

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

June 2019

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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.

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ACYCLOVIR SODIUM

INJECTABLE; INJECTION
 ACYCLOVIR SODIUM
 RX ZYDUS PHARMS EQ 500MG BASE/VIAL A206535 001 Aug 31, 2018 RLD: N018603
 RX EQ 1GM BASE/VIAL A206535 002 Aug 31, 2018 RLD: N018603

AMINOCAPROIC ACID

TABLET; ORAL
 AMINOCAPROIC ACID
 RX SUNNY PHARMTECH 1GM A209060 002 Nov 27, 2018 RLD: N015197
 INC

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 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

BISMUTH SUBSALICYLATE; METRONIDAZOLE; TETRACYCLINE HYDROCHLORIDE

TABLET, CHEWABLE, TABLET, CAPSULE; ORAL
 BISMUTH SUBSALICYLATE, METRONIDAZOLE AND TETRACYCLINE HYDROCHLORIDE
 RX AILEX PHARMS LLC 262.4MG, N/A, N/A; N/A, 250MG, A202584 001 Nov 30, 2018 RLD: N050719
 N/A; N/A, N/A, 500MG

BISOPROLOL FUMARATE

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

BRETYLIUM TOSYLATE

INJECTABLE; INJECTION
 BRETYLIUM TOSYLATE
 RX BAS ANDA 50MG/ML A204386 001 Dec 21, 2018 RLD: N019030

BROMOCRIPTINE MESYLATE

CAPSULE; ORAL
 BROMOCRIPTINE MESYLATE
 RX MYLAN EQ 5MG BASE A077226 001 Apr 04, 2005 RLD: N017962

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TABLET; ORAL					
BROMOCRIPTINE MESYLATE					
RX	PADDOCK LLC	EQ 2.5MG BASE	A077646	001	Oct 01, 2008 RLD: N017962
<u>BUPROPION HYDROCHLORIDE</u>					
TABLET; ORAL					
BUPROPION HYDROCHLORIDE					
RX	APOTEX INC	100MG	A076143	002	Jan 17, 2006 RLD: N018644
<u>CALCITONIN SALMON</u>					
SPRAY, METERED; NASAL					
CALCITONIN-SALMON					
RX	APOTEX INC	200 IU/SPRAY	A076396	001	Nov 17, 2008 RLD: N020313
<u>CEFOTAXIME SODIUM</u>					
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
<u>CETIRIZINE HYDROCHLORIDE</u>					
SYRUP; ORAL					
CETIRIZINE HYDROCHLORIDE					
RX	PERRIGO PHARMS CO	5MG/5ML	A078398	001	Jun 17, 2008 RLD: N020346
<u>CHLOROQUINE PHOSPHATE</u>					
TABLET; ORAL					
CHLOROQUINE PHOSPHATE					
RX	NATCO PHARMA LTD	EQ 300MG BASE	A090612	001	Jan 21, 2011 RLD: N006002
<u>CHLORZOXAZONE</u>					
TABLET; ORAL					
CHLORZOXAZONE					
RX	MIKART	250MG	A207483	001	Jun 24, 2016 RLD: N011300
<u>CIPROFLOXACIN</u>					
INJECTABLE; INJECTION					
CIPROFLOXACIN					
RX	BAXTER HLTHCARE CORP	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
<u>CLOBETASOL PROPIONATE</u>					
OINTMENT; TOPICAL					
CLOBETASOL PROPIONATE					
RX	FOUGERA PHARMS	0.05%	A074407	001	Feb 23, 1996 RLD: N019323
<u>CYTARABINE</u>					
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
<u>DACARBAZINE</u>					
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

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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 GENERICS 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

DOXORUBICIN HYDROCHLORIDE

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

DYCLONINE HYDROCHLORIDE

SOLUTION; TOPICAL
 DYCLOPRO
 RX NOVOCOL INC 0.5% A200480 001 Nov 20, 2018 RLD: N009925
 RX 1% A200480 002 Nov 20, 2018 RLD: N009925

ESOMEPRAZOLE SODIUM

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

ETHINYL ESTRADIOL; NORETHINDRONE

TABLET; ORAL-28
 BALZIVA-28
 RX BARR 0.035MG;0.4MG A076238 001 Apr 22, 2004 RLD: N017716

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 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

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FLUOXETINE HYDROCHLORIDE

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

FLUTAMIDE

CAPSULE; ORAL
 FLUTAMIDE
 RX CIPLA 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

