Prescription List of Off-Patent, Off-Exclusivity Drugs without an Approved Generic

To improve transparency and encourage the development and submission of abbreviated new drug applications (ANDAs) for drugs with limited competition, FDA is publishing a list, consistent with the methodology described below, of approved and active prescription new drug application (NDA) drug products that are off-patent and off-exclusivity, and for which the FDA has not approved an ANDA referencing that NDA drug product.

Part I of the list identifies those prescription drug products for which FDA could immediately accept an ANDA without prior discussion.

Part II identifies prescription drug products for which ANDA development or approval may raise potential legal, regulatory, or scientific issues that should be addressed with the Agency prior to considering submission of an ANDA.

The Appendix identifies prescription NDA drug products that were removed from Part I or Part II of the list because one or more ANDAs referencing such NDA drug products have been approved since the previous list publication.

Sponsors wishing to pursue approval of ANDAs referencing drug products identified in Part II of this list generally should submit an initial inquiry to the Office of Generic Drugs at genericdrugs@fda.hhs.gov. Sponsors may be referred to the Office of New Drugs under certain circumstances, for example if the product is not eligible for submission or approval as an ANDA but may be considered for submission under another abbreviated approval pathway. Sponsors should identify the product's established name and NDA number in any inquiry.

- For some products in Part II of the list, submission and/or approval of an ANDA via the 505(j) pathway may not be appropriate; section 505(b)(2) of the FD&C Act may be an appropriate abbreviated approval pathway for such products.
- For other products in Part II of the list, there are regulatory or scientific complexities that may be addressed with additional information exchange between FDA and a prospective ANDA sponsor (e.g., there is no applicable product-specific guidance or the product is a complex mixture).

We have excluded any NDA drug products that have been approved within the past year, as it generally is too soon for an ANDA referencing such a product to have been approved.

FDA intends to update the list every six months. The current methodology for creating and reviewing the list is set forth at the bottom of the list. We welcome suggestions concerning the methodology, as well as suggestions for any prescription NDA drug products that should be added to (or, in limited cases, removed from) the list. Please direct correspondence to genericdrugs@fda.hhs.gov, providing your name, e-mail address, phone number, NDA number, established name, and dosage form of any NDA drug product that should be added to or, in limited cases, removed from the list.

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
ACETAMINOPHEN	N206968	SOLUTION	1GM/100ML (10MG/ML)
ACETIC ACID, GLACIAL	N018523	SOLUTION	250MG/100ML
ACETIC ACID, GLACIAL	N018161	SOLUTION	250MG/100ML
ACETIC ACID, GLACIAL	N017656	SOLUTION	250MG/100ML
ACETYLCHOLINE CHLORIDE	N020213	FOR SOLUTION	20MG/VIAL
ACYCLOVIR; HYDROCORTISONE	N022436	CREAM	5%;1%
ALENDRONATE SODIUM; CHOLECALCIFEROL	N021762	TABLET	EQ 70MG BASE;5,600 IU
ALENDRONATE SODIUM; CHOLECALCIFEROL	N021762	TABLET	EQ 70MG BASE;2,800 IU
ALPHA-TOCOPHEROL ACETATE; ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A PALMITATE; VITAMIN K	N021163	SOLUTION	2 IU/ML;40MG/ML;12MCG/ML;40 IU/ML;1MCG/ML;3MG/ML;120MCG/ML; 8MG/ML;1.2MG/ML;0.72MG/ML;1.2MG /ML;660 IU/ML;30MCG/ML
ALPHA-TOCOPHEROL ACETATE; ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A PALMITATE; VITAMIN K	N021163	SOLUTION	2 IU/ML;40MG/ML;12MCG/ML;40 IU/ML;1MCG/ML;3MG/ML;120MCG/ML; 8MG/ML;1.2MG/ML;0.72MG/ML;1.2MG /ML;660 IU/ML;0.03MG/ML
AMINO ACIDS	N020849	INJECTABLE	20% (20GM/100ML)
AMINO ACIDS	N019398	INJECTABLE	7% (7GM/100ML)
AMINO ACIDS	N018931	INJECTABLE	5.5% (5.5GM/100ML)
AMINO ACIDS	N018931	INJECTABLE	8.5% (8.5GM/100ML)
AMINO ACIDS	N018931	INJECTABLE	10% (10MG/100ML)
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N020678	INJECTABLE	2.75%;33MG/100ML;5GM/100ML;51MG /100ML;261MG/100ML;217MG/100ML; 112MG/100ML

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N020678	INJECTABLE	4.25%;33MG/100ML;20GM/100ML;51MG/100ML;261MG/100ML;297MG/100ML;77MG/100ML
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N020678	INJECTABLE	4.25%;33MG/100ML;25GM/100ML;51MG/100ML;261MG/100ML;297MG/100ML;77MG/100ML
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N020678	INJECTABLE	5%;33MG/100ML;10GM/100ML;51MG/100ML;261MG/100ML;340MG/100ML;59MG/100ML
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N020678	INJECTABLE	5%;33MG/100ML;15GM/100ML;51MG/100ML;261MG/100ML;340MG/100ML;59MG/100ML
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N020678	INJECTABLE	5%;33MG/100ML;20GM/100ML;51MG/100ML;261MG/100ML;340MG/100ML;59MG/100ML
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N020678	INJECTABLE	5%;33MG/100ML;25GM/100ML;51MG/100ML;261MG/100ML;340MG/100ML;59MG/100ML
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N020678	INJECTABLE	2.75%;33MG/100ML;10GM/100ML;51MG/100ML;261MG/100ML;217MG/100ML;112MG/100ML

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N020678	INJECTABLE	5%;33MG/100ML;35GM/100ML;51MG/100ML;261MG/100ML;340MG/100ML;59MG/100ML
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N020678	INJECTABLE	2.75%;33MG/100ML;25GM/100ML;51MG/100ML;261MG/100ML;217MG/100ML;112MG/100ML
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N020678	INJECTABLE	4.25%;33MG/100ML;5GM/100ML;51MG/100ML;261MG/100ML;297MG/100ML;77MG/100ML
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N020678	INJECTABLE	4.25%;33MG/100ML;10GM/100ML;51MG/100ML;261MG/100ML;297MG/100ML;77MG/100ML
AMINO ACIDS; DEXTROSE	N020734	INJECTABLE	8%;14GM/100ML
AMINO ACIDS; DEXTROSE	N020734	INJECTABLE	2.75%;5GM/100ML
AMINO ACIDS; DEXTROSE	N020734	INJECTABLE	4.25%;20GM/100ML
AMINO ACIDS; DEXTROSE	N020734	INJECTABLE	4.25%;25GM/100ML
AMINO ACIDS; DEXTROSE	N020734	INJECTABLE	5%;10GM/100ML
AMINO ACIDS; DEXTROSE	N020734	INJECTABLE	5%;15GM/100ML
AMINO ACIDS; DEXTROSE	N020734	INJECTABLE	5%;20GM/100ML
AMINO ACIDS; DEXTROSE	N020734	INJECTABLE	5%;25GM/100ML
AMINO ACIDS; DEXTROSE	N020734	INJECTABLE	5%;35GM/100ML
AMINO ACIDS; DEXTROSE	N020734	INJECTABLE	2.75%;10GM/100ML
AMINO ACIDS; DEXTROSE	N020734	INJECTABLE	2.75%;25GM/100ML
AMINO ACIDS; DEXTROSE	N020734	INJECTABLE	4.25%;5GM/100ML
AMINO ACIDS; DEXTROSE	N020734	INJECTABLE	4.25%;10GM/100ML
AMINOLEVULINIC ACID HYDROCHLORIDE	N208630	FOR SOLUTION	1.5GM/VIAL
ANIDULAFUNGIN	N021632	POWDER	100MG/VIAL
ANIDULAFUNGIN	N021632	POWDER	50MG/VIAL
APRACLONIDINE HYDROCHLORIDE	N019779	SOLUTION/DROPS	EQ 1% BASE
ARGATROBAN	N212035	SOLUTION	50MG/50ML (1MG/ML)
ARGATROBAN	N209552	SOLUTION	50MG/50ML (1MG/ML)
ARGININE HYDROCHLORIDE	N016931	INJECTABLE	10GM/100ML

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
ARTEMETHER; LUMEFANTRINE	N022268	TABLET	20MG;120MG
ARTICAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE	N022466	INJECTABLE	4%;EQ 0.009MG BASE/1.8ML (EQ 0.005MG BASE/ML)
ARTICAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE	N022466	INJECTABLE	4%;EQ 0.018MG BASE/1.8ML (EQ 0.01MG BASE/ML)
ASCORBIC ACID	N209112	SOLUTION	25,000MG/50ML (500MG/ML)
ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL ACETATE; VITAMIN A; VITAMIN K	N021265	INJECTABLE	80MG/VIAL;0.02MG/VIAL;400 IU/VIAL;0.001MG/VIAL;5MG/VIAL;0.14 MG/VIAL;17MG/VIAL;1MG/VIAL;1.4MG/ VIAL;1.2MG/VIAL;7 IU/VIAL;2,300 IU/VIAL;0.2MG/VIAL
ATROPINE SULFATE	N213581	SOLUTION/DROPS	1%
ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE	N017744	TABLET	0.025MG;1MG
AURANOFIN	N018689	CAPSULE	3MG
AZELAIC ACID	N020428	CREAM	20%
AZITHROMYCIN	N050810	SOLUTION/DROPS	1%
BACLOFEN	N208193	SOLUTION	10MG/5ML
BARIUM SULFATE	N208143	SUSPENSION	24% (144GM/600ML)
BARIUM SULFATE	N208036	FOR SUSPENSION	81% (120GM/BOT)
BARIUM SULFATE	N208143	SUSPENSION	40% (100GM/250ML)
BARIUM SULFATE	N208143	SUSPENSION	40% (8GM/BOT)
BARIUM SULFATE	N208143	SUSPENSION	40% (96GM/240ML)
BARIUM SULFATE	N208036	FOR SUSPENSION	96% (169GM/BOT)
BARIUM SULFATE	N208143	SUSPENSION	60% (213GM/BOT)
BARIUM SULFATE	N208844	PASTE	40%
BARIUM SULFATE	N208143	SUSPENSION	2% (9GM/BOT)
BARIUM SULFATE	N208036	FOR SUSPENSION	98% (334GM/BOT)
BENDAMUSTINE HYDROCHLORIDE	N216078	SOLUTION	100MG/4ML (25MG/ML)
BENDAMUSTINE HYDROCHLORIDE	N215033	SOLUTION	100MG/4ML (25MG/ML)
BENOXINATE HYDROCHLORIDE; FLUORESCEIN SODIUM	N208582	SOLUTION/DROPS	0.4%;0.25%
BENZNIDAZOLE	N209570	TABLET	100MG
BENZNIDAZOLE	N209570	TABLET	12.5MG
BETAXOLOL HYDROCHLORIDE	N019845	SUSPENSION/DROPS	EQ 0.25% BASE

