

Approved Drug Product List - Orange Book
Reference Listed Drugs by ANDA Reference Standard List

April 2017

Page 1 of 6

DESCRIPTION

This list refers to drug products approved under an Abbreviated New Drug Application (ANDA) that FDA has selected as reference standards and the associated reference listed drugs (RLDs). The purpose of this list is to assist applicants submitting an ANDA to seek approval of a generic drug in identifying an RLD when an ANDA RS has been selected. If the applicant has a question about which listed drug it should refer to as the RLD, the applicant may consult with FDA (refer to section 1.4 Reference Listed Drug and Reference Standard of the Orange Book Preface for more information).

This list is updated monthly. Information in this list is sorted by Active Ingredient(s), Dosage Form, Route, Trade Name, Applicant Name and Strength. Additional information included are marketing status (RX, OTC, DISCN), Application Number, Product Number, and approval date of the Reference Standard.

Approved Drug Product List - Orange Book
Reference Listed Drugs by ANDA Reference Standard List

April 2017

Page 2 of 6

ADAPALENE

SOLUTION; TOPICAL
 ADAPALENE
 RX CALL INC 0.1% A204593 001 Jan 05, 2016 RLD: N020338

AMIODARONE HYDROCHLORIDE

TABLET; ORAL
 AMIODARONE HYDROCHLORIDE
 RX SANDOZ 200MG A075315 001 Dec 23, 1998 RLD: N018972

AMOXICILLIN

TABLET, CHEWABLE; ORAL
 AMOXICILLIN
 RX TEVA 250MG A064013 001 Dec 22, 1992 RLD: N050542

AMOXICILLIN; CLAVULANATE POTASSIUM

TABLET; ORAL
 AMOXICILLIN AND CLAVULANATE POTASSIUM
 RX SANDOZ 250MG; EQ 125MG BASE A065189 001 Aug 23, 2005 RLD: N050564
 RX SANDOZ INC 500MG; EQ 125MG BASE A065117 001 Nov 27, 2002 RLD: N050564

ARIPIPIRAZOLE

SOLUTION; ORAL
 ARIPIPIRAZOLE
 RX AMNEAL PHARMS 1MG/ML A203906 001 Aug 14, 2015 RLD: N021713

ATORVASTATIN CALCIUM; EZETIMIBE

TABLET; ORAL
 EZETIMIBE AND ATORVASTATIN CALCIUM
 RX WATSON LABS TEVA EQ 80MG BASE; 10MG A206084 004 Apr 26, 2017 RLD: N200153

BISOPROLOL FUMARATE

TABLET; ORAL
 BISOPROLOL FUMARATE
 RX MYLAN 10MG A075831 002 Dec 14, 2005 RLD: N019982

BROMFENAC SODIUM

SOLUTION/DROPS; OPHTHALMIC
 BROMFENAC SODIUM
 RX APOTEX INC EQ 0.09% ACID A202435 001 Jun 19, 2014 RLD: N021664

BROMOCRIPTINE MESYLATE

CAPSULE; ORAL
 BROMOCRIPTINE MESYLATE
 RX MYLAN EQ 5MG BASE A077226 001 Apr 04, 2005 RLD: N017962
 TABLET; ORAL
 BROMOCRIPTINE MESYLATE
 RX PADDOCK LLC EQ 2.5MG BASE A077646 001 Oct 01, 2008 RLD: N017962

BUPROPION HYDROCHLORIDE

TABLET; ORAL
 BUPROPION HYDROCHLORIDE
 RX APOTEX INC 100MG A076143 002 Jan 17, 2006 RLD: N018644

CALCITONIN SALMON

SPRAY, METERED; NASAL
 CALCITONIN-SALMON
 RX APOTEX INC 200 IU/SPRAY A076396 001 Nov 17, 2008 RLD: N020313

CETIRIZINE HYDROCHLORIDE

SYRUP; ORAL
 CETIRIZINE HYDROCHLORIDE
 RX PERRIGO R AND D 5MG/5ML A078398 001 Jun 17, 2008 RLD: N020346

Approved Drug Product List - Orange Book
Reference Listed Drugs by ANDA Reference Standard List

