



# **APPROVED DRUG PRODUCTS**

**WITH**

**THERAPEUTIC  
EQUIVALENCE  
EVALUATIONS**

**34<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  
CENTER FOR DRUG EVALUATION AND RESEARCH  
OFFICE OF MEDICAL PRODUCTS AND TOBACCO  
OFFICE OF GENERIC DRUGS**

**2014**

**EXHIBIT 1024  
0001**

# **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, 2013.

## **34<sup>th</sup> EDITION**



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APPROVED DRUG PRODUCTS  
with  
Therapeutic Equivalence Evaluations**

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**FOOD AND DRUG ADMINISTRATION  
CENTER FOR DRUG EVALUATION AND RESEARCH  
APPROVED DRUG PRODUCTS**

**with  
Therapeutic Equivalence Evaluations**

**PREFACE TO THIRTY FOURTH 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 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of any product is that the product is the subject of an application with an effective approval that has not been withdrawn for safety or efficacy reasons.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 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 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 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 (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 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 Labeling and Program Support, HFD-610, Office of Generic Drugs, Center for Drug and Evaluation and Research, 7620 Standish Place, Rockville, MD 20855. Comments received are publicly available to the extent allowable under the Freedom of Information regulations.

# 1. INTRODUCTION

## 1.1 Content and Exclusion

The List is composed of four parts: (1) approved prescription drug products with therapeutic equivalence evaluations; (2) approved over-the-counter (OTC) drug products for those drugs that may not be marketed without NDAs or ANDAs because they are not covered under existing OTC monographs; (3) drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research; and (4) a cumulative list of approved products that have never been marketed, are for exportation, are for military use, have been discontinued from marketing, or have had their approvals withdrawn for other than safety or efficacy reasons subsequent to being discontinued from marketing.<sup>1</sup> This publication also includes indices of prescription and OTC drug products by trade or established name (if no trade name exists) and by applicant name (holder of the approved application). All established names for active ingredients generally conform to official compendial names or *United States Adopted Names* (USAN) as prescribed in (21 CFR 299.4(e)). The latter list includes applicants' names as abbreviated in this publication; in addition, a list of uniform terms is provided.

An *Addendum* contains drug patent and exclusivity information for the Prescription, OTC, Discontinued Drug Product Lists, and for the Drug Products with Approval under Section 505 of the Act Administered by the Center for Biologics Evaluation and Research. The publication may include additional information that the Agency deems appropriate to disseminate.

Prior to the 6th Edition, the publication had excluded OTC drug products and drug products with approval under Section 505 of the Act administered by the Center for Biologics Evaluation and Research because the main purpose of the publication was to provide information to states regarding FDA's recommendation as to which generic prescription drug products were acceptable candidates for drug product selection. The 1984 Amendments required the Agency to begin publishing an up-to-date list of all marketed drug products, OTC as well as prescription, that have been approved for safety and efficacy and for which new drug applications are required.

Under the 1984 Amendments, some drug products are given tentative approvals. The Agency will not include drug products with tentative approval in the List. Tentative approval lists are available at [ANDA \(Generic\) Drug Approvals](#). When the tentative approval becomes a full approval through a subsequent action letter to the application holder, the Agency will list the drug product and the final approval date in the appropriate approved drug product list.

Distributors or repackagers of products on the List are not identified. Because distributors or repackagers are not required to notify FDA when they shift their sources of supply from one approved manufacturer to another, it is not possible to maintain complete information linking product approval with the distributor or repackager handling the products.

## 1.2 Therapeutic Equivalence-Related Terms

**Pharmaceutical Equivalents.** Drug products are considered pharmaceutical equivalents if they contain the same active ingredient(s), are of the same

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<sup>1</sup> Newly approved products are added to parts 1, 2, or 3, of the List, depending on the dispensing requirements (prescription or OTC) or approval authority, unless the Orange Book staff is otherwise notified before publication.

