supplement 11 (November 2022). The current cumulative supplement can be accessed as a pdf by selecting “*Orange Book Current Cumulative Supplement*” under the “Orange Book Publications” section found at the following FDA link:

- <https://www.fda.gov/drugs/drug-approvals-and-databases/approved-drug-products-therapeutic-equivalence-evaluations-orange-book>

The Department of Health has adopted FDA's List of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations (Purple Book), which includes the December 2022 update to the Purple Book database. 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 and gene therapy, hematologic, and vaccine products regulated by the Center for Biologics Evaluation and Research (CBER). The searchable Purple Book database can be found at the following FDA link:

- <https://purplebooksearch.fda.gov/>

By adopting the above, this letter serves as notification that Hawaii pharmacists can substitute in accordance with Section 328-92, Hawaii Revised Statute (HRS), and Section 328-96, HRS.

Please email us at doh.fdbinfo@doh.hawaii.gov if you have any questions.

Sincerely,
Food and Drug Branch
Hawaii Department of Health
<http://health.hawaii.gov/food-drug/>