April 2017

Page 3 of 6

CHLORZOXAZONE

TABLET; ORAL
 CHLORZOXAZONE
 RX MIKART INC 250MG A207483 001 Jun 24, 2016 RLD: N011300

CIPROFLOXACIN

INJECTABLE; INJECTION
 CIPROFLOXACIN
 RX CLARIS 200MG/20ML (10MG/ML) A078062 001 Apr 29, 2008 RLD: N019847
 RX 400MG/40ML (10MG/ML) A078062 002 Apr 29, 2008 RLD: N019847
 CIPROFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER
 RX HOSPIRA 200MG/100ML A077753 001 Mar 18, 2008 RLD: N019857
 RX 400MG/200ML A077753 002 Mar 18, 2008 RLD: N019857

CLOBETASOL PROPIONATE

OINTMENT; TOPICAL
 CLOBETASOL PROPIONATE
 RX FOUGERA PHARMS 0.05% A074407 001 Feb 23, 1996 RLD: N019323

DACARBAZINE

INJECTABLE; INJECTION
 DACARBAZINE
 RX FRESENIUS KABI USA 100MG/VIAL A075371 001 Aug 27, 1999 RLD: N017575
 RX 200MG/VIAL A075371 002 Aug 27, 1999 RLD: N017575

DESOGESTREL; ETHINYL ESTRADIOL

TABLET; ORAL-28
 DESOGESTREL AND ETHINYL ESTRADIOL
 RX DURAMED PHARMS 0.15MG;0.03MG A075256 002 Aug 12, 1999 RLD: N020301
 BARR

DICLOFENAC SODIUM

TABLET, EXTENDED RELEASE; ORAL
 DICLOFENAC SODIUM
 RX DEXCEL LTD 100MG A076201 001 Nov 06, 2002 RLD: N020254

DICYCLOMINE HYDROCHLORIDE

SYRUP; ORAL
 DICYCLOMINE HYDROCHLORIDE
 RX MIKART 10MG/5ML A040169 001 Mar 24, 2005 RLD: N007961

DOCETAXEL

INJECTABLE; INJECTION
 DOCETAXEL
 RX JIANGSU HENGRUI 40MG/ML A203170 001 Feb 15, 2017 RLD: N020449
 MED

FAMCICLOVIR

TABLET; ORAL
 FAMCICLOVIR
 RX TEVA PHARMS 500MG A077487 003 Aug 24, 2007 RLD: N020363

FLUCONAZOLE

INJECTABLE; INJECTION
 FLUCONAZOLE IN DEXTROSE 5% IN PLASTIC CONTAINER
 RX HOSPIRA 200MG/100ML (2MG/ML) A076304 001 Jul 29, 2004 RLD: N019950
 RX 400MG/200ML (2MG/ML) A076304 002 Jul 29, 2004 RLD: N019950
 FLUCONAZOLE IN SODIUM CHLORIDE 0.9% IN PLASTIC CONTAINER
 RX ACS DOBFAR INFO SA 200MG/100ML (2MG/ML) A079104 001 Jul 30, 2009 RLD: N019950
 RX 400MG/200ML (2MG/ML) A079104 002 Jul 30, 2009 RLD: N019950

FLUDEOXYGLUCOSE F-18

INJECTABLE; INTRAVENOUS
 FLUDEOXYGLUCOSE F18
 RX QUEEN HAMAMATSU 10-100mCi/ML A203771 001 Aug 31, 2015 RLD: N021768
 PET

Approved Drug Product List - Orange Book
Reference Listed Drugs by ANDA Reference Standard List

