

Drug/Strength	Petition No	Dosage Form	Status	Status Date
ABACAVIR SULFATE 60 MG	07P-0407	TABLETS	Pending	10/31/2007
abiraterone acetate, 250mg	15P-2374	Tablet; Oral	Pending	7/7/2015
ACETAMINOPHEN 120 MG	94P-0182	CHEWABLE TABLET	Withdrawn	3/26/2007
ACETAMINOPHEN 150 MG	94P-0212	TABLET	Withdrawn	3/26/2007
ACETAMINOPHEN 150 MG	94P-0211	TABLET	Withdrawn	3/26/2007
ACETAMINOPHEN 150 MG	94P-0210	TABLET	Withdrawn	3/26/2007
ACETAMINOPHEN 150 MG	92P-0282	CAPSULE OR TABLET	Withdrawn	3/26/2007
ACETAMINOPHEN 150 MG	92P-0282	CAPSULE OR TABLET	Withdrawn	3/26/2007
ACETAMINOPHEN 150 MG	92P-0282	CAPSULE OR TABLET	Withdrawn	3/26/2007
ACETAMINOPHEN 150 MG	92P-0282	CAPSULE OR TABLET	Withdrawn	3/26/2007
ACETAMINOPHEN 160 MG/5ML	87P-0323	SYRUP	Withdrawn	3/26/2007
ACETAMINOPHEN 200MG;200MG; 200MG, HYDROCODONE BITARTRATE 5MG;7.5MG;10MG	02P-0004	TABLET; ORAL	Denied	3/17/2003
ACETAMINOPHEN 300 MG	85P-0543	SOFT GELATIN CAPSULE	Withdrawn	3/26/2007
ACETAMINOPHEN 300 MG, BUTALBITAL 50 MG	04P-0561	CAPSULES	Approved	3/31/2005
ACETAMINOPHEN 300 MG, BUTALBITAL 50 MG	04P-0560	CAPSULES	Approved	3/31/2005
ACETAMINOPHEN 312.5 mg, CAFFEINE 60 mg	12P-0775	TABLET	Pending	7/26/2012
ACETAMINOPHEN 312.5 MG, PENTAZOCINE HCL 25 MG	12P-0478	TABLETS	Pending	5/24/2012
ACETAMINOPHEN 320.5 MG, CAFFEINE 30 MG	11P-0728	CAPSULES	Approved	7/7/2012
ACETAMINOPHEN 325 MG	93P-0346	CAPSULE OR TABLET	Withdrawn	3/26/2007
ACETAMINOPHEN 325 MG	86P-0361	TABLET	Withdrawn	3/26/2007
ACETAMINOPHEN 325 MG ; 325 MG, OXYCODONE HYDROCHLORIDE 4.5 MG ; 2.25 MG	98P-1219	TABLET; ORAL	Denied	2/26/2001
ACETAMINOPHEN 325 MG BUTALBITAL 25 MG	11P-0093	TABLETS	Approved	4/18/2012
ACETAMINOPHEN 325 MG, CAFFEINE 30 MG	11P-0096	TABLETS	Approved	9/27/2012

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ACETAMINOPHEN 325 MG/ PROPOXYPHENE NAPSYLATE 100 MG	99P-2247	TABLET; ORAL, CAPSULE;ORAL	Denied	3/2/2001
ACETAMINOPHEN 400 MG, BUTALBITAL 50 MG	07P-0030	CAPSULES	Approved	6/9/2008
ACETAMINOPHEN 400 MG;400 MG:400MG; HYDROCODONE BITARTRATE 5MG;7.5 MG:10 MG	99P-4107	LIQUID; ORAL	Denied	3/2/2001
ACETAMINOPHEN 50 MG	99P-4649	TABLET/CAPSUL ES; ORAL	Denied	3/1/2001
ACETAMINOPHEN 500 MG	10P-0011	TABLETS	Withdrawn	1/25/2010
ACETAMINOPHEN 500 MG	93P-0314	CAPSULE OR TABLET	Withdrawn	3/26/2007
ACETAMINOPHEN 500 MG	85P-0581	SOFT GELATIN CAPSULE	Withdrawn	3/26/2007
ACETAMINOPHEN 500 MG	85P-0543	SOFT GELATIN CAPSULE	Withdrawn	3/26/2007
ACETAMINOPHEN 500 MG	85P-0543	SOFT GELATIN CAPSULE	Withdrawn	3/26/2007
ACETAMINOPHEN 500 MG	84P-0228	CAPSULE	Withdrawn	3/26/2007
ACETAMINOPHEN 500 MG BUTALBITAL 50 MG	99P-2149	TABLET; ORAL, CAPSULE;ORAL	Denied	4/14/2000
ACETAMINOPHEN 500 mg OXYCODONE HYDROCHLORIDE 10 mg	99P-2798	TABLET; ORAL	Approved	6/13/2000
ACETAMINOPHEN 500 MG, CODEINE PHOSPHATE 15 MG, 30 MG, 60 MG	08P-0127	TABLET, EFFERVESCENT	Withdrawn	3/23/2011
ACETAMINOPHEN 500 MG/15 ML/ OXYCODONE HYDROCHLORIDE 7.5 MG/15 ML	99P-2776	LIQUID; ORAL	Denied	6/13/2000
ACETAMINOPHEN 534.6 MG, CAFFEINE 45 MG	07P-0272	TABLETS	Withdrawn	11/30/2011
ACETAMINOPHEN 650 MG	86P-0200	CAPSULE OR TABLET	Withdrawn	3/26/2007
ACETAMINOPHEN 650 MG, BUTALBITAL 50 MG	07P-0194	CAPSULES	Withdrawn	11/30/2011
ACETAMINOPHEN 650 MG/BUTALBITAL 50 MG	99P-1657	TABLET; ORAL, CAPSULE;ORAL	Approved	4/14/2000
ACETAMINOPHEN 750 MG BUTALBITAL 50 MG	99P-2150	TABLET; ORAL, CAPSULE;ORAL	Approved	4/14/2000
ACETAMINOPHEN 770 MG, 385 MG, CAFFEINE 60 MG, 30 MG	03P-0505	TABLET	Withdrawn	10/19/2004

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ACETAMINOPHEN; 320 MG/10 ML, HYDROCODONE BITARTRATE 10 MG/10 ML	01P-0130	SOLUTION; ORAL	Denied	7/9/2002
ACETAMINOPHEN; 325 MG & 500MG/15 ML, HYDROCODONE BITARTRATE 10 MG/15 ML	00P-1243	SOLUTION; ORAL	Denied	5/7/2001
ACETAMINOPHEN; 325 MG/15 ML, HYDROCODONE BITARTRATE 7.5 MG/15 ML	01P-0214	SOLUTION; ORAL	Approved	8/20/2001
ACETAMINOPHEN; 325mg and 325 mg, OXYCODONE HYDROCHLORIDE 7.5 mg and 10 mg	00P-1270	TABLET; ORAL	Approved	9/9/2000
ACETAMINOPHEN; 325MG/10ML, HYDROCODONE BITARTRATE 10MG/10ML	00P-1291	SOLUTION; ORAL	Denied	5/7/2001
ACETAMINOPHEN; 400mg per tab, OXYCODONE HYDROCHLORIDE 2.5mg;5mg;7.5mg;10mg	00P-1271	TABLET; ORAL	Approved	9/9/2000
ACETAMINOPHEN; 500 MG, HYDROCODONE BITARTRATE 10 MG	01P-0251	SOLUTION; ORAL	Withdrawn	8/23/2001
ACETAMINOPHEN; 500 MG, PROPOXYPHENE NAPSYLATE 100 MG	00P-1324	TABLETS AND/OR CAPSULES	Denied	4/30/2001
ACETAMINOPHEN; 500 MG/15 ML, HYDROCODONE BITARTRATE 10 MG/15 ML	01P-0144	SOLUTION; ORAL	Approved	8/20/2001
ACETAMINOPHEN; 650 MG/ 30 ML HYDROCODONE BITARTRATE 10 MG/30 ML	00P-1243	SOLUTION; ORAL	Denied	5/7/2001
ACETAMINOPHEN; 650 MG/15 ML, HYDROCODONE BITARTRATE 10 MG/15 ML	01P-0130	SOLUTION; ORAL	Approved	8/20/2001
ACETAMINOPHEN; 650MG/30 ML; HYDROCODONE BITARTRATE 10MG/30ML	00P-1431	SOLUTION; ORAL	Withdrawn	9/6/2000
ACETAZOLAMIDE 500 MG	13P-1296	TABLET; EXTENDED- RELEASE; ORAL	Pending	11/15/2013

