

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

June 2018

Page 1 of 8

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

June 2018

Page 2 of 8

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; CLARITHROMYCIN; LANSOPRAZOLE

CAPSULE, CAPSULE, DELAYED REL PELLETS, TABLET;ORAL
 LANSOPRAZOLE, AMOXICILLIN AND CLARITHROMYCIN
 RX RISING PHARMS INC 500MG,N/A,N/A;N/A,500MG,N/A;N/A A206006 001 Oct 07, 2016 RLD: N050757
 ,N/A,30MG

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

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

CEFOTAXIME SODIUM

INJECTABLE;INJECTION
 CEFOTAXIME
 RX HIKMA EQ 500MG BASE/VIAL A065072 001 Nov 20, 2002 RLD: N050547
 RX EQ 1GM BASE/VIAL A065072 002 Nov 20, 2002 RLD: N050547
 RX EQ 2GM BASE/VIAL A065072 003 Nov 20, 2002 RLD: N050547
 RX EQ 10GM BASE/VIAL A065071 001 Nov 20, 2002 RLD: N050547

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

June 2018

Page 3 of 8

CETIRIZINE HYDROCHLORIDE

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

CHLOROQUINE PHOSPHATE

TABLET; ORAL
 CHLOROQUINE PHOSPHATE
 RX NATCO PHARMA LTD EQ 300MG BASE A090612 001 Jan 21, 2011 RLD: N006002

CHLORZOXAZONE

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

CIPROFLOXACIN

INJECTABLE; INJECTION
 CIPROFLOXACIN
 RX BAXTER HLTHCARE 200MG/20ML (10MG/ML) A078062 001 Apr 29, 2008 RLD: N019847
 CORP
 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

CYTARABINE

INJECTABLE; INJECTION
 CYTARABINE
 RX FRESENIUS KABI USA 100MG/ML A076512 001 Jan 15, 2004 RLD: N016793
 RX HOSPIRA 20MG/ML A071868 001 Jun 04, 1990 RLD: N016793

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

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

June 2018

Page 4 of 8

DOXORUBICIN HYDROCHLORIDE

INJECTABLE, LIPOSOMAL; INJECTION
 DOXORUBICIN HYDROCHLORIDE (LIPOSOMAL)
 RX SUN PHARMA GLOBAL 20MG/10ML (2MG/ML) A203263 001 Feb 04, 2013 RLD: N050718
 RX 50MG/25ML (2MG/ML) A203263 002 Feb 04, 2013 RLD: N050718

ERYTHROMYCIN

SOLUTION; TOPICAL
 ERYTHROMYCIN
 RX PERRIGO NEW YORK 2% A063038 001 Jan 11, 1991 RLD: A062405

ESOMEPRAZOLE SODIUM

INJECTABLE; INTRAVENOUS
 ESOMEPRAZOLE SODIUM
 RX AUROBINDO PHARMA EQ 40MG BASE/VIAL A204657 002 Aug 10, 2016 RLD: N021689
 LTD

FAMCICLOVIR

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

FEXOFENADINE HYDROCHLORIDE

SUSPENSION; ORAL
 FEXOFENADINE HYDROCHLORIDE
 RX ACTAVIS MID 30MG/5ML A201311 001 Jul 25, 2012 RLD: N021963
 ATLANTIC

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 INFORLIFE 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

FLUOXETINE HYDROCHLORIDE

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

FLUPHENAZINE HYDROCHLORIDE

TABLET; ORAL
 FLUPHENAZINE HYDROCHLORIDE
 RX MYLAN 10MG A089804 001 Aug 12, 1988 RLD: N011751

FLUTAMIDE

CAPSULE; ORAL
 FLUTAMIDE
 RX CIPLA LTD 125MG A075780 001 Sep 19, 2001 RLD: N018554

FLUTICASONE PROPIONATE

SPRAY, METERED; NASAL
 FLUTICASONE PROPIONATE
 RX WEST-WARD PHARMS 0.05MG/SPRAY A076504 001 Feb 22, 2006 RLD: N020121
 INT

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

June 2018

Page 5 of 8

GALANTAMINE HYDROBROMIDE

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

GLYBURIDE; METFORMIN HYDROCHLORIDE

TABLET; ORAL
 GLYBURIDE AND METFORMIN HYDROCHLORIDE
 RX AUROBINDO PHARMA 2.5MG;500MG A077870 002 Nov 14, 2007 RLD: N021178

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

HYDROCODONE BITARTRATE; IBUPROFEN

TABLET; ORAL
 HYDROCODONE BITARTRATE AND IBUPROFEN
 RX AMNEAL PHARMS NY 7.5MG;200MG A076642 001 Oct 12, 2004 RLD: N020716

IMIPRAMINE PAMOATE

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

IPRATROPIUM BROMIDE

SPRAY, METERED; NASAL
 IPRATROPIUM BROMIDE
 RX WEST-WARD PHARMS 0.021MG/SPRAY A076664 001 Nov 05, 2003 RLD: N020393
 INT
 RX 0.042MG/SPRAY A076598 001 Nov 05, 2003 RLD: N020394