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
BORTEZOMIB	N209191	POWDER	2.5MG/VIAL
BORTEZOMIB	N209191	POWDER	1MG/VIAL
BUDESONIDE	N021949	POWDER, METERED	0.08MG/INH
BUDESONIDE	N021949	POWDER, METERED	0.16MG/INH
BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE	N018304	INJECTABLE	0.75%;0.0091MG/ML
BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE	N016964	INJECTABLE	0.75%;0.0091MG/ML
BUSULFAN	N009386	TABLET	2MG
CALCITRIOL	N022087	OINTMENT	3MCG/GM
CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE	N018469	SOLUTION	0.154MG/ML;0.92MG/ML;0.184MG/ML; 0.2MG/ML;0.38MG/ML;2.1MG/ML;7.14 MG/ML;0.42MG/ML
CALCIUM CHLORIDE; DEXTROSE; LACTIC ACID; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE	N021703	INJECTABLE	N/A/1000ML;20GM/1000ML;5.4GM/100 0ML;3.05GM/1000ML;0.314GM/1000M L;2.21GM/1000ML;7.07GM/1000ML (5000ML)
CALCIUM CHLORIDE; DEXTROSE; LACTIC ACID; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE	N021703	INJECTABLE	N/A/1000ML;N/A/1000ML;5.4GM/1000 ML;2.44GM/1000ML;N/A/1000ML;3.09 GM/1000ML;6.46GM/1000ML (5000ML)
CALCIUM CHLORIDE; DEXTROSE; LACTIC ACID; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE	N021703	INJECTABLE	N/A/1000ML;20GM/1000ML;5.4GM/100 0ML;2.44GM/1000ML;0.314GM/1000M L;3.09GM/1000ML;6.46GM/1000ML (5000ML)
CALCIUM CHLORIDE; DEXTROSE; LACTIC ACID; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE	N021703	INJECTABLE	N/A/1000ML;20GM/1000ML;5.4GM/100 0ML;2.03GM/1000ML;0.157GM/1000M L;3.09GM/1000ML;6.46GM/1000ML (5000ML)

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
CALCIUM CHLORIDE; DEXTROSE; LACTIC ACID; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE	N021703	INJECTABLE	5.15GM/1000ML;20GM/1000ML;5.4GM/1000ML;2.03GM/1000ML;0.157GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)
CALCIUM CHLORIDE; DEXTROSE; LACTIC ACID; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE	N021703	INJECTABLE	3.68GM/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;0.314GM/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)
CALCIUM CHLORIDE; DEXTROSE; LACTIC ACID; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE	N021703	INJECTABLE	3.68GM/1000ML;20GM/1000ML;5.4GM/1000ML;3.05GM/1000ML;N/A/1000ML;3.09GM/1000ML;6.46GM/1000ML (5000ML)
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N020163	SOLUTION	25.7MG/100ML;1.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N020163	SOLUTION	25.7MG/100ML;2.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N020163	SOLUTION	25.7MG/100ML;4.25GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N020183	SOLUTION	18.3MG/100ML;4.25GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N018883	SOLUTION	25.7MG/100ML;1.5GM/100ML;15.2MG/100ML;567MG/100ML;392MG/100ML

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N017512	SOLUTION	25.7MG/100ML;1.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N017512	SOLUTION	18.3MG/100ML;3.5GM/100ML;5.08MG/100ML;538MG/100ML;448MG/100ML
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N018883	SOLUTION	25.7MG/100ML;2.5GM/100ML;15.2MG/100ML;567MG/100ML;392MG/100ML
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N018883	SOLUTION	25.7MG/100ML;4.25GM/100ML;15.2MG/100ML;567MG/100ML;392MG/100ML
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	N020577	INJECTABLE	0.2MG/ML;0.8MG/ML;0.3MG/ML;0.3MG/ML;1.9MG/ML;7.3MG/ML;0.2MG/ML
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N019634	INJECTABLE	10MG/100ML;2.5GM/100ML;15MG/100ML;300MG/100ML;160MG/100ML
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N019367	INJECTABLE	20MG/100ML;5GM/100ML;105MG/100ML;600MG/100ML;310MG/100ML
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE	N018895	INJECTABLE	16.5MG/ML;25.4MG/ML;74.6MG/ML;121MG/ML;16.1MG/ML

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE	N207026	INJECTABLE	3.68GM/1000ML;3.05GM/1000ML;0.314GM/1000ML ;3.09GM/1000ML;6.34GM/1000ML;0.187GM/1000ML (5000ML)
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE	N207026	INJECTABLE	N/A/1000ML;3.05GM/1000ML;0.314GM/1000ML;2.21GM/1000ML;6.95GM/1000ML;0.187GM/1000ML (5000ML)
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N020002	INJECTABLE	33MG/100ML;30MG/100ML;860MG/100ML
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018495	SOLUTION	33MG/100ML;30MG/100ML;860MG/100ML
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018251	INJECTABLE	33MG/100ML;30MG/100ML;860MG/100ML
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018156	SOLUTION	33MG/100ML;30MG/100ML;860MG/100ML
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N017635	SOLUTION	33MG/100ML;30MG/100ML;860MG/100ML
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N016693	INJECTABLE	33MG/100ML;30MG/100ML;860MG/100ML
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N019416	SOLUTION	20MG/100ML;30MG/100ML;600MG/100ML;310MG/100ML
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N018921	SOLUTION	20MG/100ML;30MG/100ML;600MG/100ML;310MG/100ML
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N018681	SOLUTION	20MG/100ML;30MG/100ML;600MG/100ML;310MG/100ML
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N018494	SOLUTION	20MG/100ML;30MG/100ML;600MG/100ML;310MG/100ML

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
CARBAMAZEPINE	N021710	CAPSULE, EXTENDED RELEASE	100MG
CARBAMAZEPINE	N021710	CAPSULE, EXTENDED RELEASE	200MG
CARBAMAZEPINE	N021710	CAPSULE, EXTENDED RELEASE	300MG
CARBIDOPA; LEVODOPA	N203952	SUSPENSION	4.63MG/ML;20MG/ML
CEFAZOLIN SODIUM	N211413	POWDER	EQ 2GM BASE/VIAL
CEFAZOLIN SODIUM	N216109	POWDER	EQ 2GM BASE/VIAL
CEFAZOLIN SODIUM	N216109	POWDER	EQ 3GM BASE/VIAL
CEFAZOLIN SODIUM	N207131	SOLUTION	EQ 1GM BASE/50ML (EQ 20MG BASE/ML)
CEFAZOLIN SODIUM	N207131	SOLUTION	EQ 2GM BASE/100ML (EQ 20MG BASE/ML)
CEFAZOLIN SODIUM	N050779	INJECTABLE	EQ 1GM BASE/VIAL
CEFAZOLIN SODIUM	N207131	SOLUTION	EQ 3GM BASE/150ML (EQ 20MG BASE/ML)
CEFEPIME HYDROCHLORIDE	N050817	INJECTABLE	EQ 1GM BASE/50ML (EQ 20MG BASE/ML)
CEFEPIME HYDROCHLORIDE	N050817	INJECTABLE	EQ 2GM BASE/100ML (EQ 20MG BASE/ML)
CHLORAMBUCIL	N010669	TABLET	2MG
CHLOROTHIAZIDE	N011870	SUSPENSION	250MG/5ML
CHLORTHALIDONE	N019574	TABLET	25MG
CHLORTHALIDONE	N019574	TABLET	15MG
CHOLIC ACID	N205750	CAPSULE	250MG
CHOLIC ACID	N205750	CAPSULE	50MG
CIPROFLOXACIN HYDROCHLORIDE	N020369	OINTMENT	EQ 0.3% BASE
CIPROFLOXACIN HYDROCHLORIDE; HYDROCORTISONE	N020805	SUSPENSION/DROPS	EQ 0.2% BASE;1%
CITALOPRAM HYDROBROMIDE	N215428	CAPSULE	EQ 30MG BASE
CITRIC ACID; GLUCONOLACTONE; MAGNESIUM CARBONATE	N019481	SOLUTION	6.602GM/100ML;198MG/100ML;3.177GM/100ML
CITRIC ACID; UREA C-13	N021314	FOR SOLUTION, TABLET, FOR SOLUTION	4GM;75MG
CLINDAMYCIN PHOSPHATE	N208083	SOLUTION	EQ 300MG BASE/50ML (EQ 6MG BASE/ML)
CLINDAMYCIN PHOSPHATE	N208083	SOLUTION	EQ 600MG BASE/50ML (EQ 12MG BASE/ML)