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ACYCLOVIR 200 MG	99P-5452	TABLETS FOR ORAL SUSPENSION	Approved	6/13/2000
ACYCLOVIR 400MG & 800 MG	99P-5453	TABLET; FOR ORAL SUSPENSION	Approved	6/13/2000
ACYCLOVIR 5%	96P-0307	CREAM; TOPICAL	Withdrawn	3/26/2007
ACYCLOVIR SODIUM 5 MG/ML	95P-0268	READY TO USE INFUSION	Withdrawn	3/26/2007
ADENOSINE 18 MG/6 ML, 30 MG/10 ML	04P-0326	INJECTION	Denied	8/22/2007
ALBUTEROL SULFATE .083% (base)	02P-0448	INHALATION SOLUTION	Denied	12/17/2003
ALBUTEROL SULFATE 0.0417%	00P-0913	SOLUTION; INHALATION	Approved	6/13/2000
ALBUTEROL SULFATE 0.25%	08P-0344	SOLUTION; INHALATION	Pending	6/18/2008
ALBUTEROL SULFATE 2 MG & 4 MG	97P-0387	TABLET; SUBLINGUAL	Withdrawn	3/26/2007
ALBUTEROL SULFATE 2 MG, AND	92P-0335	CHEWABLE TABLET	Withdrawn	3/26/2007
ALBUTEROL SULFATE 4 MG	91P-0348	CAPSULE; ETENDED-RELEASE	Withdrawn	3/26/2007
ALCLOMETASONE DIPROPIONATE 0.05%	06P-0369	LOTION; TOPICAL	Withdrawn	1/6/2012
ALLOPURINOL 100 MG PER 5 ML	08P-0209	SUSPENSION	Pending	4/16/2008
ALLOPURINOL 100 MG/5 ML	11P-0740	LIQUID SUSPENSION	Pending	10/24/2011
ALPRAZOLAM 0.25 MG	06P-0339 (OLD 2006-0288)	ORALLY DISINTEGRATING TABLETS	Complete	1/9/2007
amantadine HCL, 100 mg	14P-0462		Pending	4/17/2014
amantadine HCL, 100mg	14P-0461	CAPSULE; ORAL	Pending	4/17/2014
AMINO ACID 15 % 1 L GLASS BOTTLE	07P-0300	INJECTION	Approved	4/8/2009
AMINO ACID 15%	07P-0113	INJECTION	Approved	4/8/2009
AMINO ACIDS 10% 1000mL & 2000mL	00P-1470	INJECTION	Approved	1/11/2001
AMIODARONE 100 MG	01P-0445	TABLET; ORAL	Withdrawn	10/16/2001
AMIODARONE 400 MG	99P-0343	TABLET; ORAL	Approved	7/21/1999
AMIODARONE HYDROCHLORIDE 100 MG	01P-0125	TABLET; ORAL	Approved	8/2/2001

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AMIODARONE HYDROCHLORIDE 300 mg	02P-0394	TABLETS	Approved	3/6/2003
AMIODARONE HYDROCHLORIDE 300mg/6mL, 450mg/9mL	02P-0484	INJECTION	Approved	2/25/2003
AMIODARONE HYDROCHLORIDE 450 mg/9 mL	02P-0480	INJECTION	Approved	2/25/2003
AMIODARONE HYDROCHLORIDE 50 MG/ ML 9 ML VIALS	02P-0346	INJECTION	Approved	2/25/2003
AMIODARONE HYDROCHLORIDE 50mg/mL, 18mL vial	02P-0419	INJECTION	Withdrawn	4/22/2003
AMIODARONE HYDROCHLORIDE 900 MG/18 ML	00P-1352	INJECTION	Approved	1/16/2001
AMLODIPINE 5 MG & 10 MG	01P-0239	CAPSULE; ORAL	Withdrawn	2/12/2004
AMLODIPINE BESYLATE 2.5 MG, 5 MG, 10 MG	05P-0066	CAPSULES	Denied	6/7/2006
AMMONIA N 13 3.75 - 260 mCi/mL	11P-0337	INJECTION	Approved	9/1/2011
AMOXICILLIN 125MG,250MG,200MG, 400MG,500MG,875MG	99P-5450	TABLETS FOR ORAL SUSPENSION	Approved	6/13/2000
AMOXICILLIN 200 MG, 400 MG, CLAVULANATE POTASSIUM 28.5 MG, 57 MG	04P-0157	TABLETS FOR ORAL SUSPENSION	Approved	9/28/2006
AMOXICILLIN 300 mg, 600 mg	02P-0358	TABLETS FOR ORAL SUSPENSION	Approved	11/26/2002
AMOXICILLIN 600mg, CLAVULANATE POTASSIUM 42.9mg	02P-0406	TABLETS FOR ORAL SUSPENSION	Denied	10/15/2004
Amphetamine Sulfate Tablets , 5mg and 10mg	14P-1038	Tablet; Oral	Pending	9/2/2014
Argatroban, 1mg/mL in a 125mg/125mL strength	14P-0813	Injection	Pending	6/18/2014
ASPIRIN 325 MG, HYDROCODONE BITARTRATE 5 MG	12P-1267	TABLET; ORAL	Withdrawn	1/9/2013
ASPIRIN 356.4MG	86P-0359	TABLET	Withdrawn	3/26/2007
ASPIRIN 650 MG	96P-0021	CAPSULES	Withdrawn	3/26/2007
Aspirin and codiene phosphate tablets USP, 300/mg/60mg	15P-1004	Tablet; Oral	Pending	3/27/2015

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Aspirin and codiene phosphate tablets USP, 300/mg/60mg	15P-1003	Tablet; Oral	Pending	3/27/2015
ATORVASTATIN CALCIUM 10 MG, 20 MG, 40 MG, 80 MG	08P-0085	CAPSULES	Approved	8/25/2010
ATORVASTATIN CALCIUM 10MG/20MG/40MG/80MG	04P-0418	CAPSULES	Withdrawn	7/1/2005
ATROPINE SULFATE 1.0 MG/ML	12P-0986	INJECTION	Pending	9/21/2012
Atropine Sulfate Plastic Syringe, 0.1 mg/ml, 10 ml (1 mg total drug content)	14P-1670	Injection	Pending	10/21/2014
Atropine Sulfate Ansyr® Plastic Syringe, 0.1 mg/mL, 10 mL (1 mg total drug content)	14P-2142	Injection	Pending	12/8/2014
AZACITIDINE 150 MG/VIAL	08P-0418	INJECTION	Pending	7/28/2008
AZATADINE MALEATE 1 MG	95P-0351	TABLET; ORAL	Withdrawn	3/23/2000
AZATADINE MALEATE 1 MG	85P-0492	EXTENDED-RELEASE CAPSULE	Withdrawn	3/26/2007
AZATHIOPRINE 75 MG & 100 MG	01P-0379	TABLET; ORAL	Approved	12/17/2001
BACLOFEN 10 mg, 20 mg	02P-0078	ORALLY DISINTEGRATING TABLETS	Approved	2/3/2004
BACLOFEN 10 MG/5 ML	05P-0156	ORAL SOLUTION	Withdrawn	7/18/2005
BACLOFEN 5 MG	08P-0325	TABLETS	Approved	3/18/2010
BACTERIOSTATIC WATER 20 ML/30 CC VIAL	09P-0067	INJECTION	Approved	6/22/2011
BENDAMUSTINE HYDROCHLORIDE 200 MG/VIAL	13P-0769	INJECTION	Pending	7/15/2013
BENZONATATE 125 MG, 175 MG	09P-0190	CAPSULES	Denied	10/8/2013
BENZONATATE 150 MG	04P-0321	CAPSULES	Approved	11/23/2004
BENZPHETAMINE HYDROCHLORIDE 25 MG, 50 MG	05P-0406	CAPSULES	Approved	6/27/2007
BENZTROPINE MESYLATE 0.5 MG/5 ML	85P-0423	SYRUP	Withdrawn	3/26/2007
BETAMETHASONE VALERATE 0.12%	06P-0535	NON-AEROSOL FOAM	Pending	11/7/2006

