Celebrating 40 Years: An In-Depth Examination of the FDA Orange Book

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Approved Drug Products with Therapeutic Equivalence Evaluations (Orange Book)

APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC EQUIVALENCE EVALUATIONS

40th EDITION

THE PRODUCTS IN THIS LIST HAVE BEEN APPROVED UNDER SECTION 505 OF THE FEDERAL FOOD, DRUG, AND COSMETIC ACT.

U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION
OFFICE OF MEDICAL PRODUCTS AND TOBACCO
CENTER FOR DRUG EVALUATION AND RESEARCH
OFFICE OF GENERIC DRUGS
OFFICE OF GENERIC DRUG POLICY

2020

Important Dates in Orange Book History

31 Oct. 1980	1984	2016	2017
First "Orange Book" published	Drug Price Competition and Patent Term Restoration Act or "Hatch-Waxman Amendments"	Final Rule: Abbreviated New Drug Applications and 505(b)(2) Applications	FDA Reauthorization Act

Our conference topics include:

- History of the Orange Book
- Orange Book 101
- Updates to Orange Book Information
- Orange Book Content
- Patent Information in the Orange Book
- Best Practices for 505(b)(2) and ANDA Applicants
- Exclusivity Information in the Orange Book
- Therapeutic Equivalence

Drug Competition Action Plan

Recent Dockets and Guidances

NATIONAL ARCHIVES

FEDERAL REGISTER

The Daily Journal of the United States Government

Notice

Approved Drug Products With Therapeutic Equivalence Evaluations (the "Orange Book"); Establishment of a Public Docket; Request for Comments

A Notice by the Food and Drug Administration on 06/01/2020

PUBLISHED DOCUMENT

AGENCY:

Food and Drug Administration, HHS.

DOCUMENT DETAILS

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PDF

Publication Date:

Thank you!


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