April 2017

Page 4 of 6

FLUOXETINE HYDROCHLORIDE

TABLET;ORAL
 FLUOXETINE HYDROCHLORIDE
 RX MYLAN EQ 20MG BASE A075755 002 Aug 02, 2001 RLD: N020974

GALANTAMINE HYDROBROMIDE

SOLUTION;ORAL
 GALANTAMINE HYDROBROMIDE
 RX WEST-WARD PHARMS 4MG/ML A078185 001 Jan 30, 2009 RLD: N021224
 INT

GLIMEPIRIDE; ROSIGLITAZONE MALEATE

TABLET;ORAL
 ROSIGLITAZONE MALEATE AND GLIMEPIRIDE
 RX TEVA PHARMS USA 1MG;4MG A078709 001 Apr 01, 2016 RLD: N021700

GLYCOPYRROLATE

INJECTABLE;INJECTION
 GLYCOPYRROLATE
 RX HIKMA FARMACEUTICA 0.2MG/ML A090963 001 Sep 21, 2011 RLD: N017558

HYDROCHLOROTHIAZIDE; MOEXIPRIL HYDROCHLORIDE

TABLET;ORAL
 MOEXIPRIL HYDROCHLORIDE AND HYDROCHLOROTHIAZIDE
 RX TEVA 25MG;15MG A076980 002 Mar 07, 2007 RLD: N020729

IMIPRAMINE PAMOATE

CAPSULE;ORAL
 IMIPRAMINE PAMOATE
 RX WEST-WARD PHARMS EQ 75MG HCL A091099 001 Apr 16, 2010 RLD: N017090
 INT

ISOSULFAN BLUE

INJECTABLE;INJECTION
 ISOSULFAN BLUE
 RX MYLAN 1% A090874 001 Jul 20, 2010 RLD: N018310
 INSTITUTIONAL

KETOTIFEN FUMARATE

SOLUTION/DROPS;OPHTHALMIC
 KETOTIFEN FUMARATE
 OTC ALCON PHARMS LTD EQ 0.025% BASE A077200 001 Sep 02, 2008 RLD: N021066

LACTULOSE

SOLUTION;ORAL
 LACTULOSE
 RX HI TECH PHARMA 10GM/15ML A074076 001 Jul 03, 1995 RLD: N017884

LEVOFLOXACIN

INJECTABLE;INJECTION
 LEVOFLOXACIN IN DEXTROSE 5% IN PLASTIC CONTAINER
 RX ACS DOBFAR INFO SA EQ 250MG/50ML (EQ 5MG/ML) A090343 001 Jul 07, 2011 RLD: N020635
 RX EQ 500MG/100ML (EQ 5MG/ML) A090343 002 Jul 07, 2011 RLD: N020635
 RX EQ 750MG/150ML (EQ 5MG/ML) A090343 003 Jul 07, 2011 RLD: N020635

LEVONORGESTREL

TABLET;ORAL
 LEVONORGESTREL
 RX PERRIGO R AND D 0.75MG A090740 001 Dec 30, 2010 RLD: N021045
 OTC 0.75MG A090740 001 Dec 30, 2010 RLD: N021045

LIDOCAINE HYDROCHLORIDE

SOLUTION;ORAL
 LIDOCAINE HYDROCHLORIDE VISCOUS
 RX VINTAGE 2% A040708 001 Feb 27, 2007 RLD: N009470

Approved Drug Product List - Orange Book
Reference Listed Drugs by ANDA Reference Standard List

April 2017

Page 5 of 6

LOPERAMIDE HYDROCHLORIDE

CAPSULE;ORAL
 LOPERAMIDE HYDROCHLORIDE
 RX MYLAN 2MG A072741 001 Sep 18, 1991 RLD: N017694

LOPERAMIDE HYDROCHLORIDE; SIMETHICONE

TABLET, CHEWABLE;ORAL
 LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE
 OTC FERRIGO 2MG;125MG A076029 001 Aug 30, 2002 RLD: N020606