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BISOPROLOL FUMARATE 5 MG, 10 MG, 20 MG, HYDROCHLOROTHIAZIDE 12.5 MG	07P-0071	TABLETS	Denied	10/8/2013
Bisoprolol Fumarate and Hydrochlorothiazide, 10mg/6.25mg	14P-0984	Tablet; Oral	Pending	7/8/2014
BORTEZOMIB 1 MG, 2.5 MG	12P-0272	INJECTION	Pending	3/23/2012
BROMPHENIRAMINE MALEATE 12 MG	83N-0095	EXTENDED-RELEASE CAPSULE	Withdrawn	3/26/2007
BUMETANIDE 6.25 MG/25 ML	05P-0068	INJECTION	Pending	1/18/2005
BUPRENORPHINE HYDROCHLORIDE 8 MG, NALOXONE HYDROCHLORIDE 2 MG	09P-0459	ORAL STRIP	Pending	9/29/2009
buprenorphine Hydrochloride and Naloxone Hydrochloride Sublingual Tablets, 8mg/2mg	14P-1383	Tablet; Oral	Pending	8/28/2014
Buprenorphine Hydrochloride and Naloxone Hydrochloride Sublingual Film, 12mg/3mg	14P-2058	Film	Pending	11/26/2014
BUTALBITAL 25 MG, 50 MG, ACETAMINOPHEN 300 MG, 600 MG	02P-0056	TABLET; ORAL	Approved	2/28/2003
BUTALBITAL 50 MG	95P-0279	CAPSULES AND TABLETS	Withdrawn	3/26/2007
BUTALBITAL 50 MG	95P-0279	CAPSULES AND TABLETS	Withdrawn	3/26/2007
BUTALBITAL 50 MG	95P-0279	CAPSULES AND TABLETS	Withdrawn	3/26/2007
BUTALBITAL 50 MG	95P-0279	CAPSULES AND TABLETS	Withdrawn	3/26/2007
BUTALBITAL 50 MG, ACETAMINOPHEN 300 MG	11P-0167	CAPSULES	Approved	7/7/2012
BUTALBITAL 50 MG, ACETAMINOPHEN 300 MG	11P-0106	CAPSULES	Withdrawn	3/28/2011
BUTALBITAL 50 MG, ACETAMINOPHEN 300 MG	06P-0086	TABLETS	Approved	8/18/2006
BUTALBITAL 50 MG, ASPIRIN 500 MG	08P-0156	CAPSULES	Approved	8/18/2010

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BUTALBITAL 50 MG, ASPIRIN 500 MG	08P-0155	CAPSULES	Approved	8/18/2010
CALCITONIN, SALMON 2500 IU/0.25 MG	05P-0070	TABLET OR CAPSULE	Denied	6/2/2006
CALCITONIN-SALMON 100 IU/ML-1ML VIALS	00P-1213	INJECTION	Approved	6/13/2000
CALCIUM ACETATE 667 MG/5 ML	11P-0115	ORAL SOLUTION	Withdrawn	5/7/2012
CALCIUM ACETATE 667 MG/5 ML	08P-0175	ORAL SOLUTION	Withdrawn	3/19/2008
CAPTOPRIL 25 MG/5 ML	98P-0199	SOLUTION; ORAL	Withdrawn	3/26/2007
CAPTOPRIL 25 MG/ML	95P-0008	ORAL SOLUTION	Withdrawn	3/26/2007
CARBAMAZEPINE 100mg, 300mg, 400mg	03P-0083	TABLETS	Approved	12/17/2003
CARBAMAZEPINE 200 MG	01P-0028	TABLET; CHEWABLE	Approved	5/8/2001
CARBAMAZEPINE 200 MG/5 ML	03P-0304	ORAL SUSPENSION	Denied	1/16/2013
CARBAMAZEPINE 200 MG/5 ML	89P-0399	ORAL SUSPENSION	Withdrawn	3/26/2007
CARBIDOPA 25 MG; 10 MG; 25 MG, LEVODOPA 100MG; 100MG; 250MG	02P-0033	TABLETS; ORALLY DISINTEGRATING	Approved	9/25/2002
CARBIDOPA/LEVODOPA 25/100 MG	95P-0100	POWDER FOR ORAL SOLUTION	Withdrawn	3/26/2007
CARBIDOPA; 10MG & 25MG & 25MG/ LEVODOPA 100MG & 100MG &250MG	01P-0358	TABLET FOR ORAL SUSPENSION	Approved	8/9/2002
CARBINOXAMINE MALEATE 4 MG	04P-0284	CHEWABLE TABLET	Complete	3/24/2006
CARBINOXAMINE MALEATE 6 MG	08P-0167	TABLETS	Approved	3/7/2011
CARBOPLATIN 1000 MG/100 ML	08P-0660	INJECTION	Pending	1/5/2009
CARBOPLATIN 1000 MG/100 ML MULTIPLE DOSE VIAL	05P-0398	INJECTION	Approved	9/29/2009
CARBOPLATIN 50 MG/5 ML ;10MG/ML; 150 MG/15 ML;10MG/ML	01P-0036	INJECTION	Approved	11/30/2001
CARBOPLATIN 600 MG/60 ML	03P-0220	INJECTION	Denied	2/3/2004
CARISOPRODOL 200 MG	01P-0526	TABLET; ORAL	Denied	7/3/2002



