



# APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC  
EQUIVALENCE  
EVALUATIONS

36<sup>th</sup> 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

2016

# APPROVED DRUG PRODUCTS with THERAPEUTIC EQUIVALENCE EVALUATIONS

The products in this list have been approved under section 505 of the Federal Food, Drug, and Cosmetic Act. This volume is current through December 31, 2015.

## 36<sup>th</sup> EDITION



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

2016

**FOOD AND DRUG ADMINISTRATION  
 CENTER FOR DRUG EVALUATION AND RESEARCH  
 APPROVED DRUG PRODUCTS  
 with  
 Therapeutic Equivalence Evaluations**

**CONTENTS**

	<i>PAGE</i>
PREFACE TO THIRTY SIXTH EDITION.....	iv
1 INTRODUCTION.....	vi
1.1 Content and Exclusion .....	vi
1.2 Therapeutic Equivalence-Related Terms .....	vi
1.3 Further Guidance on Bioequivalence .....	ix
1.4 Reference Listed Drug .....	ix
1.5 General Policies and Legal Status .....	x
1.6 Practitioner/User Responsibilities .....	x
1.7 Therapeutic Equivalence Evaluations Codes .....	xii
1.8 Description of Certain Special Situations .....	xx
1.9 Therapeutic Equivalence Code Change for a Drug Entity .....	xxii
1.10 Change of the Therapeutic Equivalence Evaluation for a Single Product .....	xxii
1.11 Discontinued Section .....	xxiii
1.12 Changes to the Orange Book.....	xxiii
1.13 Availability of the Edition .....	xxiv
2 HOW TO USE THE DRUG PRODUCTS LISTS .....	2-1
2.1 Key Sections for Using the Drug Product Lists .....	2-1
2.2 Drug Product Illustration .....	2-3
2.3 Therapeutic Equivalence Evaluations Illustration .....	2-4
<b>DRUG PRODUCT LISTS</b>	
Prescription Drug Product List .....	3-1
OTC Drug Product List .....	4-1
Drug Products with Approval under Section 505 of the FD&C Act Administered by the Center for Biologics Evaluation and Research List .....	5-1
Discontinued Drug Product List .....	6-1
Orphan Products Designations and Approvals List .....	7-1
Drug Products Which Must Demonstrate in vivo Bioavailability Only if Product Fails to Achieve Adequate Dissolution .....	8-1
<b>APPENDICES</b>	
A. Product Name Index .....	A-1
B. Product Name Index Listed by Applicant .....	B-1
C. Uniform Terms .....	C-1
PATENT AND EXCLUSIVITY INFORMATION ADDENDUM .....	AD1
A. Patent and Exclusivity Lists .....	ADA1
B. Patent and Exclusivity Terms .....	ADB1

**FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH  
APPROVED DRUG PRODUCTS  
with  
Therapeutic Equivalence Evaluations**

**PREFACE TO THIRTY SIXTH EDITION**

The publication, *Approved Drug Products with Therapeutic Equivalence Evaluations* (the List, commonly known as the Orange Book), identifies drug products approved on the basis of safety and effectiveness by the Food and Drug Administration (FDA) under the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Drugs on the market approved only on the basis of safety (covered by the ongoing Drug Efficacy Study Implementation [DESI] review [e.g., Donnatal® Tablets and Librax® Capsules] or pre-1938 drugs [e.g., Phenobarbital Tablets]) are not included in this publication. The main criterion for the inclusion of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons. Inclusion of products on the List is independent of any current regulatory action through administrative or judicial means against a drug product. In addition, the List contains therapeutic equivalence evaluations for approved multisource prescription drug products. These evaluations have been prepared to serve as public information and advice to state health agencies, prescribers, and pharmacists to promote public education in the area of drug product selection and to foster containment of health care costs. Therapeutic equivalence evaluations in this publication are not official FDA actions affecting the legal status of products under the FD&C Act.

**Background of the Publication.** To contain drug costs, virtually every state has adopted laws and/or regulations that encourage the substitution of drug products. These state laws generally require either that substitution be limited to drugs on a specific list (the positive formulary approach) or that it be permitted for all drugs except those prohibited by a particular list (the negative formulary approach). Because of the number of requests in the late 1970s for FDA assistance in preparing both positive and negative formularies, it became apparent that FDA could not serve the needs of each state on an individual basis. The Agency also recognized that providing a single list based on common criteria would be preferable to evaluating drug products on the basis of differing definitions and criteria in various state laws. As a result, on May 31, 1978, the Commissioner of the Food and Drug Administration sent a letter to officials of each state stating FDA's intent to provide a list of all prescription drug products that are approved by FDA for safety and effectiveness, along with therapeutic equivalence determinations for multisource prescription products.

The List was distributed as a proposal in January 1979. It included only currently marketed prescription drug products approved by FDA through new drug applications (NDAs) and abbreviated new drug applications (ANDAs) under the provisions of Section 505 of the FD&C Act.

The therapeutic equivalence evaluations in the List reflect FDA's application of specific criteria to the multisource prescription drug products on the List approved under Section 505 of the FD&C Act. These evaluations are presented in the form of code letters that indicate the basis

for the evaluation made. An explanation of the code appears in the *Introduction*.

A complete discussion of the background and basis of FDA's therapeutic equivalence evaluation policy was published in the *Federal Register* on January 12, 1979 (44 FR 2932). The final rule, which includes FDA's responses to the public comments on the proposal, was published in the *Federal Register* on October 31, 1980 (45 FR 72582). The first publication, October 1980, of the final version of the List incorporated appropriate corrections and additions. Each subsequent edition has included the new approvals and made appropriate changes in data.

On September 24, 1984, the President signed into law the Drug Price Competition and Patent Term Restoration Act of 1984 (1984 Amendments). The 1984 Amendments require that FDA, among other things, make publicly available a list of approved drug products with monthly supplements. The *Approved Drug Products with Therapeutic Equivalence Evaluations* publication and its monthly Cumulative Supplements satisfy this requirement. The *Addendum* to this publication identifies drugs that qualify under the 1984 Amendments for periods of exclusivity (during which ANDAs or applications described in Section 505(b)(2) of the FD&C Act for those drugs may not be submitted for a specified period of time and, if allowed to be submitted, would be tentatively approved) and provides patent information concerning the listed drugs which also may delay the approval of ANDAs or Section 505(b)(2) applications. The *Addendum* also provides additional information that may be helpful to those submitting a new drug application to the Agency.

The Agency intends to use this publication to further its objective of obtaining input and comment on the publication itself and related Agency procedures. Therefore, if you have comments on how the publication can be improved, please send them to the Director, Division of Legal & Regulatory Support, Office of Generic Drugs, Center for Drug and Evaluation and Research, 7620 Standish Place, Rockville, MD 20855-2773. Comments received are publicly available to the extent allowable under the Freedom of Information regulations.

# Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

## Real-Time Litigation Alerts



Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

## Advanced Docket Research



With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

## Analytics At Your Fingertips



Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

## API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

## LAW FIRMS

Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

## FINANCIAL INSTITUTIONS

Litigation and bankruptcy checks for companies and debtors.

## E-DISCOVERY AND LEGAL VENDORS

Sync your system to PACER to automate legal marketing.