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
CLINDAMYCIN PHOSPHATE	N208083	SOLUTION	EQ 900MG BASE/50ML (EQ 18MG BASE/ML)
CLINDAMYCIN PHOSPHATE	N050767	SUPPOSITORY	100MG
CLINDAMYCIN PHOSPHATE	N050635	INJECTABLE	EQ 900MG BASE/100ML
CONIVAPTAN HYDROCHLORIDE	N021697	INJECTABLE	20MG/100ML (0.2MG/ML)
CYCLOPHOSPHAMIDE	N217150	SOLUTION	1GM/10ML (100MG/ML)
CYCLOPHOSPHAMIDE	N217150	SOLUTION	2GM/20ML (100MG/ML)
CYCLOPHOSPHAMIDE	N217150	SOLUTION	500MG/5ML (100MG/ML)
CYCLOPHOSPHAMIDE	N217651	SOLUTION	1GM/5ML (200MG/ML)
CYCLOPHOSPHAMIDE	N217651	SOLUTION	500MG/2.5ML (200MG/ML)
CYCLOSPORINE	N050625	CAPSULE	50MG
CYSTEAMINE HYDROCHLORIDE	N211302	SOLUTION/DROPS	EQ 0.37% BASE
CYSTEAMINE HYDROCHLORIDE	N200740	SOLUTION/DROPS	EQ 0.44% BASE
DALTEPARIN SODIUM	N020287	INJECTABLE	10,000IU/4ML (2,500IU/ML)
DALTEPARIN SODIUM	N020287	INJECTABLE	12,500IU/0.5ML (25,000IU/ML)
DALTEPARIN SODIUM	N020287	INJECTABLE	15,000IU/0.6ML (25,000IU/ML)
DALTEPARIN SODIUM	N020287	INJECTABLE	18,000IU/0.72ML (25,000IU/ML)
DALTEPARIN SODIUM	N020287	INJECTABLE	95,000IU/3.8ML (25,000IU/ML)
DALTEPARIN SODIUM	N020287	INJECTABLE	7,500IU/0.3ML (25,000IU/ML)
DALTEPARIN SODIUM	N020287	INJECTABLE	10,000IU/ML (10,000IU/ML)
DALTEPARIN SODIUM	N020287	INJECTABLE	5,000IU/0.2ML (25,000IU/ML)
DALTEPARIN SODIUM	N020287	INJECTABLE	2,500IU/0.2ML (12,500IU/ML)
DAPTOMYCIN	N213645	SOLUTION	350MG/50ML (7MG/ML)
DAPTOMYCIN	N213645	SOLUTION	500MG/50ML (10MG/ML)
DAPTOMYCIN	N213645	SOLUTION	700MG/100ML (7MG/ML)
DAPTOMYCIN	N213645	SOLUTION	1GM/100ML (10MG/ML)
DAPTOMYCIN	N209949	POWDER	350MG/VIAL
DECITABINE	N205582	POWDER	50MG/VIAL
DESLORATADINE; PSEUDOEPHEDRINE SULFATE	N021313	TABLET, EXTENDED RELEASE	2.5MG;120MG
DESVENLAFAXINE	N204150	TABLET, EXTENDED RELEASE	50MG
DESVENLAFAXINE	N204150	TABLET, EXTENDED RELEASE	100MG
DEXAMETHASONE; TOBRAMYCIN	N050616	OINTMENT	0.1%;0.3%
DEXTROSE	N019445	INJECTABLE	250MG/ML
DEXTROSE	N020179	INJECTABLE	5GM/100ML
DEXTROSE	N020047	INJECTABLE	50GM/100ML
DEXTROSE	N020047	INJECTABLE	70GM/100ML
DEXTROSE	N019893	INJECTABLE	70GM/100ML

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
DEXTROSE	N019626	INJECTABLE	5GM/100ML
DEXTROSE	N019479	INJECTABLE	5GM/100ML
DEXTROSE	N019466	INJECTABLE	5GM/100ML
DEXTROSE	N019345	INJECTABLE	30GM/100ML
DEXTROSE	N018562	INJECTABLE	40GM/100ML
DEXTROSE	N018564	INJECTABLE	20GM/100ML
DEXTROSE	N018563	INJECTABLE	50GM/100ML
DEXTROSE	N018561	INJECTABLE	70GM/100ML
DEXTROSE	N016730	INJECTABLE	5GM/100ML
DEXTROSE	N016673	INJECTABLE	5GM/100ML
DEXTROSE; MAGNESIUM ACETATE; POTASSIUM ACETATE; SODIUM CHLORIDE	N017610	INJECTABLE	5GM/100ML;21MG/100ML;128MG/100ML;234MG/100ML
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE	N019873	INJECTABLE	5GM/100ML;31MG/100ML;130MG/100ML;26MG/100ML;320MG/100ML
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM LACTATE	N017484	INJECTABLE	5GM/100ML;31MG/100ML;141MG/100ML;20MG/100ML;12MG/100ML;260MG/100ML
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM LACTATE; SODIUM PHOSPHATE, MONOBASIC ANHYDROUS	N019513	INJECTABLE	5GM/100ML;30MG/100ML;141MG/100ML;15MG/100ML;260MG/100ML;25MG/100ML
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	N017609	INJECTABLE	5GM/100ML;30MG/100ML;37MG/100ML;222MG/100ML;526MG/100ML;502MG/100ML
DEXTROSE; POTASSIUM CHLORIDE	N019699	INJECTABLE	5GM/100ML;300MG/100ML
DEXTROSE; POTASSIUM CHLORIDE	N018371	INJECTABLE	5GM/100ML;149MG/100ML
DEXTROSE; POTASSIUM CHLORIDE	N017634	INJECTABLE	5GM/100ML;224MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	3.3GM/100ML;75MG/100ML;300MG/100ML

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	3.3GM/100ML;110MG/100ML;300MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	3.3GM/100ML;150MG/100ML;300MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	3.3GM/100ML;220MG/100ML;300MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	3.3GM/100ML;300MG/100ML;300MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;37MG/100ML;110MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;220MG/100ML;200MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;37MG/100ML;330MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;110MG/100ML;330MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;220MG/100ML;330MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;37MG/100ML;450MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;75MG/100ML;110MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;110MG/100ML;450MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;220MG/100ML;450MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;37MG/100ML;900MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;110MG/100ML;900MG/100ML

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;220MG/100ML;900MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;110MG/100ML;110MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;37MG/100ML;200MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;75MG/100ML;200MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;110MG/100ML;200MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;150MG/100ML;200MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;220MG/100ML;200MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;300MG/100ML;200MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;37MG/100ML;450MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;75MG/100ML;450MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;110MG/100ML;450MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;150MG/100ML;110MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;150MG/100ML;450MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;220MG/100ML;450MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;300MG/100ML;450MG/100ML

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;37MG/100ML;900MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;75MG/100ML;900MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;110MG/100ML;900MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;150MG/100ML;900MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;220MG/100ML;900MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	10GM/100ML;300MG/100ML;900MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;220MG/100ML;110MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;300MG/100ML;110MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;37MG/100ML;200MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;110MG/100ML;200MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE	5GM/100ML;300MG/100ML;900MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019308	INJECTABLE	5GM/100ML;150MG/100ML;900MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019308	INJECTABLE	5GM/100ML;300MG/100ML;900MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019308	INJECTABLE	5GM/100ML;224MG/100ML;900MG/100ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019308	INJECTABLE	5GM/100ML;75MG/100ML;900MG/100ML

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018008	INJECTABLE	5GM/100ML;75MG/100ML;450MG/100 ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018037	INJECTABLE	5GM/100ML;224MG/100ML;200MG/10 0ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018629	INJECTABLE	5GM/100ML;75MG/100ML;330MG/100 ML
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018008	INJECTABLE	5GM/100ML;150MG/100ML;450MG/10 0ML
DEXTROSE; SODIUM CHLORIDE	N019631	INJECTABLE	3.3GM/100ML;300MG/100ML
DEXTROSE; SODIUM CHLORIDE	N019631	INJECTABLE	2.5GM/100ML;110MG/100ML
DEXTROSE; SODIUM CHLORIDE	N019631	INJECTABLE	10GM/100ML;110MG/100ML
DEXTROSE; SODIUM CHLORIDE	N019631	INJECTABLE	10GM/100ML;200MG/100ML
DEXTROSE; SODIUM CHLORIDE	N019631	INJECTABLE	10GM/100ML;330MG/100ML
DEXTROSE; SODIUM CHLORIDE	N019631	INJECTABLE	10GM/100ML;450MG/100ML
DEXTROSE; SODIUM CHLORIDE	N019631	INJECTABLE	2.5GM/100ML;200MG/100ML
DEXTROSE; SODIUM CHLORIDE	N019631	INJECTABLE	2.5GM/100ML;330MG/100ML
DEXTROSE; SODIUM CHLORIDE	N019631	INJECTABLE	2.5GM/100ML;900MG/100ML
DEXTROSE; SODIUM CHLORIDE	N019631	INJECTABLE	5GM/100ML;110MG/100ML
DEXTROSE; SODIUM CHLORIDE	N019631	INJECTABLE	10GM/100ML;900MG/100ML
DEXTROSE; SODIUM CHLORIDE	N016687	INJECTABLE	5GM/100ML;330MG/100ML
DEXTROSE; SODIUM CHLORIDE	N016689	INJECTABLE	5GM/100ML;200MG/100ML
DIAZEPAM	N020648	GEL	2.5MG/0.5ML (5MG/ML)
DICLOFENAC EPOLAMINE	N021234	SYSTEM	1.3%
DIMERCAPROL	N005939	INJECTABLE	10%
DINOPROSTONE	N020411	INSERT, EXTENDED RELEASE	10MG
DINOPROSTONE	N019617	GEL	0.5MG/3GM

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
DISOPYRAMIDE PHOSPHATE	N018655	CAPSULE, EXTENDED RELEASE	EQ 100MG BASE
DOBUTAMINE HYDROCHLORIDE	N020201	INJECTABLE	EQ 400MG BASE/100ML
DOBUTAMINE HYDROCHLORIDE	N020201	INJECTABLE	EQ 100MG BASE/100ML
DOBUTAMINE HYDROCHLORIDE	N020201	INJECTABLE	EQ 200MG BASE/100ML
DOBUTAMINE HYDROCHLORIDE	N020201	INJECTABLE	EQ 50MG BASE/100ML
DOBUTAMINE HYDROCHLORIDE	N020255	INJECTABLE	EQ 100MG BASE/100ML
DOBUTAMINE HYDROCHLORIDE	N020255	INJECTABLE	EQ 200MG BASE/100ML
DOBUTAMINE HYDROCHLORIDE	N020255	INJECTABLE	EQ 400MG BASE/100ML
DOBUTAMINE HYDROCHLORIDE	N020255	INJECTABLE	EQ 50MG BASE/100ML
DOCETAXEL	N022234	INJECTABLE	160MG/8ML (20MG/ML)
DOCETAXEL	N203551	INJECTABLE	140MG/7ML (20MG/ML)
DOCETAXEL	N022234	INJECTABLE	20MG/ML (20MG/ML)
DOCETAXEL	N022234	INJECTABLE	80MG/4ML (20MG/ML)
DOPAMINE HYDROCHLORIDE	N019615	INJECTABLE	640MG/100ML
DOPAMINE HYDROCHLORIDE	N019615	INJECTABLE	160MG/100ML
DOPAMINE HYDROCHLORIDE	N018826	INJECTABLE	80MG/100ML
DOPAMINE HYDROCHLORIDE	N018132	INJECTABLE	80MG/100ML
DOXAZOSIN MESYLATE	N021269	TABLET, EXTENDED RELEASE	EQ 4MG BASE
DOXAZOSIN MESYLATE	N021269	TABLET, EXTENDED RELEASE	EQ 8MG BASE
DROSPIRENONE; ESTRADIOL	N021355	TABLET	0.5MG;1MG
ECHOTHIOPHATE IODIDE	N011963	FOR SOLUTION	0.125%
EMTRICITABINE	N021896	SOLUTION	10MG/ML
ENTECAVIR	N021798	SOLUTION	0.05MG/ML
EPHEDRINE HYDROCHLORIDE	N213536	SOLUTION	47MG/10ML (4.7MG/ML)
EPINEPHRINE	N211363	SOLUTION	1MG/10ML (0.1MG/ML)
EPINEPHRINE	N209359	SOLUTION	1MG/10ML (0.1MG/ML)
EPINEPHRINE	N205029	SOLUTION	1MG/ML (1MG/ML)
EPINEPHRINE	N205029	SOLUTION	30MG/30ML (1MG/ML)