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CARISOPRODOL 350 mg	02P-0138	ORALLY DISINTEGRATING TABLETS	Withdrawn	7/25/2002
CARVEDILOL PHOSPHATE 10, 20, 40, 80 MG	07P-0058	TABLET; EXTENDED- RELEASE; ORAL	Pending	4/2/2007
CEFACLOR 125 MG, 187 MG, 250 MG, 375 MG	99P-5447	TABLET; CHEWABLE;ORAL	Approved	6/13/2000
CEFACLOR 125 MG, 375 MG, 500 MG	99P-5448	TABLETS FOR ORAL SUSPENSION	Approved	6/13/2000
CEFACLOR 500 MG	00P-1397	TABLET; CHEWABLE	Approved	4/17/2001
CEFADROXIL HEMIHYDRATE 125MG,250MG,500MG	99P-5449	TABLETS FOR ORAL SUSPENSION	Approved	6/13/2000
CEFAZOLIN 2 G VIALS	07P-0406	INJECTION	Pending	6/5/2007
CEFAZOLIN SODIUM, STERILE 100 G & 300 G	99P-4870	FOR INJECTION	Approved	4/12/2002
CEFDINIR 187.5, 250, 300 MG	06P-0013	CHEWABLE TABLETS	Pending	7/5/2006
CEFDITOREN PIVOXIL 400 MG	05P-0176	TABLETS	Approved	7/14/2005
CEFEPIME 100 GRAM	08P-0539	INJECTION USP	Approved	9/10/2010
CEFEPIME INTRAVENOUS ONLY	06P-0461	INJECTION	Withdrawn	8/15/2008
CEFIXIME 100 MG/ML	07P-0404	ORAL SUSPENSION	Approved	9/1/2010
CEFIXIME 100MG, 150MG, 200MG	04P-0263	CHEWABLE TABLETS	Approved	10/6/2005
CEFIXIME 200 MG, 400 MG	08P-0534	CAPSULES	Withdrawn	10/24/2011
CEFIXIME 200 MG/5 ML	05P-0013	ORAL SUSPENSION	Approved	4/8/2005
CEFOXITIN 100 GRAM, 300 GRAM	03P-0227	INJECTION	Approved	10/1/2003
CEFPODOXIME PROXETIL 50 mg, 100 mg	02P-0444	TABLETS FOR ORAL SUSPENSION	Denied	6/7/2005
CEFPROZIL 125 MG, 250 MG	04P-0173	TABLETS FOR ORAL SUSPENSION	Denied	6/7/2005
CEFTAZIDIME 100GM PHARM BULK PKG	03P-0292	INJECTION	Approved	12/23/2003
CEFTAZIDIME 3 GRAM/VIAL	14P-0282	INJECTION	Pending	3/10/2014
CEFTRIAXONE 100 GRAM	05P-0114	INJECTION	Approved	7/14/2005

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CEFUROXIME AXETIL 125 MG, 250 MG	02P-0414	TABLETS FOR ORAL SUSPENSION	Denied	2/19/2013
CEFUROXIME AXETIL 125mg and 250mg	02P-0414	TABLETS FOR ORAL SUSPENSION	Denied	4/29/2004
CEFUROXIME SODIUM, STERILE 75 G & 225 G	99P-4871	FOR INJECTION	Approved	4/12/2002
CEPHALEXIN 125MG,250MG,500MG	99P-5451	TABLETS FOR ORAL SUSPENSION	Approved	6/13/2000
CETIRIZINE HYDROCHLORIDE 5 MG, 10 MG	06P-0122	ORALLY DISINTEGRATING TABLETS	Withdrawn	1/6/2012
CETIRIZINE HYDROCHLORIDE 5 MG; 10 MG	06P-0207	CAPSULES, SOFT GELATIN	Withdrawn	2/1/2010
CHLORHEXIDINE GLUCONATE 0.5%	88P-0036	SPRAY	Withdrawn	3/26/2007
CHLORHEXIDINE GLUCONATE 2%	04P-0528	SOLUTION; TOPICAL	Pending	12/6/2004
CHLORHEXIDINE GLUCONATE 2% W/V, ISOPROPYL ALCOHOL 70% V/V	05P-0200 (OLD 2005P-0226)	PREOPERATIVE SKIN PREP	Pending	6/17/2005
CHLORHEXIDINE GLUCONATE 2%/ISOPROPYL ALCOHOL 70%	05P-0137 (OLD 2005P-0074)	TOPICAL SOLUTION	Pending	4/8/2005
CHLORPHENIRAMINE MALEATE 8 MG, PSEUDOEPHEDRINE HYDROCHLORIDE 120 MG	09P-0478	CAPSULE, EXTENDED RELEASE; ORAL	Pending	10/13/2009
CHLORPHENIRAMINE MALEATE 8 MG/ PSEUDOEPHEDRINE HYDROCHLORIDE 120 MG	09P-0320	TABLET; EXTENDED-RELEASE; ORAL	Pending	7/27/2009
CHLORZOXAZONE 250 MG	90P-0084	CAPSULE	Withdrawn	3/26/2007
CHLORZOXAZONE 375 MG	05P-0044	TABLETS	Approved	4/8/2005
CHLORZOXAZONE 500 MG	82N-0032	CAPSULE	Withdrawn	3/26/2007
CHOLESTYRAMINE 2 G	95P-0277	TABLET; ORAL (CHEWABLE)	Withdrawn	3/26/2007
CHOLESTYRAMINE 4 GM	86P-0123	CHEWABLE TABLET	Withdrawn	3/26/2007
CHOLESTYRAMINE 500 MG	86P-0474	CAPSULE	Withdrawn	3/26/2007
CHOLESTYRAMINE RESIN 4 G	87P-0301	GEL	Approved	3/26/2007
CIMETIDINE 200,300,400 OR 800MG	93P-0048	EFFERVESCENT TABLET	Withdrawn	3/26/2007

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CIPROFLOXACIN HYDROCHLORIDE 0.4 ML UNIT DOSE	04P-0222	OPHTHALMIC SOLUTION	Approved	11/18/2009
CIPROFLOXACIN HYDROCHLORIDE 100 MG, 250 MG, 500 MG, 750 MG	07P-0014	CAPSULES	Pending	4/4/2007
CISPLATIN 10 MG/10 ML, 25 MG/25 ML	14P-0284	INJECTION	Pending	3/14/2014
CITALOPRAM HYDROBROMIDE 10 MG, 20 MG, 40 MG	03P-0551	CAPSULE	Approved	3/29/2005
CLADRIBINE 2 MG/ML - 5 ML VIAL	00P-1621	INJECTION	Denied	8/1/2001
CLARITHROMYCIN 1000 MG	03P-0238	EXTENDED- RELEASE TABLETS	Approved	12/18/2003
CLEMASTINE FUMARATE 1.34 MG	88P-0350	EXTENDED- RELEASE CAPSULE	Withdrawn	3/26/2007
CLEMASTINE FUMARATE 1.34 MG	87P-0314	CONTROLLED- RELEASE TABLET	Withdrawn	3/26/2007
CLINDAMYCIN PHOSPHATE 1%	07P-0059	FOAM; NON- AEROSOL	Pending	4/4/2007
CLOBETASOL PROPIONATE 0.05%	06P-0387	FOAM	Pending	9/21/2006
CLOBETASOL PROPIONATE 0.05%	98P-0068	LOTION; TOPICAL	Withdrawn	3/26/2007
CLOBETASOL PROPIONATE 0.05%	90P-0198	LOTION	Withdrawn	3/26/2007
CLONAZEPAM 1 MG/5 ML	03P-0464	ORAL SUSPENSION	Approved	10/17/2005
CLONIDINE HYDROCHLORIDE 0.05 MG	08P-0489	TABLETS	Denied	10/19/2010
CLOZAPINE 12.5 MG	99P-1267	TABLET;ORAL	Approved	2/17/2000
CLOZAPINE 150 MG	08P-0289	TABLETS	Approved	3/7/2011
CLOZAPINE 150 MG, 200 MG	08P-0294	TABLETS; ORAL DISINTEGRATING	Withdrawn	3/9/2011
CLOZAPINE 200 MG	99P-1268	TABLET; ORAL	Approved	2/17/2000
CLOZAPINE 50 mg	02P-0247	TABLETS	Approved	11/26/2002
CLOZAPINE 50 MG/ML	09P-0046	ORAL SUSPENSION	Withdrawn	5/7/2012
CODEINE PHOSPHATE 10 MG/5 ML	85P-0269	SYRUP	Withdrawn	3/26/2007