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

HYDROMORPHONE HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
 HYDROMORPHONE HYDROCHLORIDE
 RX OSMOTICA 32MG A205629 004 Jul 07, 2016 RLD: N021217

HYDROXYPROGESTERONE CAPROATE

SOLUTION; INTRAMUSCULAR
 HYDROXYPROGESTERONE CAPROATE
 RX ASPEN GLOBAL INC 1250MG/5ML (250MG/ML) A200271 001 Aug 24, 2015 RLD: N016911

IMIPRAMINE PAMOATE

CAPSULE; ORAL
 IMIPRAMINE PAMOATE
 RX WEST-WARD PHARMS EQ 75MG HYDROCHLORIDE 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

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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
 ZADITOR
 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
 SOLUTION; ORAL
 LEVOFLOXACIN
 RX HI TECH PHARMA 250MG/10ML A091678 001 Jun 20, 2011 RLD: N021721

LEVONORGESTREL

TABLET; ORAL
 LEVONORGESTREL
 RX L PERRIGO CO 0.75MG A090740 001 Dec 30, 2010 RLD: N021045
 OTC 0.75MG A090740 001 Dec 30, 2010 RLD: N021045

LEVORPHANOL TARTRATE

TABLET; ORAL
 LEVORPHANOL TARTRATE
 RX SENTYNL THERAPS 3MG A074278 003 Jun 18, 2018 RLD: N008720
 INC

LIDOCAINE HYDROCHLORIDE

SOLUTION; ORAL
 LIDOCAINE HYDROCHLORIDE VISCOUS
 RX LANNETT CO INC 2% A040708 001 Feb 27, 2007 RLD: N009470
 SOLUTION; TOPICAL
 LIDOCAINE HYDROCHLORIDE
 RX WEST-WARD PHARMS 4% A088803 001 Apr 03, 1985 RLD: N010417
 INT

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 PERRIGO 2MG; 125MG A076029 001 Aug 30, 2002 RLD: N020606

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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
 TABLET, EXTENDED RELEASE;ORAL
 METHYLPHENIDATE HYDROCHLORIDE
 RX OSMOTICA 72MG A205327 005 Jul 28, 2017 RLD: N021121

METOPROLOL TARTRATE

TABLET;ORAL
 METOPROLOL TARTRATE
 RX MYLAN 100MG A076704 003 Jan 16, 2004 RLD: N017963

MOEXIPRIL HYDROCHLORIDE

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

MOXIFLOXACIN HYDROCHLORIDE

SOLUTION;INTRAVENOUS
 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

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

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

PANCURONIUM BROMIDE

INJECTABLE;INJECTION
 PANCURONIUM BROMIDE
 RX DR REDDYS 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

POTASSIUM CHLORIDE

TABLET, EXTENDED RELEASE;ORAL
 KLOF-CON M20
 RX UPSHER SMITH LABS 20MEQ A074726 001 Nov 20, 1998 RLD: N019439

PRILOCAINE HYDROCHLORIDE

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

SELEGILINE HYDROCHLORIDE

CAPSULE;ORAL
 SELEGILINE HYDROCHLORIDE
 RX APOTEX 5MG A075321 001 Dec 04, 1998 RLD: N020647

SODIUM POLYSTYRENE SULFONATE

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

SUCCINYLCHOLINE CHLORIDE

INJECTABLE;INJECTION
 SUCCINYLCHOLINE CHLORIDE
 RX ZYDUS PHARMS 20MG/ML A209467 001 May 04, 2018 RLD: N008845

SULFADIAZINE

TABLET;ORAL
 SULFADIAZINE
 RX SANDOZ 500MG A040091 001 Jul 29, 1994 RLD: N004122

TERBUTALINE SULFATE

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

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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

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
TABLET; ORAL
TIMOLOL MALEATE
RX MYLAN 20MG A072668 001 Jun 08, 1990 RLD: N018017

VERAPAMIL HYDROCHLORIDE

TABLET, EXTENDED RELEASE; ORAL
VERAPAMIL HYDROCHLORIDE
RX GLENMARK GENERICS 180MG A090700 002 Aug 03, 2011 RLD: N019152
TABLET; ORAL
VERAPAMIL HYDROCHLORIDE
RX HERITAGE PHARMS 120MG A071881 001 Apr 05, 1988 RLD: N018593
INC

VINBLASTINE SULFATE

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