**PRESCRIPTION AND OTC DRUG PRODUCT PATENT AND EXCLUSIVITY LIST**

See report footnote for information regarding report content

APPL/PROD NO	PATENT NO	PATENT EXPIRATION DATE	PATENT CODES	PATENT DELIST REQUESTED	EXCLUSIVITY CODE(S)	EXCLUSIVITY EXPIRATION DATE
<u>CYANOCOBALAMIN - NASCOBAL</u>						
N 021642 001	7229636	Jun 11, 2024	DP U-817			
	7404489	Mar 12, 2024	DP			
	7879349	Jun 01, 2024	DP U-1152			
<u>CYCLOBENZAPRINE HYDROCHLORIDE - AMRIX</u>						
N 021777 001	7387793	Feb 26, 2025	DP			
	7544372	Nov 14, 2023	U-979			
	7790199	Nov 14, 2023	DP			
	7820203	Nov 14, 2023	DP			
	7829121	Nov 14, 2023	U-1088			
<u>CYCLOBENZAPRINE HYDROCHLORIDE - AMRIX</u>						
N 021777 002	7387793	Feb 26, 2025	DP			
	7544372	Nov 14, 2023	U-979			
	7790199	Nov 14, 2023	DP			
	7820203	Nov 14, 2023	DP			
	7829121	Nov 14, 2023	U-1088			
<u>CYCLOSPORINE - NEORAL</u>						
N 050715 001	5985321	Sep 26, 2014	DP			
<u>CYCLOSPORINE - NEORAL</u>						
N 050715 002	5985321	Sep 26, 2014	DP			
<u>CYCLOSPORINE - NEORAL</u>						
N 050715 003	5985321	Sep 26, 2014	DP			
<u>CYCLOSPORINE - NEORAL</u>						
N 050716 001	5985321	Sep 26, 2014	DP			
<u>CYCLOSPORINE - RESTASIS</u>						
N 050790 001	5474979	May 17, 2014	DP			
	8629111	Aug 27, 2024	DP			
<u>CYSTEAMINE BITARTRATE - PROCYSBI</u>						
N 203389 001	8026284	Sep 22, 2027	U-1399		NDF	Apr 30, 2016
	8129433	Jan 26, 2027	DP			
<u>CYSTEAMINE BITARTRATE - PROCYSBI</u>						
N 203389 002	8026284	Sep 22, 2027	U-1399		NDF	Apr 30, 2016
	8129433	Jan 26, 2027	DP			
<u>CYSTEAMINE HYDROCHLORIDE - CYSTARAN</u>						
N 200740 001					NP ODE	Oct 02, 2015 Oct 02, 2019
<u>CYTARABINE - DEPOCYT</u>						
N 021041 001	5723147	Mar 03, 2015	DP U-806			
<u>DABIGATRAN ETEXILATE MESYLATE - PRADAXA</u>						
N 022512 001	6087380	Feb 18, 2018	DS DP U-1089		NCE	Oct 19, 2015
	7866474	Aug 31, 2027	DP			
	7932273	Sep 07, 2025	DS DP			
<u>DABIGATRAN ETEXILATE MESYLATE - PRADAXA</u>						
N 022512 002	6087380	Feb 18, 2018	DS DP U-1089		NCE	Oct 19, 2015
	7866474	Aug 31, 2027	DP			
	7932273	Sep 07, 2025	DS DP			
<u>DABRAFENIB MESYLATE - TAFINLAR</u>						
N 202806 001	7994185	Jan 20, 2030	DS DP U-1406		NCE	May 29, 2018
	8415345	Jan 20, 2030	DS DP U-1406		ODE	May 29, 2020
<u>DABRAFENIB MESYLATE - TAFINLAR</u>						
N 202806 002	7994185	Jan 20, 2030	DS DP U-1406		NCE	May 29, 2018
	8415345	Jan 20, 2030	DS DP U-1406		ODE	May 29, 2020
<u>DALEFAMPRIDINE - AMPYRA</u>						
N 022250 001	5540938	Jul 30, 2018	U-1030		NCE	Jan 22, 2015
	8007826	May 26, 2027	U-1030		ODE	Jan 22, 2017
	8354437	Dec 22, 2026	U-1030			
	8440703	Apr 08, 2025	U-1030			