Drug/Strength	Petition No	Dosage Form	Status	Status Date
COLCHICINE 0.3 MG, 1.2 MG, 1.8 MG	12P-0632	TABLETS	Pending	6/19/2012
COLISTIMETHATE SODIUM 150 MG/2 ML	05P-0050	SOLUTION	Approved	10/17/2005
CYCLOBENZAPRINE HYDROCHLORIDE 15 MG, 30 MG	09P-0168	TABLET; EXTENDED-RELEASE; ORAL	Approved	4/6/2015
CYCLOBENZAPRINE HYDROCHLORIDE 7.5 MG	03P-0461	TABLET; ORAL	Approved	10/15/2004
CYCLOPHOSPHAMIDE 20 MG/ML, 250 ML PBP	88P-0379	INJECTION	Withdrawn	3/26/2007
CYCLOPHOSPHAMIDE 20 MG/ML, 500 ML,PBP	88P-0011	INJECTION	Withdrawn	3/26/2007
CYCLOSPORINE 25 MG; 50 MG; 100 MG	98P-0858	TABLET; ORAL	Approved	9/16/1999
CYTARABINE 20 MG/ML, 12.5 ML	92P-0381	INJECTION	Withdrawn	3/26/2007
DACTINOMYCIN 0.5 MG/ML	09P-0367	INJECTION	Pending	8/12/2009
DAPSONE 50 MG	13P-0800	TABLETS	Pending	7/15/2013
DEFEROXAMINE MESYLATE 1 GRAM	07P-0298	INJECTION	Pending	6/7/2007
DEXAMETHASONE SODIUM PHOSPHATE 10 MG/ML, 1 ML FILL SIZE	07P-0126	INJECTION	Pending	5/9/2007
DEXBROMPHENIRAMINE MALEATE 6 MG	87P-0265	CONTROLLED-RELEASE TABLET	Withdrawn	3/26/2007
DEXBROMPHENIRAMINE MALEATE 6 MG	85P-0238	EXTENDED-RELEASE CAPSULE	Withdrawn	3/26/2007
DEXBROMPHENIRAMINE MALEATE 6 MG	85P-0140	EXTENDED-RELEASE CAPSULE	Withdrawn	3/26/2007
DEXBROMPHENIRAMINE MALEATE 6 MG	85P-0140	EXTENDED-RELEASE CAPSULE	Withdrawn	3/26/2007
DEXMEDETOMIDINE HYDROCHLORIDE 400 MCG/4 ML VIAL	12P-1147	INJECTION	Pending	11/20/2012
DEXMEDETOMIDINE HYDROCHLORIDE 400 MCG/4 ML, 1000 MCG/10 ML	11P-0381	SOLUTION (CONCENTRATE)	Withdrawn	10/6/2011
DEXTROAMPHETAMINE SULFATE 2.5 MG, 7.5 MG, 15 MG, 20 MG, 30 MG	06P-0267	TABLETS	Approved	3/20/2007

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DEXTROAMPHETAMINE SULFATE 2.5 MG, 7.5 MG, 15 MG, 20 MG, 30 MG	05P-0418	TABLETS	Withdrawn	11/1/2005
DIAZEPAM 2 MG/5 ML	85P-0499	SYRUP	Withdrawn	3/26/2007
DICLOFENAC POTASSIUM 25 MG	03P-0298	CAPSULES	Withdrawn	2/3/2004
DICLOFENAC SODIUM 50 MG, 75 MG, MISOPROSTOL 200 MCG	07P-0428	CAPSULES	Approved	9/1/2010
DIFLUNISAL USP 375 MG	07P-0247	TABLETS	Approved	3/7/2011
DIGOXIN 0.05 MG/ML	01P-0449	SOLUTION; ORAL	Withdrawn	12/20/2001
DIGOXIN 0.25 MG/5 ML	02P-0503	ELIXIR	Withdrawn	
DIHYDROERGOTAMINE MESYLATE 2 MG/ML	03P-0556	INJECTION	Denied	4/1/2005
DILTIAZEM HYDROCHLORIDE 120 MG 180 MG 240 MG	97P-0195	TABLET; EXTENDED- RELEASE; ORAL	Withdrawn	3/26/2007
DILTIAZEM HYDROCHLORIDE 120 MG 180 MG 240 MG	97P-0192	TABLET; EXTENDED- RELEASE; ORAL	Withdrawn	3/26/2007
DILTIAZEM HYDROCHLORIDE 120 MG 180 MG 240 MG	96P-0510	TABLETS;EXTEN DED-RELEASE	Withdrawn	3/26/2007
DILTIAZEM HYDROCHLORIDE 125MG/5ML;250MG/10ML	98P-0189	INJECTION	Withdrawn	
DIPHENOXYLATE HYDROCHLORIDE 5 MG/ ATROPINE SULFATE 0.05 MG/5 ML	05P-0162	ORAL SOLUTION	Denied	12/10/2008
DIPHENOXYLATE HYDROCHLORIDE 5 MG/ ATROPINE SULFATE 0.05 MG/5 ML	05P-0161	TABLETS	Denied	12/10/2008
DISOPYRAMIDE PHOSPHATE 200 MG OR 300 MG	84N-0116	EXTENDED- RELEASE TABLET	Withdrawn	3/26/2007
DISULFIRAM 500 MG/30 ML	85P-0215	ORAL SUSPENSION	Withdrawn	3/26/2007
DIVALPROEX SODIUM 1000 MG	03P-0178	EXTENDED RELEASE TABLETS	Approved	8/18/2003
DIVALPROEX SODIUM 750 MG	04P-0195	EXTENDED RELEASE TABLETS	Approved	9/28/2004
DOCETAXEL 160 MG/8 ML	12P-0589	INJECTION	Withdrawn	11/7/2012

Drug/Strength	Petition No	Dosage Form	Status	Status Date
DOCETAXEL 20 MG, 80 MG, 200 MG	10P-0086	INJECTION; POWDER FOR SOLUTION	Denied	1/19/2011
DOCETAXEL 20 MG/ML	10P-0130	INJECTION	Withdrawn	5/7/2012
DOCETAXEL 200 MG	10P-0639	INJECTION	Approved	3/27/2012
DONEPEZIL HYDROCHLORIDE 5 MG, 10 MG	07P-0226	ORALLY DISSOLVING FILM STRIPS	Withdrawn	6/1/2009
DOXORUBICIN HYDROCHLORIDE 100 MG/50 ML	12P-0200	INJECTION	Approved	1/23/2013
DOXYCYCLINE (MONOHYDRATE) 125 MG	06P-0341 (old 2006p-0417)	TABLETS	Pending	10/24/2006
DOXYCYCLINE 150 MG	04P-0219	CAPSULES	Approved	9/28/2004
DOXYCYCLINE 150 MG	01P-0516	TABLET; ORAL	Approved	4/12/2002
DOXYCYCLINE 50 MG AND 100 MG	99P-4958	TABLET; ORAL	Approved	2/4/2000
DOXYCYCLINE 75 MG	01P-0515	TABLET; ORAL	Approved	4/12/2002
DOXYCYCLINE 75 MG	01P-0109	CAPSULE; ORAL	Approved	8/2/2001
DOXYCYCLINE HYCLATE 75 MG, 100 MG	04P-0390	TABLETS	Complete	9/21/2004
DOXYCYCLINE HYCLATE 75 MG, 100 MG	04P-0054	CAPSULES	Withdrawn	4/12/2004
DRONABINOL 0.25 MG, 0.5 MG, 1.0 MG	10P-0353	NASAL SPRAY	Pending	7/7/2010
DULOXETINE HYDROCHLORIDE 40 MG	10P-0535	CAPSULE, DELAYED RELEASE	Approved	4/18/2012
ECONAZOLE NITRATE 1%	98P-0745	OINTMENT; TOPICAL	Withdrawn	3/26/2007
EDETATE DISODIUM	05P-0085	INJECTION	Pending	2/23/2005
EFAVIRENZ 50 MG, 100 MG, 200 MG	08P-0460	TABLETS	Pending	8/27/2008
EFAVIRENZ 50 MG/100 MG/200 MG	05P-0407	TABLETS FOR ORAL SUSPENSION	Withdrawn	1/11/2010
EPIRUBICIN HYDROCHLORIDE 10mg/ 5mL;150mg/75mL	03P-0110	INJECTION	Approved	8/13/2003
EPIRUBICIN HYDROCHLORIDE 2 MG/ML, 10 MG/5 ML	06P-0012 (old 2006p-0131)	INJECTION	Pending	4/11/2006
ESCITALOPRAM OXALATE 10 MG, 20 MG	04P-0247	CAPSULE	Approved	3/29/2005