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
ESTRADIOL	N022014	SPRAY	1.53MG/SPRAY
ESTRADIOL	N021813	GEL, METERED	0.06% (0.87GM/ACTIVATION)
ESTRADIOL; LEVONORGESTREL	N021258	FILM, EXTENDED RELEASE	0.045MG/24HR;0.015MG/24HR
ESTRADIOL; NORETHINDRONE ACETATE	N020870	FILM, EXTENDED RELEASE	0.05MG/24HR;0.14MG/24HR
ESTRADIOL; NORETHINDRONE ACETATE	N020870	FILM, EXTENDED RELEASE	0.05MG/24HR;0.25MG/24HR
ESTROGENS, CONJUGATED	N004782	TABLET	0.45MG
ESTROGENS, CONJUGATED	N004782	TABLET	0.9MG
ESTROGENS, CONJUGATED	N010402	INJECTABLE	25MG/VIAL
ESTROGENS, CONJUGATED	N004782	TABLET	1.25MG
ESTROGENS, CONJUGATED	N004782	TABLET	0.3MG
ESTROGENS, CONJUGATED	N004782	TABLET	0.625MG
ETHANOLAMINE OLEATE	N019357	INJECTABLE	50MG/ML
ETHINYL ESTRADIOL; LEVONORGESTREL	N209405	TABLET	0.02MG;0.1MG
ETHIODIZED OIL	N009190	OIL	EQ 4.8GM IODINE/10ML (EQ 480MG IODINE/ML)
ETHIONAMIDE	N013026	TABLET	250MG
ETOPOSIDE PHOSPHATE	N020457	INJECTABLE	EQ 100MG BASE/VIAL
FENOFIBRATE	N021612	CAPSULE	50MG
FENOFIBRATE	N021612	CAPSULE	150MG
FENTANYL CITRATE	N019101	INJECTABLE	EQ 0.025MG BASE/0.5ML
FLORBETAPIR F-18	N202008	SOLUTION	10-100ML (13.5-51MCI/ML)
FLUOCINOLONE ACETONIDE; HYDROQUINONE; TRETINOIN	N021112	CREAM	0.01%;4%;0.05%
FLUORESCEIN SODIUM	N021980	INJECTABLE	EQ 500MG BASE/5ML (EQ 100MG BASE/ML)
FLUORODOPA F-18	N200655	SOLUTION	1-40MCI/ML
FLUOROESTRADIOL F-18	N212155	SOLUTION	50ML (4-100MCI/ML)
FLUOROURACIL	N022259	CREAM	4%
FORMOTEROL FUMARATE; MOMETASONE FUROATE	N022518	AEROSOL, METERED	0.005MG/INH;0.05MG/INH
FORMOTEROL FUMARATE; MOMETASONE FUROATE	N022518	AEROSOL, METERED	0.005MG/INH;0.1MG/INH
FORMOTEROL FUMARATE; MOMETASONE FUROATE	N022518	AEROSOL, METERED	0.005MG/INH;0.2MG/INH
GABAPENTIN	N022544	TABLET	450MG
GABAPENTIN	N022544	TABLET	750MG
GABAPENTIN	N022544	TABLET	900MG
GADOBENATE DIMEGLUMINE	N021357	INJECTABLE	2.645GM/5ML (529MG/ML)
GADOBENATE DIMEGLUMINE	N021357	INJECTABLE	5.29GM/10ML (529MG/ML)

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
GADOBENATE DIMEGLUMINE	N021357	INJECTABLE	7.935GM/15ML (529MG/ML)
GADOBENATE DIMEGLUMINE	N021357	INJECTABLE	10.58GM/20ML (529MG/ML)
GADOBENATE DIMEGLUMINE	N021358	INJECTABLE	26.45GM/50ML (529MG/ML)
GADOBENATE DIMEGLUMINE	N021358	INJECTABLE	52.9GM/100ML (529MG/ML)
GADODIAMIDE	N020123	INJECTABLE	287MG/ML
GADOXETATE DISODIUM	N022090	SOLUTION	2.72145GM/15ML (181.43MG/ML)
GADOXETATE DISODIUM	N022090	SOLUTION	1.8143GM/10ML (181.43MG/ML)
GEMCITABINE HYDROCHLORIDE	N209604	SOLUTION	200MG/2ML (100MG/ML)
GEMCITABINE HYDROCHLORIDE	N209604	SOLUTION	1GM/10ML (100MG/ML)
GEMCITABINE HYDROCHLORIDE	N209604	SOLUTION	1.5GM/15ML (100MG/ML)
GEMCITABINE HYDROCHLORIDE	N209604	SOLUTION	2GM/20ML (100MG/ML)
GLYCINE	N017865	SOLUTION	1.5GM/100ML
GLYCINE	N018315	SOLUTION	1.5GM/100ML
GLYCINE	N016784	SOLUTION	1.5GM/100ML
GLYCOPYRROLATE	N214919	SOLUTION	0.6MG/3ML (0.2MG/ML)
GLYCOPYRROLATE	N210997	SOLUTION	1MG/5ML (0.2MG/ML)
GLYCOPYRROLATE	N210997	SOLUTION	0.2MG/ML (0.2MG/ML)
GLYCOPYRROLATE	N210997	SOLUTION	0.4MG/2ML (0.2MG/ML)
GRANISETRON	N022445	INJECTABLE	10MG/0.4ML (10MG/0.4ML)
GRANISETRON	N022198	FILM, EXTENDED RELEASE	3.1MG/24HR
HEPARIN SODIUM	N017029	INJECTABLE	100 UNITS/ML
HEPARIN SODIUM	N017029	INJECTABLE	50 UNITS/ML
HEPARIN SODIUM	N019952	INJECTABLE	4,000 UNITS/100ML
HEPARIN SODIUM	N019339	INJECTABLE	5,000 UNITS/100ML
HEPARIN SODIUM	N018916	INJECTABLE	5,000 UNITS/100ML
HEPARIN SODIUM	N018916	INJECTABLE	10,000 UNITS/100ML
HEPARIN SODIUM	N017037	INJECTABLE	5,000 UNITS/0.5ML
HYDROCORTISONE ACETATE	N017351	AEROSOL, METERED	10%
HYDROMORPHONE HYDROCHLORIDE	N200403	INJECTABLE	4MG/ML
HYDROMORPHONE HYDROCHLORIDE	N217812	SOLUTION	40MG/20ML (2MG/ML)
HYDROMORPHONE HYDROCHLORIDE	N200403	INJECTABLE	0.25MG/0.5ML
HYDROMORPHONE HYDROCHLORIDE	N200403	INJECTABLE	0.5MG/0.5ML

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
HYDROXYCHLOROQUINE SULFATE	N214581	TABLET	200MG
HYDROXYCHLOROQUINE SULFATE	N214581	TABLET	300MG
HYDROXYUREA	N208843	TABLET	100MG
HYDROXYUREA	N208843	TABLET	1GM
INDOMETHACIN	N022536	INJECTABLE	EQ 1MG BASE/VIAL
IOHEXOL	N018956	SOLUTION	1.9%
IOHEXOL	N018956	SOLUTION	2.6%
IOHEXOL	N020608	SOLUTION	64.7%
IOHEXOL	N020608	SOLUTION	75.5%
IOHEXOL	N018956	INJECTABLE	30.2%
IOHEXOL	N018956	SOLUTION	38.8%
IOHEXOL	N018956	SOLUTION	51.8%
IOHEXOL	N018956	SOLUTION	64.7%
IOHEXOL	N018956	SOLUTION	75.5%
IOPROMIDE	N021425	INJECTABLE	62.3%
IOPROMIDE	N021425	INJECTABLE	76.9%
IOPROMIDE	N020220	INJECTABLE	76.9%
IOPROMIDE	N020220	INJECTABLE	62.3%
IOTHALAMATE MEGLUMINE	N017057	SOLUTION	17.2%
IOTHALAMATE MEGLUMINE	N013295	INJECTABLE	60%
IOTHALAMATE SODIUM I-125	N017279	INJECTABLE	250-300UCI/ML
IOVERSOL	N020923	INJECTABLE	64%
IOVERSOL	N020923	INJECTABLE	68%
IOVERSOL	N020923	INJECTABLE	74%
IOVERSOL	N019710	INJECTABLE	64%
IOVERSOL	N019710	INJECTABLE	74%
IOVERSOL	N019710	INJECTABLE	68%
ISOCARBOXAZID	N011961	TABLET	10MG
IXABEPILONE	N022065	INJECTABLE	15MG/VIAL
IXABEPILONE	N022065	INJECTABLE	45MG/VIAL
KETOROLAC TROMETHAMINE	N022382	SPRAY, METERED	15.75MG/SPRAY
LABETALOL HYDROCHLORIDE	N213330	SOLUTION	100MG/100ML (1MG/ML)
LABETALOL HYDROCHLORIDE	N213330	SOLUTION	200MG/200ML (1MG/ML)
LABETALOL HYDROCHLORIDE	N213330	SOLUTION	300MG/300ML (1MG/ML)
LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE	N022141	TABLET	300MG;300MG
LANREOTIDE ACETATE	N215395	SOLUTION	EQ 120MG BASE/0.5ML (EQ 120MG BASE/0.5ML)
LANREOTIDE ACETATE	N215395	SOLUTION	EQ 60MG BASE/0.2ML (EQ 60MG BASE/0.2ML)

