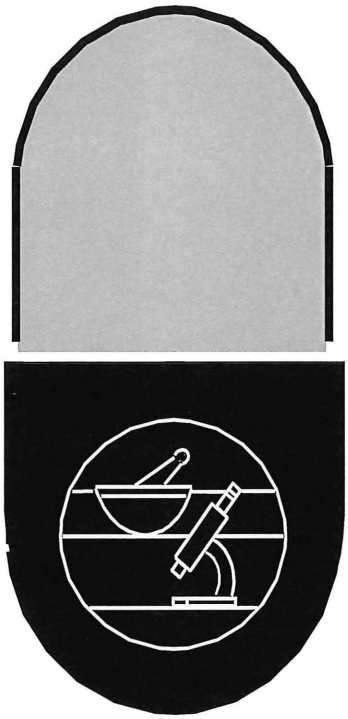

APPROVED DRUG PRODUCTS

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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APPROVED DRUG PRODUCTS
With
Therapeutic Equivalence Evaluations

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MORPHINE SULFATE
TABLET, EXTENDED RELEASE;ORAL

MORPHINE SULFATE						
AB			100MG	A077855	001	Sep 27, 2007
AB			200MG	A077855	002	Sep 27, 2007
AB		NOVEL LABS INC	15MG	A203602	001	Dec 16, 2015
AB			30MG	A203602	002	Dec 16, 2015
AB			60MG	A203602	003	Dec 16, 2015
AB			100MG	A203602	004	Dec 16, 2015
AB			200MG	A203602	005	Dec 16, 2015
AB		RHODES PHARMS	15MG	A074862	001	Jul 07, 1998
AB			30MG	A074862	002	Jul 07, 1998
AB			60MG	A074862	003	Jul 07, 1998
AB			100MG	A074769	001	Jul 02, 1998
AB			200MG	A074769	002	Jul 02, 1998
AB		SPECGX LLC	15MG	A076412	001	Jul 31, 2003
AB			30MG	A076412	002	Jul 31, 2003
AB			60MG	A076412	003	Jul 31, 2003
AB			100MG	A076438	001	Jul 03, 2003
AB			200MG	A076438	002	Jul 03, 2003
AB		SUN PHARM INDS LTD	15MG	A078761	001	May 11, 2012
AB			30MG	A078761	002	May 11, 2012
AB			60MG	A078761	003	May 11, 2012
AB			100MG	A078761	004	May 11, 2012
AB			200MG	A078761	005	May 11, 2012
AB		SUN PHARM INDUSTRIES	15MG	A205634	001	Aug 25, 2016
AB			30MG	A205634	002	Aug 25, 2016
AB			60MG	A205634	003	Aug 25, 2016
AB			100MG	A205634	004	Aug 25, 2016
AB			200MG	A205634	005	Aug 25, 2016
AB		VINTAGE PHARMS LLC	15MG	A075295	001	Oct 28, 1998
AB			30MG	A075295	002	Oct 28, 1998
AB			60MG	A075295	003	Oct 28, 1998
AB			100MG	A075295	004	Sep 15, 2000
AB			200MG	A075295	005	Sep 15, 2000
MS CONTIN						
AB	+	PURDUE PHARMA LP	15MG	N019516	003	Sep 12, 1989
AB	+		30MG	N019516	001	May 29, 1987
AB	+		60MG	N019516	002	Apr 08, 1988
AB	+!		100MG	N019516	004	Jan 16, 1990
AB	+		200MG	N019516	005	Nov 08, 1993
ARYMO ER						
	+	EGALET	15MG	N208603	001	Jan 09, 2017
	+		30MG	N208603	002	Jan 09, 2017
	+		60MG	N208603	003	Jan 09, 2017
MORPHABOND ER						
	+	DAIICHI SANKYO INC	15MG	N206544	001	Oct 02, 2015
	+		30MG	N206544	002	Oct 02, 2015
	+		60MG	N206544	003	Oct 02, 2015
	+!		100MG	N206544	004	Oct 02, 2015

MORPHINE SULFATE; NALTREXONE HYDROCHLORIDE
CAPSULE, EXTENDED RELEASE;ORAL

EMBEDA						
	+	ALPHARMA PHARMS	20MG;0.8MG	N022321	001	Aug 13, 2009
	+		30MG;1.2MG	N022321	002	Aug 13, 2009
	+		50MG;2MG	N022321	003	Aug 13, 2009
	+!		60MG;2.4MG	N022321	004	Aug 13, 2009
	+		80MG;3.2MG	N022321	005	Aug 13, 2009
	+		100MG;4MG	N022321	006	Aug 13, 2009

MOXIFLOXACIN HYDROCHLORIDE
SOLUTION;IV (INFUSION)

MOXIFLOXACIN HYDROCHLORIDE						
	+!	FRESENIUS KABI USA	EQ 400MG BASE/250ML (EQ 1.6MG BASE/ML)	N205572	001	Apr 03, 2015
MOXIFLOXACIN HYDROCHLORIDE IN SODIUM CHLORIDE 0.8% IN PLASTIC CONTAINER						
	!	MYLAN LABS LTD	400MG/250ML (1.6MG/ML)	A205833	001	May 05, 2017

SOLUTION/DROPS;OPHTHALMIC

MOXIFLOXACIN HYDROCHLORIDE						
AT1		AKORN	EQ 0.5% BASE	A202916	001	Nov 09, 2017
AT1		APOTEX INC	EQ 0.5% BASE	A090080	001	Jun 30, 2017