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ESCITALOPRAM OXALATE 5 MG, 10 MG, 20 MG	08P-0216	TABLETS, ORALLY DISINTEGRATING	Pending	4/16/2008
ESCITALOPRAM OXALATE 5 MG, 10 MG, 20 MG	07P-0239	ORALLY DISSOLVING FILM STRIPS	Withdrawn	6/1/2009
ESMOLOL HYDROCHLORIDE 2500 MG/VIAL	04P-0085	INJECTION	Denied	6/7/2005
ESOMEPRAZOLE MAGNESIUM 20 MG, 40 MG	08P-0080	TABLETS, DELAYED- RELEASE	Pending	2/7/2008
Esomeprazole Magnesium Delayed-Release	15P-2230	Capsules; oral	Pending	6/17/2015
ESTROPIPATE 1.2 mg	02P-0141	TABLETS	Approved	9/24/2002
ETHINYL ESTRADIOL 0.035 MG/ NORETHINDRONE 0.4 MG	99P-1150	TABLET; CHEWABLE	Approved	4/14/2000
FAMOTIDINE 10 MG	04P-0353	ORALLY DISSOLVING STRIPS	Approved	7/5/2005
FAMOTIDINE 10 MG	97P-0404	TABLET; ORAL; EFFERVESCENT	Withdrawn	3/26/2007
FAMOTIDINE 10MG	00P-1422	TABLET; ORALLY DISINTEGRATING	Approved	4/17/2001
FASPROFEN 100 MG	12P-1112	ORALLY DISINTEGRATING TABLET	Denied	1/13/2015
FENOFIBRATE 107 mg	02P-0148	TABLETS	Approved	9/25/2002
FENOPROFEN CALCIUM 400 MG	07P-0293	CAPSULES	Withdrawn	9/28/2009
FENTANYL 12.5 mcg/hr	02P-0478	TRANSDERMAL SYSTEM	Withdrawn	10/14/2003
FENTANYL 37.5 mcg/hr, 62.5 mcg/hr	04P-0069	TRANSDERMAL SYSTEM	Approved	7/7/2004
FENTANYL CITRATE 1000 MCG, 1400 MCG	07P-0022	ORAL TRANSMUCOSAL	Approved	5/9/2011
FENTANYL CITRATE 50 MCG/1 ML	10P-0413	INJECTION	Approved	1/28/2013
FENTANYL CITRATE 500 ML VIAL	10P-0222	INJECTION SOLUTION	Withdrawn	5/7/2012
FEXOFENADINE HCL 120 MG	10P-0230	TABLETS	Withdrawn	5/10/2010

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FEXOFENADINE HCL 15 MG	10P-0232	ORALLY DISINTEGRATING TABLET	Withdrawn	3/1/2011
FEXOFENADINE HCL 15 MG/5 ML	10P-0231	SUSPENSION; ORAL	Approved	1/28/2013
FEXOFENADINE HYDROCHLORIDE 30 MG/5 ML, 60 MG/5 ML	06P-0397	ORAL SUSPENSION	Pending	10/6/2006
Florinal with Codeine, 325mg	14P-2168	Tablet; Oral	Pending	12/10/2014
Florinal, 325mg	14P-2169	Tablet; Oral	Pending	12/10/2014
FLOXURIDINE 500 MG/5 ML	86P-0242	INJECTION	Withdrawn	3/26/2007
FLUCONAZOLE 100 MG/50 ML	04P-0434	INJECTION	Approved	8/18/2006
FLUDARABINE PHOSPHATE 25 mg/mL	02P-0245	SOLUTION FOR INJECTION	Approved	4/27/2004
FLUDEOXYGLUCOSE F 18 500 MCI/ML	10P-0444	INJECTION	Approved	5/20/2011
FLUDEOXYGLUCOSE F18 0.9- 475 MCI/ML	07P-0408	INJECTION	Pending	4/9/2007
FLUDEOXYGLUCOSE F18 1-20 mCi/mL EOS	12P-0387	INJECTION	Approved	6/7/2012
FLUOCINOLONE ACETONIDE 0.01%, HYDROQUINONE 4%	03P-0279	TOPICAL SOLUTION	Denied	4/1/2005
FLUOCINONIDE 0.05%	87P-0004	LOTION	Withdrawn	3/26/2007
FLUOROURACIL 1 GM/20 ML	08P-0218 (OLD 08P-0003)	INJECTION	Withdrawn	12/2/2008
FLUOROURACIL 2.5%	01P-0288	SOLUTION; TOPICAL	Approved	1/8/2002
FLUOROURACIL 5%	94P-0263	TOPICAL GEL	Withdrawn	3/26/2007
FLUOXETINE 20 MG & 40 MG	01P-0243	CAPSULE; ORAL	Withdrawn	7/31/2001
FLUOXETINE 40 MG	00P-1365	TABLET; ORAL	Approved	1/12/2001
FLURANDRENOLIDE 0.004 MG/SQ	09P-0229	TOPICAL LIQUID	Pending	5/27/2009
FLURAZEPAM HYDROCHLORIDE 15 MG/5ML	85P-0091	ORAL SOLUTION	Withdrawn	3/26/2007
FLURAZEPAM HYDROCHLORIDE 30 MG/ML	85P-0081	ORAL SOLUTION	Withdrawn	3/26/2007
GABAPENTIN 100MG,300MG,400MG	00P-1419	TABLET; ORAL	Approved	1/12/2001
GANCICLOVIR 500 MG/10 ML	13P-1061	SOLUTION	Pending	10/7/2013
GANCICLOVIR SODIUM 50 MG/ML	09P-0222	INJECTION	Approved	11/16/2010
GANCICLOVIR SODIUM 500 MG/10 ML	01P-0440	INJECTION	Complete	2/5/2003
GEMCITABINE 2 GM/VIAL	06P-0145	INJECTION	Approved	8/22/2007



Drug/Strength	Petition No	Dosage Form	Status	Status Date
GEMCITABINE HCL 38 MG/ML	08P-0392	INJECTION	Withdrawn	12/3/2009
GEMCITABINE HYDROCHLORIDE 10 MG/ML	10P-0096	INJECTION	Pending	2/24/2010
GEMCITABINE HYDROCHLORIDE 38 MG/ML	09P-0076	INJECTION	Pending	2/19/2009
GLIMEPIRIDE 3 MG, 6 MG	04P-0123	TABLETS	Approved	7/7/2004
GLIMEPIRIDE 8 MG	03P-0283	TABLETS	Approved	10/6/2003
GLIPIZIDE 2.5 MG, 5 MG, METFORMIN HYDROCHLORIDE 250 MG, 500 MG	04P-0208	TABLETS FOR ORAL SUSPENSION	Approved	11/23/2004
GLIPIZIDE 2.5 MG, 5 MG, METFORMIN HYDROCHLORIDE 250 MG, 500 MG	03P-0218	TABLETS FOR ORAL SOLUTION	Approved	7/30/2004
GLIPIZIDE 2.5 MG, 5 MG, METFORMIN HYDROCHLORIDE 250mg/5mL;500mg/10mL	04P-0168	ORAL SOLUTION	Approved	11/23/2004
GLYBURIDE 1.25 MG, 2.5 MG, 5MG, METFORMIN HYDROCHLORIDE 250 MG, 500 MG	04P-0209	TABLETS FOR ORAL SUSPENSION	Approved	11/23/2004
GLYBURIDE 1.25MG, 2.5MG, 5 MG, METFORMIN HYDROCHLORIDE 250MG, 500MG	03P-0534	ORAL SOLUTION	Approved	7/30/2004
GLYBURIDE 1.25mg, 2.5mg, 5mg, METFORMIN HYDROCHLORIDE 250mg, 500mg, 500mg	03P-0188	TABLETS FOR ORAL SOLUTION	Approved	7/30/2004
GLYCOPYRROLATE 1 MG/5 ML	08P-0414	SOLUTION	Withdrawn	3/9/2011
GLYCOPYRROLATE 1.5 MG	06P-0300	TABLETS	Approved	3/20/2007
GRISEOFULVIN 187.5 MG AND 375 MG	13P-0799	TABLETS	Pending	7/15/2013
GRISEOFULVIN ULTRAMICROSIZED 250 MG/5 ML	08P-0303	SUSPENSION; ORAL	Approved	12/29/2011
HOMATROPINE METHYLBROMIDE 1.5 MG	88P-0061	SOFT GELATIN CAPSULE	Withdrawn	3/26/2007
HYDRALAZINE HYDROCHLORIDE 25 MG/5ML	85P-0074	ORAL SOLUTION	Withdrawn	3/26/2007