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
LANREOTIDE ACETATE	N215395	SOLUTION	EQ 90MG BASE/0.3ML (EQ 90MG BASE/0.3ML)
LEFLUNOMIDE	N020905	TABLET	100MG
LEUPROLIDE ACETATE	N205054	FOR SUSPENSION	22.5MG/VIAL
LEUPROLIDE ACETATE	N020263	POWDER	11.25MG
LEUPROLIDE ACETATE	N020263	POWDER	30MG
LEUPROLIDE ACETATE	N020517	INJECTABLE	30MG
LEUPROLIDE ACETATE	N020708	INJECTABLE	11.25MG
LEUPROLIDE ACETATE	N020517	INJECTABLE	22.5MG
LEUPROLIDE ACETATE	N020011	INJECTABLE	3.75MG
LEUPROLIDE ACETATE	N020263	POWDER	15MG
LEUPROLIDE ACETATE	N020263	POWDER	7.5MG
LEUPROLIDE ACETATE	N019732	INJECTABLE	7.5MG
LEVOTHYROXINE SODIUM	N021924	CAPSULE	0.0375MG
LEVOTHYROXINE SODIUM	N021924	CAPSULE	0.044MG
LEVOTHYROXINE SODIUM	N021924	CAPSULE	0.0625MG
LEVOTHYROXINE SODIUM	N021924	CAPSULE	0.013MG
LEVOTHYROXINE SODIUM	N021924	CAPSULE	0.025MG
LEVOTHYROXINE SODIUM	N021924	CAPSULE	0.05MG
LIDOCAINE HYDROCHLORIDE	N019830	INJECTABLE	800MG/100ML
LIDOCAINE HYDROCHLORIDE	N018461	INJECTABLE	800MG/100ML
LINEZOLID	N206473	SOLUTION	600MG/300ML (2MG/ML)
LOMUSTINE	N017588	CAPSULE	10MG
LOMUSTINE	N017588	CAPSULE	40MG
LOMUSTINE	N017588	CAPSULE	100MG
LOTEPREDNOL ETABONATE	N200738	OINTMENT	0.5%
LOTEPREDNOL ETABONATE; TOBRAMYCIN	N050804	SUSPENSION/DROPS	0.5%;0.3%
LOVASTATIN	N021316	TABLET, EXTENDED RELEASE	20MG
LOVASTATIN	N021316	TABLET, EXTENDED RELEASE	40MG
LOVASTATIN	N021316	TABLET, EXTENDED RELEASE	60MG

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	N019696	INJECTABLE	30MG/100ML;37MG/100ML;0.82MG/100ML;370MG/100ML;530MG/100ML;500MG/100ML;12MG/100ML
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	N019711	INJECTABLE	30MG/100ML;37MG/100ML;370MG/100ML;530MG/100ML;500MG/100ML
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	N019024	SOLUTION	30MG/100ML;37MG/100ML;370MG/100ML;530MG/100ML;500MG/100ML
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	N017637	SOLUTION	30MG/100ML;37MG/100ML;222MG/100ML;526MG/100ML;502MG/100ML
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	N017586	INJECTABLE	30MG/100ML;37MG/100ML;222MG/100ML;526MG/100ML;502MG/100ML
MAGNESIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE	N021910	SOLUTION	0.21GM/100ML;2.8GM/100ML;9.07GM/100ML
MAGNESIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE	N021910	SOLUTION	0.21GM/100ML;3.97GM/100ML;8.3GM/100ML
MAGNESIUM SULFATE	N019316	SOLUTION	25GM/50ML (500MG/ML)
MAGNESIUM SULFATE	N020488	INJECTABLE	2GM/100ML
MAGNESIUM SULFATE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM PHOSPHATE	N018508	SOLUTION	20MG/100ML;40MG/100ML;6.25MG/100ML;800MG/100ML;8.75MG/100ML

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
MAGNESIUM SULFATE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM PHOSPHATE	N018336	SOLUTION	20MG/100ML;40MG/100ML;6.25MG/100ML;800MG/100ML;8.75MG/100ML
MANGANESE CHLORIDE	N018962	INJECTABLE	EQ 0.1MG MANGANESE/ML
MANNITOL	N020006	INJECTABLE	20GM/100ML
MANNITOL	N019603	INJECTABLE	20GM/100ML
MANNITOL	N013684	INJECTABLE	5GM/100ML
MARAVIROC	N208984	SOLUTION	20MG/ML
MELOXICAM	N021530	SUSPENSION	7.5MG/5ML
MEROPENEM	N202106	POWDER	500MG/VIAL
MEROPENEM	N202106	POWDER	1GM/VIAL
MESALAMINE	N020049	CAPSULE, EXTENDED RELEASE	250MG
METFORMIN HYDROCHLORIDE; SITAGLIPTIN	N216743	TABLET	1GM;50MG
METFORMIN HYDROCHLORIDE; SITAGLIPTIN	N216743	TABLET	500MG;50MG
METHACHOLINE CHLORIDE	N019193	FOR SOLUTION	100MG/VIAL
METRONIDAZOLE	N021806	GEL	0.75%
METRONIDAZOLE	N020743	CREAM	1%
MICAFUNGIN SODIUM	N216142	SOLUTION	EQ 100MG BASE/100ML (EQ 1MG BASE/ML)
MICAFUNGIN SODIUM	N216142	SOLUTION	EQ 150MG BASE/150ML (EQ 1MG BASE/ML)
MICAFUNGIN SODIUM	N216142	SOLUTION	EQ 50MG BASE/50ML (EQ 1MG BASE/ML)
MICAFUNGIN SODIUM	N212156	POWDER	EQ 100MG BASE/VIAL
MICAFUNGIN SODIUM	N212156	POWDER	EQ 50MG BASE/VIAL
MICONAZOLE	N022404	TABLET	50MG
MIDAZOLAM HYDROCHLORIDE	N216359	SOLUTION	EQ 10MG BASE/0.7ML (EQ 10MG BASE/0.7ML)
MILTEFOSINE	N204684	CAPSULE	50MG
MINOCYCLINE HYDROCHLORIDE	N050781	POWDER, EXTENDED RELEASE	EQ 1MG BASE
MITOTANE	N016885	TABLET	500MG
MOMETASONE FUROATE	N205641	AEROSOL, METERED	0.05MG/INH
MOMETASONE FUROATE	N205641	AEROSOL, METERED	0.10MG/INH

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
MOMETASONE FUROATE	N205641	AEROSOL, METERED	0.20MG/INH
MOMETASONE FUROATE	N021067	POWDER	0.11MG/INH
MOMETASONE FUROATE	N021067	POWDER	0.22MG/INH
MORPHINE SULFATE	N202515	INJECTABLE	50MG/ML
MOXIFLOXACIN HYDROCHLORIDE	N205572	SOLUTION	EQ 400MG BASE/250ML (EQ 1.6MG BASE/ML)
NAFCILLIN SODIUM	N050655	INJECTABLE	EQ 20MG BASE/ML
NAFCILLIN SODIUM	N050655	INJECTABLE	EQ 2GM BASE/100ML
NELFINAVIR MESYLATE	N021503	TABLET	EQ 625MG BASE
NELFINAVIR MESYLATE	N020779	TABLET	EQ 250MG BASE
NEOSTIGMINE METHYLSULFATE	N204078	SOLUTION	5MG/5ML (1MG/ML)
NEOSTIGMINE METHYLSULFATE	N203629	SOLUTION	10MG/10ML (1MG/ML)
NEOSTIGMINE METHYLSULFATE	N203629	SOLUTION	5MG/10ML (0.5MG/ML)
NICOTINE	N020385	SPRAY, METERED	0.5MG/SPRAY
NITROFURANTOIN	N009175	SUSPENSION	50MG/5ML
NITROGLYCERIN	N021780	AEROSOL, METERED	0.4MG/SPRAY
NITROGLYCERIN	N020145	FILM, EXTENDED RELEASE	0.3MG/HR
NITROGLYCERIN	N020145	FILM, EXTENDED RELEASE	0.8MG/HR
OLANZAPINE PAMOATE	N022173	SUSPENSION, EXTENDED RELEASE	EQ 210MG BASE/VIAL
OLANZAPINE PAMOATE	N022173	SUSPENSION, EXTENDED RELEASE	EQ 300MG BASE/VIAL
OLANZAPINE PAMOATE	N022173	SUSPENSION, EXTENDED RELEASE	EQ 405MG BASE/VIAL
OLSALAZINE SODIUM	N019715	CAPSULE	250MG
OMEPRAZOLE MAGNESIUM	N022056	FOR SUSPENSION, DELAYED RELEASE	EQ 2.5MG BASE/PACKET
OMEPRAZOLE MAGNESIUM	N022056	FOR SUSPENSION, DELAYED RELEASE	EQ 10MG BASE/PACKET
ORLISTAT	N020766	CAPSULE	120MG
OXACILLIN SODIUM	N050640	INJECTABLE	EQ 20MG BASE/ML
OXACILLIN SODIUM	N050640	INJECTABLE	EQ 40MG BASE/ML
OXAPROZIN	N217927	CAPSULE	300MG
OXICONAZOLE NITRATE	N020209	LOTION	EQ 1% BASE
PACLITAXEL	N211875	POWDER	100MG/VIAL
PALONOSETRON HYDROCHLORIDE	N203050	SOLUTION	EQ 0.25MG BASE/5ML (EQ 0.05MG BASE/ML)