ISOSULFAN BLUE

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

ISRADIPINE

CAPSULE; ORAL
 ISRADIPINE
 RX WATSON LABS TEVA 5MG A077317 002 Jan 05, 2006 RLD: N019546

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 INFORLIFE 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

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

June 2018

Page 6 of 8

SOLUTION; ORAL					
LEVOFLOXACIN					
RX	HI TECH PHARMA	250MG/10ML	A091678	001	Jun 20, 2011 RLD: N021721
<u>LEVONORGESTREL</u>					
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
<u>LIDOCAINE HYDROCHLORIDE</u>					
SOLUTION; ORAL					
LIDOCAINE HYDROCHLORIDE VISCOUS					
RX	LANNETT CO INC	2%	A040708	001	Feb 27, 2007 RLD: N009470
<u>LOPERAMIDE HYDROCHLORIDE</u>					
CAPSULE; ORAL					
LOPERAMIDE HYDROCHLORIDE					
RX	MYLAN	2MG	A072741	001	Sep 18, 1991 RLD: N017694
<u>LOPERAMIDE HYDROCHLORIDE; SIMETHICONE</u>					
TABLET, CHEWABLE; ORAL					
LOPERAMIDE HYDROCHLORIDE AND SIMETHICONE					
OTC	PERRIGO	2MG;125MG	A076029	001	Aug 30, 2002 RLD: N020606
<u>MEFLOQUINE HYDROCHLORIDE</u>					
TABLET; ORAL					
MEFLOQUINE HYDROCHLORIDE					
RX	BARR	250MG	A076392	001	Dec 29, 2003 RLD: N019591
<u>METHSCOPOLAMINE BROMIDE</u>					
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
<u>METHYLERGONOVINE MALEATE</u>					
TABLET; ORAL					
METHYLERGONOVINE MALEATE					
RX	NOVEL LABS INC	0.2MG	A091577	001	May 02, 2011 RLD: N006035
<u>METHYLPHENIDATE HYDROCHLORIDE</u>					
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
TABLET, EXTENDED RELEASE; ORAL					
METHYLPHENIDATE HYDROCHLORIDE					
RX	OSMOTICA	72MG	A205327	005	Jul 28, 2017 RLD: N021121
<u>METOPROLOL TARTRATE</u>					
TABLET; ORAL					
METOPROLOL TARTRATE					
RX	MYLAN	100MG	A076704	003	Jan 16, 2004 RLD: N017963
<u>MOEXIPRIL HYDROCHLORIDE</u>					
TABLET; ORAL					
MOEXIPRIL HYDROCHLORIDE					
RX	TEVA	15MG	A076204	002	May 08, 2003 RLD: N020312
<u>MOXIFLOXACIN HYDROCHLORIDE</u>					
SOLUTION; IV (INFUSION)					
MOXIFLOXACIN HYDROCHLORIDE IN SODIUM CHLORIDE 0.8% IN PLASTIC CONTAINER					
RX	MYLAN LABS LTD	400MG/250ML (1.6MG/ML)	A205833	001	May 05, 2017 RLD: N021277

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

June 2018

Page 7 of 8

NAFTIFINE HYDROCHLORIDE

CREAM; TOPICAL
 NAFTIFINE HYDROCHLORIDE
 RX TARO PHARMS 1% A205975 001 Sep 08, 2016 RLD: N019599

NALTREXONE HYDROCHLORIDE

TABLET; ORAL
 NALTREXONE HYDROCHLORIDE
 RX SPECGX LLC 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

PANCURONIUM BROMIDE

INJECTABLE; INJECTION
 PANCURONIUM BROMIDE
 RX TEVA PHARMS USA 1MG/ML A072759 001 Jul 31, 1990 RLD: N017015
 RX 2MG/ML A072760 001 Jul 31, 1990 RLD: N017015

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

PRILOCAINE HYDROCHLORIDE

INJECTABLE; INJECTION
 PRILOCAINE HYDROCHLORIDE
 RX SEPTODONT INC 4% A079235 001 Sep 29, 2010 RLD: N021382

SODIUM POLYSTYRENE SULFONATE

POWDER; ORAL, RECTAL
 KALEXATE
 RX KVK TECH 454GM/BOT A040905 001 Mar 30, 2009 RLD: N011287

TERBUTALINE SULFATE

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

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

June 2018

Page 8 of 8

TERCONAZOLE

CREAM; VAGINAL
TERCONAZOLE
RX TARO 0.8% A075953 001 Apr 06, 2004 RLD: N019964

TESTOSTERONE

SOLUTION, METERED; TRANSDERMAL
TESTOSTERONE
RX FERRIGO ISRAEL 30MG/1.5ML ACTUATION A204255 001 Feb 28, 2017 RLD: N022504

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

VINBLASTINE SULFATE

INJECTABLE; INJECTION
VINBLASTINE SULFATE
RX WEST-WARD PHARMS 10MG/VIAL A089395 001 Apr 09, 1987 RLD: N012665
INT