Drug/Strength	Petition No	Dosage Form	Status	Status Date
HYDROCHLOROTHIAZIDE 12.5 MG	05P-0060	TABLETS	Approved	4/8/2005
HYDROCHLOROTHIAZIDE 50 MG	86P-0427	CAPSULE	Withdrawn	3/26/2007
HYDROCODONE BITARTRATE 10 MG, 7.5 MG; ACETAMINOPHEN 400 MG, 400 MG	01P-0504	TABLET; ORAL	Withdrawn	1/2/2002
HYDROCODONE BITARTRATE 10 MG/ ACETAMINOPHEN 300 MG	01P-0441	TABLET; ORAL	Approved	12/20/2001
HYDROCODONE BITARTRATE 10 MG/ IBUPROFEN 200 MG	01P-0442	TABLET; ORAL	Approved	12/20/2001
HYDROCODONE BITARTRATE 10 MG/15 ML, ACETAMINOPHEN 300 MG/15 ML	01P-0524	SOLUTION; ORAL	Approved	8/6/2002
HYDROCODONE BITARTRATE 2.5 MG PER 5 ML, HOMATROPINE METHYLBROMIDE 0.75 MG PER 5 ML	07P-0004	SYRUP	Pending	4/5/2007
HYDROCODONE BITARTRATE 2.5 MG, HOMATROPINE METHYLBROMIDE 0.75 MG	07P-0124	TABLETS	Pending	4/12/2007
HYDROCODONE BITARTRATE 2.5 MG; IBUPROFEN 200 MG	05P-0180	TABLETS	Approved	7/14/2005
HYDROCODONE BITARTRATE 2.5, 3.75, 5 MG, ACETAMINOPHEN 250 MG, 325 MG	12P-0964	TABLETS	Withdrawn	12/6/2012
HYDROCODONE BITARTRATE 2.5, 5, 7.5, 10 MG, ACETAMINOPHEN 325 MG	11P-0302	EFFERVESCENT TABLETS	Denied	7/30/2012
HYDROCODONE BITARTRATE 2.5, 5, 7.5, 10 MG, ACETAMINOPHEN 500 MG	08P-0134	TABLET; EFFERVESCENT	Withdrawn	3/23/2011
HYDROCODONE BITARTRATE 2.5, 5, 7.5, 10 MG, ASPIRIN 325 MG	08P-0438	TABLETS	Denied	2/11/2015
HYDROCODONE BITARTRATE 4 MG, 6 MG, 8 MG, ACETAMINOPHEN 300 MG	13P-0813	TABLETS	Pending	7/15/2013
HYDROCODONE BITARTRATE 5 MG, 7.5 MG, 10 MG, ACETAMINOPHEN 700 MG	04P-0252	TABLETS	Approved	10/17/2005

Drug/Strength	Petition No	Dosage Form	Status	Status Date
HYDROCODONE BITARTRATE 5 MG, 7.5 MG, 10 MG, IBUPROFEN 400 MG	03P-0331	TABLETS	Denied	4/1/2005
HYDROCODONE BITARTRATE 5 MG, 7.5MG & 10 MG, ACETAMINOPHEN 300 MG,300 MG&300 MG	03P-0436	TABLET; ORAL	Approved	10/10/2003
HYDROCODONE BITARTRATE 5 MG, ACETAMINOPHEN 300 MG	03P-0414	TABLET	Approved	11/23/2004
HYDROCODONE BITARTRATE 5 MG, ACETAMINOPHEN 325 MG	03P-0475	LIQUID; ORAL	Withdrawn	2/4/2004
HYDROCODONE BITARTRATE 5 mg, ACETAMINOPHEN 500 mg	02P-0233	ORALLY DISINTEGRATING TABLETS	Approved	2/11/2004
HYDROCODONE BITARTRATE 5 MG, BUTALBITAL 50 MG	03P-0398	CAPSULE	Withdrawn	
HYDROCODONE BITARTRATE 5 MG, HOMATROPINE METHYLBROMIDE 1.5 MG	07P-0176	CAPSULES	Pending	8/10/2007
HYDROCODONE BITARTRATE 5 mg, IBUPROFEN 200 mg	02P-0270	TABLETS	Approved	9/25/2002
HYDROCODONE BITARTRATE 7.5 MG & 10 MG, ACETAMINOPHEN 250 MG & 250 MG	01P-0521	TABLET; ORAL	Denied	7/3/2002
HYDROCODONE BITARTRATE 7.5 MG, ACETAMINOPHEN 300 MG	03P-0413	TABLET	Approved	9/28/2004
HYDROCODONE BITARTRATE 7.5 mg, IBUPROFEN 200 mg	02P-0386	ORAL SUSPENSION	Withdrawn	2/3/2004
HYDROCODONE BITARTRATE 7.5 MG/15ML/ ACETAMINOPHEN 325MG/15ML	01P-0374	SOLUTION; ORAL	Withdrawn	1/7/2002
HYDROCODONE BITARTRATE; 10 MG/15 ML; ACETAMINOPHEN 325 MG/15ML	00P-1641	SOLUTION; ORAL	Approved	4/17/2001
HYDROCODONE POLISTIREX 5 MG, 10 MG; CHLORPHENIRAMINE POLISTIREX 4 MG, 8 MG	03P-0091	EXTENDED RELEASE CAPSULES	Approved	8/31/2004
HYDROCORTISONE ACETATE 1%	90P-0154	OINTMENT	Withdrawn	3/26/2007

