

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



First “Orange Book” published

31 Oct. 1980

Drug Price Competition and Patent Term Restoration Act or “Hatch-Waxman Amendments”

1984

Final Rule: Abbreviated New Drug Applications and 505(b)(2) Applications

2016

FDA Reauthorization Act

2017

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

FDA Drug Competition Action Plan

Helps remove barriers to generic drug development and market entry so that consumers can get access to needed medicines



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Bringing more drug competition to the market and addressing the high cost of medicines is a top priority of the Administration, the Department of Health and Human Services (HHS), and FDA. In 2017, FDA announced the Drug Competition Action Plan (DCAP) to further encourage robust and timely market competition for generic drugs and help bring greater efficiency and transparency to the generic drug review process, without sacrificing the scientific rigor underlying our generic drug program. Through this plan, FDA is helping remove barriers to generic drug development and market entry in an effort to spur

Recent Dockets and Guidances



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

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Food and Drug Administration, HHS.

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Thank you!