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
PANTOPRAZOLE SODIUM	N217512	SOLUTION	EQ 40MG BASE/100ML (EQ 0.4MG BASE/ML)
PANTOPRAZOLE SODIUM	N217512	SOLUTION	EQ 40MG BASE/50ML (EQ 0.8MG BASE/ML)
PANTOPRAZOLE SODIUM	N217512	SOLUTION	EQ 80MG BASE/100ML (EQ 0.8MG BASE/ML)
PEMETREXED	N208419	SOLUTION	100MG/4ML (25MG/ML)
PEMETREXED	N208419	SOLUTION	1GM/40ML (25MG/ML)
PEMETREXED	N208419	SOLUTION	500MG/20ML (25MG/ML)
PEMETREXED DISODIUM	N214408	SOLUTION	EQ 100MG BASE/4ML (EQ 25MG BASE/ML)
PEMETREXED DISODIUM	N214408	SOLUTION	EQ 1GM BASE/40ML (EQ 25MG BASE/ML)
PEMETREXED DISODIUM	N214408	SOLUTION	EQ 500MG BASE/20ML (EQ 25MG BASE/ML)
PEMETREXED DISODIUM	N214408	SOLUTION	EQ 850MG BASE/34ML (EQ 25MG BASE/ML)
PEMETREXED DISODIUM	N214218	SOLUTION	EQ 100MG BASE/4ML (EQ 25MG BASE/ML)
PEMETREXED DISODIUM	N214218	SOLUTION	EQ 1GM BASE/40ML (EQ 25MG BASE/ML)
PEMETREXED DISODIUM	N214218	SOLUTION	EQ 500MG BASE/20ML (EQ 25MG BASE/ML)
PEMETREXED DISODIUM	N214657	SOLUTION	EQ 100MG BASE/4ML (EQ 25MG BASE/ML)
PEMETREXED DISODIUM	N214657	SOLUTION	EQ 1GM BASE/40ML (EQ 25MG BASE/ML)
PEMETREXED DISODIUM	N214657	SOLUTION	EQ 500MG BASE/20ML (EQ 25MG BASE/ML)
PEMETREXED DITROMETHAMINE	N208746	POWDER	EQ 100MG BASE/VIAL
PEMETREXED DITROMETHAMINE	N208746	POWDER	EQ 500MG BASE/VIAL
PENICILLIN G BENZATHINE; PENICILLIN G PROCAINE	N050138	INJECTABLE	900,000 UNITS/2ML;300,000 UNITS/2ML
PENICILLIN G BENZATHINE; PENICILLIN G PROCAINE	N050138	INJECTABLE	300,000 UNITS/ML;300,000 UNITS/ML
PENICILLIN G POTASSIUM	N050638	INJECTABLE	20,000 UNITS/ML
PENICILLIN G POTASSIUM	N050638	INJECTABLE	40,000 UNITS/ML
PENICILLIN G POTASSIUM	N050638	INJECTABLE	60,000 UNITS/ML
PENTOSAN POLYSULFATE SODIUM	N020193	CAPSULE	100MG
PHENDIMETRAZINE TARTRATE	N018074	CAPSULE, EXTENDED RELEASE	105MG
PHENTOLAMINE MESYLATE	N022159	INJECTABLE	0.4MG/1.7ML

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
PIPERACILLIN SODIUM; TAZOBACTAM SODIUM	N050750	INJECTABLE	EQ 40MG BASE/ML;EQ 5MG BASE/ML
PIPERACILLIN SODIUM; TAZOBACTAM SODIUM	N050750	INJECTABLE	EQ 4GM BASE/100ML;EQ 500MG BASE/100ML
PIPERACILLIN SODIUM; TAZOBACTAM SODIUM	N050750	INJECTABLE	EQ 60MG BASE/ML;EQ 7.5MG BASE/ML
PIVMECILLINAM HYDROCHLORIDE	N216483	TABLET	EQ 185MG BASE
POLIDOCANOL	N021201	SOLUTION	10MG/2ML (5MG/ML)
POLIDOCANOL	N021201	SOLUTION	20MG/2ML (10MG/ML)
POSACONAZOLE	N214770	FOR SUSPENSION, DELAYED RELEASE	300MG
POTASSIUM CHLORIDE	N208019	FOR SOLUTION	10MEQ
POTASSIUM CHLORIDE	N019904	INJECTABLE	2.24GM/100ML
POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019686	INJECTABLE	149MG/100ML;900MG/100ML
POVIDONE-IODINE	N018634	SOLUTION/DROPS	5%
PRALIDOXIME CHLORIDE	N014134	INJECTABLE	1GM/VIAL
PROCARBAZINE HYDROCHLORIDE	N016785	CAPSULE	EQ 50MG BASE
PROGESTERONE	N022057	INSERT	100MG
PROGESTERONE	N020701	GEL	4%
PROGESTERONE	N020701	GEL	8%
PROPRANOLOL HYDROCHLORIDE	N021438	CAPSULE, EXTENDED RELEASE	120MG
PROPRANOLOL HYDROCHLORIDE	N021438	CAPSULE, EXTENDED RELEASE	80MG
PYRIDOSTIGMINE BROMIDE	N017398	INJECTABLE	5MG/ML
PYRIDOSTIGMINE BROMIDE	N009830	INJECTABLE	5MG/ML
RIBOFLAVIN 5'-PHOSPHATE	N203324	SOLUTION/DROPS	0.146%
RIFAPENTINE	N021024	TABLET	150MG
RITONAVIR	N209512	POWDER	100MG/PACKET
SELEGILINE	N021336	FILM, EXTENDED RELEASE	6MG/24HR
SELEGILINE	N021336	FILM, EXTENDED RELEASE	9MG/24HR
SELEGILINE	N021336	FILM, EXTENDED RELEASE	12MG/24HR
SELEGILINE HYDROCHLORIDE	N021479	TABLET, ORALLY DISINTEGRATING	1.25MG
SERTRALINE HYDROCHLORIDE	N215133	CAPSULE	EQ 150MG BASE
SERTRALINE HYDROCHLORIDE	N215133	CAPSULE	EQ 200MG BASE
SILVER SULFADIAZINE	N018810	CREAM	1%

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
SILVER SULFADIAZINE	N018578	CREAM	1%
SILVER SULFADIAZINE	N017381	CREAM	1%
SODIUM CHLORIDE	N017427	SOLUTION	900MG/100ML
SODIUM CHLORIDE	N019635	SOLUTION	90MG/10ML (9MG/ML)
SODIUM CHLORIDE	N202832	INJECTABLE	90MG/10ML (9MG/ML)
SODIUM CHLORIDE	N019635	INJECTABLE	5GM/100ML
SODIUM CHLORIDE	N019319	SOLUTION FOR SLUSH	900MG/100ML
SODIUM CHLORIDE	N019022	INJECTABLE	5GM/100ML
SODIUM CHLORIDE	N202832	INJECTABLE	18MG/2ML (9MG/ML)
SODIUM CHLORIDE	N202832	INJECTABLE	27MG/3ML (9MG/ML)
SODIUM CHLORIDE	N202832	INJECTABLE	45MG/5ML (9MG/ML)
SODIUM CHLORIDE	N021569	INJECTABLE	1.125GM/125ML (9MG/ML)
SODIUM CHLORIDE	N017514	SOLUTION	900MG/100ML
SODIUM CHLORIDE	N017867	SOLUTION	900MG/100ML
SODIUM CHLORIDE	N018314	SOLUTION	900MG/100ML
SODIUM IODIDE I-131	N021305	CAPSULE	0.009-0.1MCI
SODIUM PHENYLBUTYRATE	N216513	PELLETS	84GM/BOT
SORBITOL	N017863	SOLUTION	3GM/100ML
SORBITOL	N016741	SOLUTION	3.3GM/100ML
STERILE WATER FOR IRRIGATION	N017428	LIQUID	100%
STERILE WATER FOR IRRIGATION	N017513	LIQUID	100%
STERILE WATER FOR IRRIGATION	N017866	LIQUID	100%
STERILE WATER FOR IRRIGATION	N018313	LIQUID	100%
SUCCIMER	N019998	CAPSULE	100MG
TAMOXIFEN CITRATE	N021807	SOLUTION	EQ 20MG BASE/10ML
TECHNETIUM TC-99M EXAMETAZIME KIT	N019829	INJECTABLE	NA
TECHNETIUM TC-99M MEDRONATE KIT	N018107	INJECTABLE	NA
TECHNETIUM TC-99M MEDRONATE KIT	N018124	INJECTABLE	NA
TECHNETIUM TC-99M MERTIATIDE KIT	N216820	POWDER	NA
TECHNETIUM TC-99M PYROPHOSPHATE KIT	N019039	INJECTABLE	NA
TECHNETIUM TC-99M PYROPHOSPHATE KIT	N017538	INJECTABLE	NA
TECHNETIUM TC-99M TETROFOSMIN KIT	N020372	INJECTABLE	NA
TEMOZOLOMIDE	N022277	POWDER	100MG/VIAL
TENOFOVIR DISOPROXIL FUMARATE	N022577	POWDER	40MG/SCOOPFUL

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
TERIPARATIDE	N211939	SOLUTION	0.56MG/2.24ML (0.25MG/ML)
TETRACAINE HYDROCHLORIDE	N208135	SOLUTION	0.5%
THALIDOMIDE	N020785	CAPSULE	100MG
THALIDOMIDE	N020785	CAPSULE	200MG
THALIDOMIDE	N020785	CAPSULE	50MG
THIOGUANINE	N012429	TABLET	40MG
TIPRANAVIR	N021814	CAPSULE	250MG
TIROFIBAN HYDROCHLORIDE	N020912	SOLUTION	EQ 3.75MG BASE/15ML (EQ 0.25MG BASE/ML)
TOPOTECAN HYDROCHLORIDE	N020981	CAPSULE	EQ 0.25MG BASE
TOPOTECAN HYDROCHLORIDE	N020981	CAPSULE	EQ 1MG BASE
TORSEMIDE	N213218	TABLET	40MG
TRAMADOL HYDROCHLORIDE	N022370	CAPSULE, EXTENDED RELEASE	100MG
TRAMADOL HYDROCHLORIDE	N022370	CAPSULE, EXTENDED RELEASE	200MG
TRAMADOL HYDROCHLORIDE	N022370	CAPSULE, EXTENDED RELEASE	300MG
TRETINOIN	N020475	GEL	0.06%
TRETINOIN	N021108	CREAM	0.02%
TRIPTORELIN PAMOATE	N021288	INJECTABLE	EQ 11.25MG BASE/VIAL
TRIPTORELIN PAMOATE	N020715	INJECTABLE	EQ 3.75MG BASE/VIAL
TRYPAN BLUE	N021670	SOLUTION	0.06%
URIDINE TRIACETATE	N208169	GRANULE	2GM/PACKET
VANCOMYCIN HYDROCHLORIDE	N210274	POWDER	EQ 10GM BASE/VIAL
VANCOMYCIN HYDROCHLORIDE	N210274	POWDER	EQ 1GM BASE/VIAL
VANCOMYCIN HYDROCHLORIDE	N210274	POWDER	EQ 500MG BASE/VIAL
VANCOMYCIN HYDROCHLORIDE	N210274	POWDER	EQ 5GM BASE/VIAL
VANCOMYCIN HYDROCHLORIDE	N050671	SOLUTION	EQ 750MG BASE/150ML (EQ 5MG BASE/ML)
VANCOMYCIN HYDROCHLORIDE	N050671	SOLUTION	EQ 1GM BASE/200ML (EQ 5MG BASE/ML)
VANCOMYCIN HYDROCHLORIDE	N050671	SOLUTION	EQ 500MG BASE/100ML (EQ 5MG BASE/ML)
VANCOMYCIN HYDROCHLORIDE	N050671	SOLUTION	EQ 1.25GM BASE/250ML (EQ 5MG BASE/ML)

