



# APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC  
EQUIVALENCE  
EVALUATIONS

38<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

2018

# 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, 2017.

## 38<sup>th</sup> EDITION



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2018

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

**APPROVED DRUG PRODUCTS  
With  
Therapeutic Equivalence Evaluations**

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## DISCONTINUED DRUG PRODUCT LIST

6-277(of 375)

\*\* See List Footnote

OXTRIPHYLLINE

SYRUP; ORAL

CHOLEDYL

PARKE DAVIS 50MG/5ML

N009268 011

OXTRIPHYLLINE PEDIATRIC

MORTON GROVE 50MG/5ML

A088242 001 Dec 05, 1983

TABLET, DELAYED RELEASE; ORAL

CHOLEDYL

PARKE DAVIS 100MG

N009268 003

200MG

N009268 007

OXTRIPHYLLINE

WATSON LABS 100MG

A087866 001 Aug 25, 1983

200MG

A087835 001 Aug 25, 1983

TABLET, EXTENDED RELEASE; ORAL

CHOLEDYL SA

WARNER CHILCOTT LLC 600MG

A086742 001

OXYBUTYNIN

GEL, METERED; TRANSDERMAL

GELNIQUE 3%

+ ALLERGAN SALES LLC 3%

N202513 001 Dec 07, 2011

OXYBUTYNIN CHLORIDE

SYRUP; ORAL

DITROPAN

+ ORTHO MCNEIL JANSSEN 5MG/5ML \*\*

N018211 001

OXYBUTYNIN CHLORIDE

APOTEX INC 5MG/5ML

A074997 001 Oct 15, 1997

MIKART 5MG/5ML

A075039 001 Jan 29, 1999

TABLET; ORAL

DITROPAN

+ JANSSEN PHARMS 5MG \*\*

N017577 001

OXYBUTYNIN CHLORIDE

QUANTUM PHARMICS 5MG

A072296 001 Dec 08, 1988

USL PHARMA 5MG

A070746 001 Mar 10, 1988

WATSON LABS 5MG

A072485 001 Apr 19, 1989

OXYCODONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL

ROXICODONE

ROXANE 10MG

N020932 001 Oct 26, 1998

30MG

N020932 002 Oct 26, 1998

OXYMETAZOLINE HYDROCHLORIDE

SOLUTION/DROPS; OPHTHALMIC

OCUCLEAR

BAYER HEALTHCARE LLC 0.025%

N018471 001 May 30, 1986

OXYMORPHONE HYDROCHLORIDE

INJECTABLE; INJECTION

OPANA

+ ENDO PHARMS 1MG/ML

N011707 002

1.5MG/ML

N011707 001

SUPPOSITORY; RECTAL

NUMORPHAN

ENDO PHARMS 5MG

N011738 004

TABLET, EXTENDED RELEASE; ORAL

OPANA ER

ENDO PHARMS 5MG \*\*

N021610 001 Jun 22, 2006

+ 5MG

N201655 001 Dec 09, 2011

7.5MG \*\*

N021610 005 Feb 29, 2008

+ 7.5MG

N201655 002 Dec 09, 2011

10MG \*\*

N021610 002 Jun 22, 2006

+ 10MG

N201655 003 Dec 09, 2011

15MG \*\*

N021610 006 Feb 29, 2008

+ 15MG

N201655 004 Dec 09, 2011

20MG \*\*

N021610 003 Jun 22, 2006

+ 20MG

N201655 005 Dec 09, 2011

30MG \*\*

N021610 007 Feb 29, 2008

+ 30MG

N201655 006 Dec 09, 2011

40MG \*\*

N021610 004 Jun 22, 2006

+ 40MG

N201655 007 Dec 09, 2011