MEFLOQUINE HYDROCHLORIDE

TABLET;ORAL
 MEFLOQUINE HYDROCHLORIDE
 RX BARR 250MG A076392 001 Dec 29, 2003 RLD: N019591

METHSCOPOLAMINE BROMIDE

TABLET;ORAL
 METHSCOPOLAMINE BROMIDE
 RX VINTAGE PHARMS 2.5MG A040624 001 Dec 28, 2006 RLD: N008848
 RX 5MG A040624 002 Dec 28, 2006 RLD: N008848

METHYLERGONOVINE MALEATE

TABLET;ORAL
 METHYLERGONOVINE MALEATE
 RX NOVEL LABS INC 0.2MG A091577 001 May 02, 2011 RLD: N006035

METHYLPHENIDATE HYDROCHLORIDE

CAPSULE, EXTENDED RELEASE;ORAL
 METHYLPHENIDATE HYDROCHLORIDE
 RX MAYNE PHARMA 60MG A078458 004 Jun 23, 2016 RLD: N021284
 TABLET, CHEWABLE;ORAL
 METHYLPHENIDATE HYDROCHLORIDE
 RX NOVEL LABS INC 10MG A204115 003 Feb 25, 2015 RLD: N021475

MOEXIPRIL HYDROCHLORIDE

TABLET;ORAL
 MOEXIPRIL HYDROCHLORIDE
 RX TEVA 15MG A076204 002 May 08, 2003 RLD: N020312

NALTREXONE HYDROCHLORIDE

TABLET;ORAL
 NALTREXONE HYDROCHLORIDE
 RX MALLINCKRODT 50MG A076264 002 Mar 22, 2002 RLD: N018932

NIZATIDINE

SOLUTION;ORAL
 NIZATIDINE
 RX AMNEAL PHARMS 15MG/ML A090576 001 Nov 18, 2009 RLD: N021494

OFLOXACIN

SOLUTION/DROPS;OTIC
 OFLOXACIN
 RX BAUSCH AND LOMB 0.3% A076128 001 Mar 17, 2008 RLD: N020799

OMEPRAZOLE

CAPSULE, DELAYED REL PELLETS;ORAL
 OMEPRAZOLE
 RX SANDOZ 20MG A075757 002 Jan 28, 2003 RLD: N019810
 RX 40MG A076515 001 Jan 21, 2009 RLD: N019810

OXALIPLATIN

INJECTABLE;IV (INFUSION)
 OXALIPLATIN
 RX QILU PHARM CO LTD 200MG/40ML (5MG/ML) A204368 003 Jun 07, 2016 RLD: N021759

Approved Drug Product List - Orange Book
Reference Listed Drugs by ANDA Reference Standard List

April 2017

Page 6 of 6

PARICALCITOL

CAPSULE;ORAL
PARICALCITOL
RX TEVA PHARMS USA 4MCG A090829 003 Sep 27, 2013 RLD: N021606

PENTOXIFYLLINE

TABLET, EXTENDED RELEASE;ORAL
PENTOXIFYLLINE
RX APOTEX 400MG A075191 001 Jun 09, 1999 RLD: N018631

PHENTERMINE HYDROCHLORIDE

TABLET;ORAL
LOMAIRA
RX AVANTHI INC 8MG A203495 001 Sep 12, 2016 RLD: N012737

TERBUTALINE SULFATE

TABLET;ORAL
TERBUTALINE SULFATE
RX LANNETT 5MG A077152 002 Mar 25, 2005 RLD: N017849

THIOTHIXENE

CAPSULE;ORAL
THIOTHIXENE
RX MYLAN 5MG A071093 004 Jun 23, 1987 RLD: N016584

TIMOLOL MALEATE

SOLUTION/DROPS;OPHTHALMIC
TIMOLOL MALEATE
RX SANDOZ INC EQ 0.25% BASE A074261 001 Apr 28, 1995 RLD: N018086
RX EQ 0.5% BASE A074262 001 Apr 28, 1995 RLD: N018086

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE;ORAL
VERAPAMIL HYDROCHLORIDE
RX GLENMARK GENERICS 180MG A090700 002 Aug 03, 2011 RLD: N019152