Rx List Part I

Ingredient	Approved NDA	Dosage Form	Strength
VANCOMYCIN HYDROCHLORIDE	N050671	SOLUTION	EQ 1.5GM BASE/300ML (EQ 5MG BASE/ML)
VASOPRESSIN	N217569	SOLUTION	20UNITS/100ML (0.2UNITS/ML)
VASOPRESSIN	N217569	SOLUTION	40UNITS/100ML (0.4UNITS/ML)
VASOPRESSIN	N212593	SOLUTION	200UNITS/10ML (20UNITS/ML)
VASOPRESSIN	N212593	SOLUTION	20UNITS/ML (20UNITS/ML)
VERAPAMIL HYDROCHLORIDE	N019614	CAPSULE, EXTENDED RELEASE	360MG
VERTEPORFIN	N021119	INJECTABLE	15MG/VIAL
VORICONAZOLE	N208562	INJECTABLE	200MG/VIAL
ZICONOTIDE ACETATE	N021060	INJECTABLE	100MCG/1ML (100MCG/ML)
ZICONOTIDE ACETATE	N021060	INJECTABLE	500MCG/20ML (25MCG/ML)
ZICONOTIDE ACETATE	N021060	INJECTABLE	500MCG/5ML (100MCG/ML)
ZILEUTON	N020471	TABLET	600MG
ZOLEDRONIC ACID	N204016	SOLUTION	EQ 4MG BASE/100ML (EQ 0.04MG BASE/ML)
ZOLPIDEM TARTRATE	N215721	CAPSULE	7.5MG

Rx List Part II

Ingredient	Approved NDA	Dosage Form	Strength
ACETOHYDROXAMIC ACID	N018749	TABLET	250MG
ALBUTEROL SULFATE	N020983	AEROSOL, METERED	EQ 0.09MG BASE/INH
AZTREONAM	N050814	FOR SOLUTION	75MG/VIAL
CARMUSTINE	N020637	IMPLANT	7.7MG
COLISTIN SULFATE; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; THONZONIUM BROMIDE	N050356	SUSPENSION/DROPS	EQ 3MG BASE/ML;10MG/ML;EQ 3.3MG BASE/ML;0.5MG/ML
CYSTEAMINE BITARTRATE	N020392	CAPSULE	EQ 50MG BASE
CYSTEAMINE BITARTRATE	N020392	CAPSULE	EQ 150MG BASE
DEXAMETHASONE	N022315	IMPLANT	0.7MG
DIATRIZOATE MEGLUMINE	N010040	SOLUTION	18%
EPINEPHRINE	N020800	INJECTABLE	EQ 0.15MG/DELIVERY
EPINEPHRINE	N020800	INJECTABLE	EQ 0.3MG/DELIVERY
ESTRADIOL	N020472	INSERT, EXTENDED RELEASE	0.0075MG/24HR
ESTRADIOL ACETATE	N021367	INSERT, EXTENDED RELEASE	EQ 0.05MG BASE/24HR
ESTRADIOL ACETATE	N021367	INSERT, EXTENDED RELEASE	EQ 0.1MG BASE/24HR
ESTROGENS, CONJUGATED	N020216	CREAM	0.625MG/GM
ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE	N020527	TABLET	0.3MG;1.5MG
ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE	N020527	TABLET	0.45MG;1.5MG
ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE	N020527	TABLET	0.625MG;5MG
ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE	N020527	TABLET	0.625MG;2.5MG
ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE	N020527	TABLET	0.625MG,0.625MG;N/A,5MG
FERRIC HEXACYANOFERRATE(II)	N021626	CAPSULE	500MG
FLUOCINOLONE ACETONIDE	N021737	IMPLANT	0.59MG
FLUOROMETHOLONE	N019216	SUSPENSION/DROPS	0.25%
FLUOROMETHOLONE ACETATE	N019079	SUSPENSION/DROPS	0.1%
FLURANDRENOLIDE	N016455	TAPE	0.004MG/SQ CM
FISH OIL; MEDIUM CHAIN TRIGLYCERIDES; OLIVE OIL; SOYBEAN OIL	N207648	EMULSION	3GM/100ML;6GM/100ML;5GM/100ML ;6GM/100ML (100ML)

Rx List Part II

Ingredient	Approved NDA	Dosage Form	Strength
FLUTICASONE PROPIONATE	N021433	AEROSOL, METERED	0.044MG/INH
FLUTICASONE PROPIONATE	N020833	POWDER	0.05MG/INH
FLUTICASONE PROPIONATE	N020833	POWDER	0.1MG/INH
FLUTICASONE PROPIONATE	N020833	POWDER	0.25MG/INH
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE	N021254	AEROSOL, METERED	0.045MG/INH;EQ 0.021MG BASE/INH
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE	N021254	AEROSOL, METERED	0.115MG/INH;EQ 0.021MG BASE/INH
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE	N021254	AEROSOL, METERED	0.23MG/INH;EQ 0.021MG BASE/INH
GADOTERIDOL	N021489	INJECTABLE	279.3MG/ML
GALLIUM CITRATE GA-67	N018058	INJECTABLE	2MCI/ML
GANCICLOVIR	N022211	GEL	0.2%
GLUCAGON HYDROCHLORIDE	N201849	POWDER	EQ 1MG BASE/VIAL
GLUCAGON HYDROCHLORIDE	N201849	POWDER	EQ 1MG BASE/VIAL
GOSERELIN ACETATE	N020578	IMPLANT	EQ 10.8MG BASE
GOSERELIN ACETATE	N019726	IMPLANT	EQ 3.6MG BASE
FISH OIL; MEDIUM CHAIN TRIGLYCERIDES; OLIVE OIL; SOYBEAN OIL	N207648	EMULSION	3GM/100ML;6GM/100ML;5GM/100ML ;6GM/100ML (250ML)
FISH OIL; MEDIUM CHAIN TRIGLYCERIDES; OLIVE OIL; SOYBEAN OIL	N207648	EMULSION	3GM/100ML;6GM/100ML;5GM/100ML ;6GM/100ML (500ML)
HEXACHLOROPHENE	N017433	SPONGE	480MG
HEXACHLOROPHENE	N017433	SPONGE	480MG
HYDROXOCOBALAMIN	N022041	INJECTABLE	5GM/VIAL (5GM/KIT)
ICODEXTRIN	N021321	SOLUTION	7.5GM/100ML
INDIUM IN-111 PENTETATE DISODIUM	N017707	INJECTABLE	1MCI/ML
IRON DEXTRAN	N017441	INJECTABLE	EQ 100MG IRON/2ML (EQ 50MG IRON/ML)
FISH OIL; MEDIUM CHAIN TRIGLYCERIDES; OLIVE OIL; SOYBEAN OIL	N207648	EMULSION	3GM/100ML;6GM/100ML;5GM/100ML ;6GM/100ML (1000ML)
LEVALBUTEROL TARTRATE	N021730	AEROSOL, METERED	EQ 0.045MG BASE/INH
LIDOCAINE; PRILOCAINE	N021451	GEL	2.5%;2.5%
MAFENIDE ACETATE	N016763	CREAM	EQ 85MG BASE/GM
MANNITOL	N022368	POWDER	N/A,5MG,10MG,20MG,40MG
MEDROXYPROGESTERONE ACETATE	N021583	INJECTABLE	104MG/0.65ML
METHOXSALEN	N020969	INJECTABLE	0.02MG/ML
METYRAPONE	N012911	CAPSULE	250MG
MUPIROCIN	N050788	OINTMENT	2%
NAFARELIN ACETATE	N019886	SPRAY, METERED	EQ 0.2MG BASE/SPRAY
NATAMYCIN	N050514	SUSPENSION	5%

Rx List Part II

Ingredient	Approved NDA	Dosage Form	Strength
OXYTOCIN	N018261	INJECTABLE	500USP UNITS/50ML (10USP UNITS/ML)
OXYTOCIN	N018248	INJECTABLE	300USP UNITS/30ML (10USP UNITS/ML)
PENICILLIN G BENZATHINE	N050141	INJECTABLE	600,000 UNITS/ML
PORFIMER SODIUM	N020451	INJECTABLE	75MG/VIAL
PREDNISOLONE ACETATE	N017100	SUSPENSION/DROPS	0.12%
RADIUM RA-223 DICHLORIDE	N203971	SOLUTION	162MCI/6ML (27MCI/ML)
RUBIDIUM CHLORIDE RB-82	N202153	SOLUTION	NA
RUBIDIUM CHLORIDE RB-82	N019414	INJECTABLE	NA
SALMETEROL XINAFOATE	N020692	POWDER	EQ 0.05MG BASE/INH
SECRETIN SYNTHETIC HUMAN	N021256	FOR SOLUTION	40MCG/VIAL
SECRETIN SYNTHETIC HUMAN	N021256	FOR SOLUTION	16MCG/VIAL
SERTACONAZOLE NITRATE	N021385	CREAM	2%
SINCALIDE	N017697	POWDER	0.005MG/VIAL
SOYBEAN OIL	N020248	INJECTABLE	20%
SOYBEAN OIL	N019942	INJECTABLE	30%
SOYBEAN OIL	N018449	INJECTABLE	20%
SULCONAZOLE NITRATE	N018737	CREAM	1%
SULCONAZOLE NITRATE	N018738	SOLUTION	1%
TALC	N205555	POWDER	2GM/VIAL
TALC	N205555	POWDER	3GM/VIAL
TALC	N205555	POWDER	4GM/VIAL
TALC	N021388	POWDER	5GM/BOT
TALC	N020587	AEROSOL	4GM/SPRAY
TECHNETIUM TC-99M BICISATE KIT	N020256	INJECTABLE	NA
TECHNETIUM TC-99M EXAMETAZIME KIT	N208870	POWDER	NA
TECHNETIUM TC-99M MEDRONATE	N018035	INJECTABLE	NA
TECHNETIUM TC-99M OXIDRONATE KIT	N018321	INJECTABLE	NA
TECHNETIUM TC-99M RED BLOOD CELL KIT	N019981	INJECTABLE	NA
TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR	N017243	SOLUTION	1-19 CI/GENERATOR
TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR	N017771	SOLUTION	1-20 CI/GENERATOR
TECHNETIUM TC-99M SUCCIMER	N214993	POWDER	NA
TERCONAZOLE	N021735	CREAM	1%

