

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

January 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 USA EQ 500MG BASE/VIAL A206535 001 Aug 31, 2018 RLD: N018603
 INC
 RX EQ 1GM BASE/VIAL A206535 002 Aug 31, 2018 RLD: N018603

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 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 ACADEMIC PHARMS 50MG/ML A204386 001 Dec 21, 2018 RLD: N019030
 INC

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

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BUPROPION HYDROCHLORIDE

TABLET;ORAL

BUPROPION HYDROCHLORIDE

RX	APOTEX INC	100MG	A076143	002	Jan 17, 2006	RLD: N018644
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CALCITONIN SALMON

SPRAY, METERED;NASAL

CALCITONIN-SALMON

RX	APOTEX INC	200 IU/SPRAY	A076396	001	Nov 17, 2008	RLD: N020313
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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

CETIRIZINE HYDROCHLORIDE

SYRUP;ORAL

CETIRIZINE HYDROCHLORIDE

RX	PERRIGO R AND D	5MG/5ML	A078398	001	Jun 17, 2008	RLD: N020346
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CHLOROQUINE PHOSPHATE

TABLET;ORAL

CHLOROQUINE PHOSPHATE

RX	NATCO PHARMA LTD	EQ 300MG BASE	A090612	001	Jan 21, 2011	RLD: N006002
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CHLORZOXAZONE

TABLET;ORAL

CHLORZOXAZONE

RX	MIKART	250MG	A207483	001	Jun 24, 2016	RLD: N011300
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CIPROFLOXACIN

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
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
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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 BARR	0.15MG;0.03MG	A075256	002	Aug 12, 1999	RLD: N020301
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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 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

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

FLUOXETINE HYDROCHLORIDE

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

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FLUPHENAZINE HYDROCHLORIDE

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

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

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

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

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

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 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

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

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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;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
<u>NAFTIFINE HYDROCHLORIDE</u>					
CREAM;TOPICAL					
NAFTIFINE HYDROCHLORIDE					
RX	TARO PHARMS	1%	A205975	001	Sep 08, 2016 RLD: N019599
<u>NALTREXONE HYDROCHLORIDE</u>					
TABLET;ORAL					
NALTREXONE HYDROCHLORIDE					
RX	SPECGX LLC	50MG	A076264	002	Mar 22, 2002 RLD: N018932
<u>NIZATIDINE</u>					
SOLUTION;ORAL					
NIZATIDINE					
RX	AMNEAL PHARMS	15MG/ML	A090576	001	Nov 18, 2009 RLD: N021494
<u>OFLOXACIN</u>					
SOLUTION/DROPS;OTIC					
OFLOXACIN					
RX	BAUSCH AND LOMB	0.3%	A076128	001	Mar 17, 2008 RLD: N020799
<u>OMEPRAZOLE</u>					
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
<u>PANCURONIUM BROMIDE</u>					
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
<u>PARICALCITOL</u>					
CAPSULE;ORAL					
PARICALCITOL					
RX	TEVA PHARMS USA	4MCG	A090829	003	Sep 27, 2013 RLD: N021606
<u>PENTOXIFYLLINE</u>					
TABLET, EXTENDED RELEASE;ORAL					
PENTOXIFYLLINE					
RX	APOTEX	400MG	A075191	001	Jun 09, 1999 RLD: N018631

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<u>PHENTERMINE HYDROCHLORIDE</u>						
TABLET; ORAL						
LOMAIRA						
RX	AVANTHI INC	8MG	A203495	001	Sep 12, 2016	RLD: N012737
<u>POTASSIUM CHLORIDE</u>						
TABLET, EXTENDED RELEASE; ORAL						
Klor-Con M20						
RX	UPSHER SMITH LABS	20MEQ	A074726	001	Nov 20, 1998	RLD: N019439
<u>PRILOCAINE HYDROCHLORIDE</u>						
INJECTABLE; INJECTION						
PRILOCAINE HYDROCHLORIDE						
RX	SEPTODONT INC	4%	A079235	001	Sep 29, 2010	RLD: N021382
<u>SELEGILINE HYDROCHLORIDE</u>						
CAPSULE; ORAL						
SELEGILINE HYDROCHLORIDE						
RX	APOTEX	5MG	A075321	001	Dec 04, 1998	RLD: N020647
<u>SODIUM POLYSTYRENE SULFONATE</u>						
POWDER; ORAL, RECTAL						
KALEXATE						
RX	KVK TECH	454GM/BOT	A040905	001	Mar 30, 2009	RLD: N011287
<u>SUCCINYLCHOLINE CHLORIDE</u>						
INJECTABLE; INJECTION						
SUCCINYLCHOLINE CHLORIDE						
RX	ZYDUS PHARMS USA INC	20MG/ML	A209467	001	May 04, 2018	RLD: N008845
<u>SULFADIAZINE</u>						
TABLET; ORAL						
SULFADIAZINE						
RX	SANDOZ	500MG	A040091	001	Jul 29, 1994	RLD: N004122
<u>TERBUTALINE SULFATE</u>						
TABLET; ORAL						
TERBUTALINE SULFATE						
RX	LANNETT CO INC	5MG	A077152	002	Mar 25, 2005	RLD: N017849
<u>TERCONAZOLE</u>						
CREAM; VAGINAL						
TERCONAZOLE						
RX	TARO	0.8%	A075953	001	Apr 06, 2004	RLD: N019964
<u>TESTOSTERONE</u>						
SOLUTION, METERED; TRANSDERMAL						
TESTOSTERONE						
RX	PERRIGO ISRAEL	30MG/1.5ML ACTUATION	A204255	001	Feb 28, 2017	RLD: N022504
<u>THIOTHIXENE</u>						
CAPSULE; ORAL						
THIOTHIXENE						
RX	MYLAN	5MG	A071093	004	Jun 23, 1987	RLD: N016584
<u>TIMOLOL MALEATE</u>						
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
<u>VERAPAMIL HYDROCHLORIDE</u>						
TABLET, EXTENDED RELEASE; ORAL						
VERAPAMIL HYDROCHLORIDE						
RX	GLENMARK GENERICS	180MG	A090700	002	Aug 03, 2011	RLD: N019152

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VINBLASTINE SULFATE

INJECTABLE; INJECTION

VINBLASTINE SULFATE

RX WEST-WARD PHARMS 10MG/VIAL
INT

A089395 001 Apr 09, 1987 RLD: N012665