



APPROVED DRUG PRODUCTS

WITH

THERAPEUTIC
EQUIVALENCE
EVALUATIONS

38th 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.

38th EDITION



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**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

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** See List Footnote

MOMETASONE FUROATE

CREAM; TOPICAL

ELOCON

MERCCK SHARP DOHME 0.1% N019625 001 May 06, 1987

OINTMENT; TOPICAL

MOMETASONE FUROATE

TARO 0.1% A076624 001 Dec 03, 2004

MONOBENZONE

CREAM; TOPICAL

BENOQUIN

VALEANT PHARM INTL 20% N008173 003

MONOCTANOIN

LIQUID; PERFUSION, BILIARY

MOCTANIN

ETHITEK 100% N019368 001 Oct 29, 1985

MORICIZINE HYDROCHLORIDE

TABLET; ORAL

ETHMOZINE

SHIRE 200MG N019753 001 Jun 19, 1990

250MG N019753 002 Jun 19, 1990

300MG N019753 003 Jun 19, 1990

MORPHINE SULFATE

CAPSULE, EXTENDED RELEASE; ORAL

AVINZA

KING PHARMS LLC 30MG N021260 001 Mar 20, 2002

45MG N021260 005 Dec 18, 2008

60MG N021260 002 Mar 20, 2002

75MG N021260 006 Dec 18, 2008

90MG N021260 003 Mar 20, 2002

120MG N021260 004 Mar 20, 2002

INJECTABLE; INJECTION

MORPHINE SULFATE

+ HOSPIRA INC 15MG/ML N202515 005 Nov 14, 2011

ICU MEDICAL INC 0.5MG/ML N019917 001 Oct 30, 1992

SPECGX LLC 1MG/ML N020631 001 Jul 03, 1996

2MG/ML N020631 002 Jul 03, 1996

WATSON LABS 0.5MG/ML A073373 001 Sep 30, 1991

0.5MG/ML A073375 001 Sep 30, 1991

1MG/ML A073374 001 Sep 30, 1991

1MG/ML A073376 001 Sep 30, 1991

INJECTABLE, LIPOSOMAL; EPIDURAL

DEPODUR

PACIRA PHARMS INC 10MG/ML (10MG/ML) N021671 001 May 18, 2004

15MG/1.5ML (10MG/ML) N021671 002 May 18, 2004

20MG/2ML (10MG/ML) N021671 003 May 18, 2004

TABLET, EXTENDED RELEASE; ORAL

MORPHINE SULFATE

WATSON LABS 100MG A075656 001 Jan 30, 2001

ORAMORPH SR

XANODYNE PHARMS INC 15MG N019977 004 Nov 23, 1994

30MG N019977 001 Aug 15, 1991

60MG N019977 002 Aug 15, 1991

100MG N019977 003 Aug 15, 1991

MOXALACTAM DISODIUM

INJECTABLE; INJECTION

MOXAM

LILLY EQ 250MG BASE/VIAL N050550 001

EQ 500MG BASE/VIAL N050550 002

EQ 1GM BASE/VIAL N050550 003

EQ 2GM BASE/VIAL N050550 004

EQ 10GM BASE/VIAL N050550 008