Rx List Part II

Ingredient	Approved NDA	Dosage Form	Strength
TOBRAMYCIN	N050555	OINTMENT	0.3%
XENON XE-133	N018327	GAS	10MCI/VIAL
XENON XE-133	N018327	GAS	20MCI/VIAL
XENON XE-133	N017284	GAS	10MCI/VIAL
XENON XE-133	N017284	GAS	20MCI/VIAL
ZANAMIVIR	N021036	POWDER	5MG
ZINC ACETATE	N020458	CAPSULE	EQ 25MG ZINC
ZINC ACETATE	N020458	CAPSULE	EQ 50MG ZINC

Rx List Appendix

Ingredient	Approved NDA	Dosage Form	Strength
ALBUMIN HUMAN	N020899	INJECTABLE	10MG/ML
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM GLYCEROPHOSPHATE; SOYBEAN OIL	N200656	EMULSION	2.4%;20MG/100ML;6.8GM/100ML;68 MG/100ML;124MG/100ML;170MG/10 0ML;105MG/100ML;3.5GM/100ML (1440ML)
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM GLYCEROPHOSPHATE; SOYBEAN OIL	N200656	EMULSION	2.4%;20MG/100ML;6.8GM/100ML;68 MG/100ML;124MG/100ML;170MG/10 0ML;105MG/100ML;3.5GM/100ML (1920ML)
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM GLYCEROPHOSPHATE; SOYBEAN OIL	N200656	EMULSION	2.4%;20MG/100ML;6.8GM/100ML;68 MG/100ML;124MG/100ML;170MG/10 0ML ;105MG/100ML;3.5GM/100ML (2400ML)
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM GLYCEROPHOSPHATE; SOYBEAN OIL	N200656	EMULSION	3.3%;29MG/100ML;9.8GM/100ML;96 MG/100ML;174MG/100ML;239MG/10 0ML ;147MG/100ML;3.9GM/100ML (1026ML)
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM GLYCEROPHOSPHATE; SOYBEAN OIL	N200656	EMULSION	3.3%;29MG/100ML;9.8GM/100ML;96 MG/100ML;174MG/100ML;239MG/10 0ML;147MG/100ML;3.9GM/100ML (1540ML)
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM GLYCEROPHOSPHATE; SOYBEAN OIL	N200656	EMULSION	3.3%;29MG/100ML;9.8GM/100ML;96 MG/100ML;174MG/100ML;239MG/10 0ML;147MG/100ML;3.9GM/100ML (2053ML)

Rx List Appendix

Ingredient	Approved NDA	Dosage Form	Strength
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM GLYCEROPHOSPHATE; SOYBEAN OIL	N200656	EMULSION	3.3%;29MG/100ML;9.8GM/100ML;96MG/100ML;174MG/100ML;239MG/100ML;147MG/100ML;3.9GM/100ML (2566ML)
AMPHOTERICIN B	N050724	INJECTABLE, LIPID COMPLEX	5MG/ML
ASCORBIC ACID	N209112	SOLUTION	25,000MG/50ML (500MG/ML)
BACLOFEN	N208193	SOLUTION	10MG/5ML
CEFAZOLIN SODIUM	N050779	INJECTABLE	EQ 1GM BASE/VIAL
CHLORTHALIDONE	N019574	TABLET	25MG
CIPROFLOXACIN HYDROCHLORIDE; HYDROCORTISONE	N020805	SUSPENSION/DROPS	EQ 0.2% BASE;1%
DECITABINE	N205582	POWDER	50MG/VIAL
DIAZEPAM	N020648	GEL	2.5MG/0.5ML (5MG/ML)
DROSPIRENONE; ESTRADIOL	N021355	TABLET	0.5MG;1MG
EPHEDRINE HYDROCHLORIDE	N213536	SOLUTION	47MG/10ML (4.7MG/ML)
EPINEPHRINE	N205029	SOLUTION	30MG/30ML (1MG/ML)
ESTROGENS, CONJUGATED	N004782	TABLET	0.9MG
ESTROGENS, CONJUGATED	N004782	TABLET	1.25MG
ESTROGENS, CONJUGATED	N004782	TABLET	0.3MG
ESTROGENS, CONJUGATED	N004782	TABLET	0.45MG
ESTROGENS, CONJUGATED	N004782	TABLET	0.625MG
ETHIONAMIDE	N013026	TABLET	250MG
FLORBETAPIR F-18	N202008	SOLUTION	10-100ML (13.5-51MCI/ML)
GABAPENTIN	N022544	TABLET	450MG
GABAPENTIN	N022544	TABLET	750MG
GABAPENTIN	N022544	TABLET	900MG
IOHEXOL	N018956	SOLUTION	64.7%
IOVERSOL	N020923	INJECTABLE	64%
IRON SUCROSE	N021135	INJECTABLE	EQ 100MG IRON/5ML (EQ 20MG IRON/ML)
IRON SUCROSE	N021135	INJECTABLE	EQ 200MG IRON/10ML (EQ 20MG IRON/ML)
IRON SUCROSE	N021135	INJECTABLE	EQ 50MG IRON/2.5ML (EQ 20MG IRON/ML)
LOMUSTINE	N017588	CAPSULE	100MG
LOMUSTINE	N017588	CAPSULE	10MG
LOMUSTINE	N017588	CAPSULE	40MG
LOTEPREDNOL ETABONATE; TOBRAMYCIN	N050804	SUSPENSION/DROPS	0.5%;0.3%

Rx List Appendix

Ingredient	Approved NDA	Dosage Form	Strength
LOVASTATIN	N021316	TABLET, EXTENDED RELEASE	20MG
LOVASTATIN	N021316	TABLET, EXTENDED RELEASE	40MG
LOVASTATIN	N021316	TABLET, EXTENDED RELEASE	60MG
MAGNESIUM SULFATE	N019316	SOLUTION	25GM/50ML (500MG/ML)
MANGANESE CHLORIDE	N018962	INJECTABLE	EQ 0.1MG MANGANESE/ML
MICAFUNGIN SODIUM	N216142	SOLUTION	EQ 100MG BASE/100ML (EQ 1MG BASE/ML)
MICAFUNGIN SODIUM	N216142	SOLUTION	EQ 150MG BASE/150ML (EQ 1MG BASE/ML)
MICAFUNGIN SODIUM	N216142	SOLUTION	EQ 50MG BASE/50ML (EQ 1MG BASE/ML)
PEMETREXED DISODIUM	N214408	SOLUTION	EQ 100MG BASE/4ML (EQ 25MG BASE/ML)
PEMETREXED DISODIUM	N214408	SOLUTION	EQ 1GM BASE/40ML (EQ 25MG BASE/ML)
PEMETREXED DISODIUM	N214408	SOLUTION	EQ 500MG BASE/20ML (EQ 25MG BASE/ML)
PEMETREXED DISODIUM	N214408	SOLUTION	EQ 850MG BASE/34ML (EQ 25MG BASE/ML)
PEMETREXED DITROMETHAMINE	N208746	POWDER	EQ 100MG BASE/VIAL
PEMETREXED DITROMETHAMINE	N208746	POWDER	EQ 500MG BASE/VIAL
PRAMLINTIDE ACETATE	N021332	INJECTABLE	EQ 1.5MG BASE/1.5ML (EQ 1MG BASE/ML)
PRAMLINTIDE ACETATE	N021332	INJECTABLE	EQ 2.7MG BASE/2.7ML (EQ 1MG BASE/ML)
PREDNISOLONE ACETATE	N017469	SUSPENSION/DROPS	1%
PROGESTERONE	N022057	INSERT	100MG
SERTRALINE HYDROCHLORIDE	N215133	CAPSULE	EQ 150MG BASE
SERTRALINE HYDROCHLORIDE	N215133	CAPSULE	EQ 200MG BASE
SODIUM CHLORIDE	N202832	INJECTABLE	90MG/10ML (9MG/ML)
SODIUM CHLORIDE	N202832	INJECTABLE	18MG/2ML (9MG/ML)
SODIUM CHLORIDE	N202832	INJECTABLE	27MG/3ML (9MG/ML)
SODIUM CHLORIDE	N202832	INJECTABLE	45MG/5ML (9MG/ML)
ZILEUTON	N020471	TABLET	600MG
ZOLEDRONIC ACID	N204016	SOLUTION	EQ 4MG BASE/100ML (EQ 0.04MG BASE/ML)

Methodology[1]

1. The list is based on the Orange Book Data Files, accessed December 15, 2025.

2. The list includes Orange Book-listed drug products that are marketed as prescription drug products.[2] The Agency has identified the corresponding NDA numbers for drug products included on the list to assist applicants with identification of the correct reference listed drug (RLD).

3. A given drug product is included on the list if:

   a. There is at least one active and approved NDA for the drug product,[3,4] and

   b. The relevant NDA for the drug product is marketed as a prescription drug product, and

   c. There are no approved ANDAs for the drug product,[5] and

   d. There are no unexpired patents or exclusivities listed in the Orange Book for the drug product.[6]

4. Each drug product and corresponding NDA number is then placed on either Part I or Part II of the list based on the following criteria:

   a. Part I of the list identifies those drug products for which FDA could immediately accept an ANDA without prior discussion with the Agency.

   b. Part II identifies drug products for which development and submission of an ANDA could involve potential legal, regulatory, or scientific issues that should be addressed with the Agency prior to considering submission of an ANDA.

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[1] FDA notes that the methodology used to compile the original list (posted in June 2017) was updated in December 2017. Under the updated methodology, the list is organized based on drug products, not active ingredients. The methodology was updated again in June 2025 to include the strength. This means that an active and approved NDA for a particular active ingredient, dosage form, and strength will be included on the list if there are no approved ANDAs for that specific active ingredient, dosage form, and strength approved in the NDA.[2] Products approved under NDAs that are marketed as prescription drugs are listed in the Orange Book with a marketing status of "RX" or "prescription."

[3] "Active and approved" means that the NDA for the relevant drug product is approved and listed in the Orange Book, and is not identified as a "discontinued" product in the Orange Book. If all approved NDAs for a given drug product are identified as "discontinued" in the Orange Book, that drug product is not included on the list.

[4] Drug products with only approved and Orange Book-listed ANDAs but no Orange Book-listed NDAs are not included on the list.

[5] Drug products with an approved but discontinued ANDA are not included on the list.

[6] Drug products that have at least one Orange Book-listed patent or exclusivity are not included on the list.