Drug/Strength	Petition No	Dosage Form	Status	Status Date
HYDROCORTISONE ACETATE 2%	01P-0085	CREAM; TOPICAL	Approved	8/1/2001
HYDROCORTISONE ACETATE 2.5%	01P-0511	LOTION; TOPICAL	Withdrawn	3/29/2011
HYDROCORTISONE ACETATE 2.5%	01P-0355	SUSPENSION; TOPICAL	Withdrawn	3/29/2011
HYDROCORTISONE ACETATE 2.5%	92P-0101	AEROSOL	Withdrawn	3/26/2007
HYDROCORTISONE ACETATE 2.5% OR 1%	90P-0049	CREAM OR LOTION	Withdrawn	3/26/2007
HYDROCORTISONE ACETATE 90 MG	96P-0376	SUPPOSITORY; RECTAL	Withdrawn	3/26/2007
HYDROCORTISONE BUTYRATE 0.1%	95P-0223	LOTION; TOPICAL	Withdrawn	3/26/2007
HYDROCORTISONE VALERATE 0.2%	89P-0029	TOPICAL SOLUTION	Withdrawn	3/26/2007
HYDROCORTISONE VALERATE 0.2%	89P-0028	LOTION	Withdrawn	3/26/2007
HYDROMORPHONE HCL 24 MG	13P-0830	TABLET; EXTENDED- RELEASE; ORAL	Pending	7/16/2013
HYDROMORPHONE HYDROCHLORIDE 0.2 MG/ML - 30 ML	98P-0821	INJECTABLE; INJECTION	Denied	9/29/1999
HYDROMORPHONE HYDROCHLORIDE 1 MG	14P-0196	TABLET	Pending	2/12/2014
HYDROMORPHONE HYDROCHLORIDE 1 MG/5 ML	14P-0076	ORAL SOLUTION	Pending	1/13/2014
HYDROMORPHONE HYDROCHLORIDE 2 MG, 4 MG	04P-0152	TABLETS	Approved	9/28/2004
HYDROQUINONE 4%, TRETINOIN 0.01%	03P-0365	TOPICAL SOLUTION	Denied	12/2/2004
HYDROXYCHLOROQUINE SULFATE 100, 300, 400 MG	13P-0170	TABLET	Pending	2/19/2013
IBUPROFEN 100 MG/5 ML	10P-0145	SUSPENSION; ORAL	Pending	4/8/2010
IBUPROFEN 200 MG	99P-0683	TABLET; ORAL	Withdrawn	9/16/1999
IBUPROFEN 300, 400 OR 600 MG	85P-0563	SOFT GELATIN CAPSULE	Withdrawn	3/26/2007
IBUPROFEN 800 MG	87P-0242	SOFT GELATIN CAPSULE	Withdrawn	3/26/2007
IBUPROFEN POTASSIUM 200 MG, PHENYLEPHRINE HYDROCHLORIDE 10 MG	06P-0469	CAPSULES	Pending	11/28/2006

Drug/Strength	Petition No	Dosage Form	Status	Status Date
IFOSFAMIDE 50 MG/ML - 20ML&60ML	98P-0146	INJECTABLE; INJECTION	Withdrawn	3/26/2007
IMATINIB 400 MG/5 ML	12P-0479	ORAL SOLUTION	Pending	5/24/2012
IMATINIB MESYLATE 100 MG, 400 MG,	10P-0360	CAPSULES	Approved	1/22/2014
IMATINIB MESYLATE 300 MG	13P-1002	TABLETS	Pending	10/7/2013
IMATINIB MESYLATE 50 MG, 200 MG, 600 MG	10P-0341	TABLETS	Approved	11/15/2012
intravenous use 0.5 mmol gadopentetate dimeglumine/ml	15P-0335	Injection	Pending	1/30/2015
IOPAMIDOL	00P-1452	INJECTION	Approved	4/23/2001
IRINOTECAN HYDROCHLORIDE 500 MG/25 ML	05P-0496	INJECTION	Approved	1/16/2007
ISONIAZID 100 MG, 300 MG	08P-0251	TABLETS; ORAL SUSPENSION	Pending	5/5/2008
ISOTRETINOIN 30 mg	02P-0161	CAPSULES	Approved	8/8/2002
KALEXATE 15 GM/BOTTLE	11P-0913	POWDER	Approved	1/28/2013
KETAMINE HYDROCHLORIDE 100 MG/ML-10ML VIALS	01P-0156	INJECTION	Approved	8/20/2001
KETOCONAZOLE 20 MG/ML	85P-0147	ORAL SUSPENSION	Withdrawn	3/26/2007
KETOPROFEN; 12.5 MG, HYDROCODONE BITARTRATE 7.5 MG	03P-0453	TABLET	Denied	3/15/2006
KETOROLAC TROMETHAMINE 30 MG/ML - 5 ML	99P-0510	INJECTABLE; INJECTION	Approved	9/16/1999
LACTATED RINGERS 3000 ML	11P-0550	INJECTION	Withdrawn	8/16/2012
LACTULOSE 10 G, 20 G	96P-0155	POWDER FOR ORAL SOLUTION (EFFERVESCENT)	Withdrawn	4/24/2000
LACTULOSE 10 GRAMS & 20 GRAMS	12P-0496	POWDER FOR ORAL SOLUTION	Withdrawn	4/9/2013
LACTULOSE CRYSTALS	10P-0398	LIQUID; ORAL	Withdrawn	1/6/2012
LAMOTRIGINE 50 MG; 250 MG	05P-0212	TABLETS	Withdrawn	7/1/2005
LEUCOVORIN CALCIUM 1 MG/ML	88P-0149	ORAL SOLUTION	Withdrawn	3/26/2007
LEUCOVORIN CALCIUM 10 MG/ML 350 MG VIAL	94P-0433	INJECTABLE; INJECTION	Withdrawn	3/26/2007

Drug/Strength	Petition No	Dosage Form	Status	Status Date
LEUCOVORIN CALCIUM 10 MG/ML 5 ML VIAL	94P-0433	INJECTABLE; INJECTION	Withdrawn	3/26/2007
LEUCOVORIN CALCIUM 5 MG/ML - 100ML VIAL	00P-1518	INJECTION	Withdrawn	2/14/2001
LEUCOVORIN CALCIUM 50 MG/5 ML, 200 MG/20 ML,	14P-0251	INJECTION	Pending	3/7/2014
LEVETIRACETAM 1000 MG, 1500 MG	09P-0285	TABLET; EXTENDED- RELEASE; ORAL	Approved	9/7/2010
LEVETIRACETAM 1000 MG/VIAL	11P-0186	INJECTION	Pending	3/29/2011
LEVOCARNITINE 200 MG/ML - 12.5 ML	99P-0553	INJECTABLE; INJECTION	Approved	9/16/1999
LEVOLEUCOVORIN CALCIUM 50 MG/5 ML	11P-0821	INJECTION	Pending	11/17/2011
LEVOMETHADYL ACETATE HCL 10 MG, 20 MG, 40 MG	07P-0403	TABLETS	Pending	10/23/2007
LEVONORGESTREL 1.5 MG	03P-0216	TABLET	Denied	12/17/2003
LEVORPHANOL TARTRATE 1 mg, 3 mg	02P-0225	TABLETS	Approved	10/16/2002
LIDOCAINE 10 MG	08P-0214	ORAL SPRAY NON-AEROSOL	Pending	1/7/2007
LIDOCAINE 5%	01P-0291	CREAM; TOPICAL	Denied	7/3/2002
LIDOCAINE HYDROCHLORIDE 12 MG	06P-0457	ORAL NON- AEROSOL SPRAY	Pending	6/15/2006
LIDOCAINE HYDROCHLORIDE 2%	05P-0243	TOPICAL (SPRAY)	Pending	1/17/2006
LIDOCAINE HYDROCHLORIDE 20 MG/ML	10P-0072	INJECTION	Withdrawn	3/22/2010
LOPERAMIDE HYDROCHLORIDE 1 MG	02P-0424	CAPSULE; ORAL	Withdrawn	7/7/2007
LOPERAMIDE HYDROCHLORIDE 1 MG	93P-0332	EFFERVESCENT TABLET	Withdrawn	3/26/2007
LOPERAMIDE HYDROCHLORIDE 2 MG	06P-0397	ORALLY DISSOLVING STRIP	Pending	7/5/2006
LOPERAMIDE HYDROCHLORIDE 2 MG	06P-0305	ORALLY DISSOLVING STRIPS	Withdrawn	7/13/2007
LOPERAMIDE HYDROCHLORIDE 2 MG	06P-0098	ORALLY DISSOLVING STRIP	Withdrawn	5/10/2006
LOPERAMIDE HYDROCHLORIDE 2 mg	02P-0380	SOFT GELATIN CAPSULES	Withdrawn	6/7/2007

Drug/Strength	Petition No	Dosage Form	Status	Status Date
LOPERAMIDE HYDROCHLORIDE 2 MG	87P-0268	TABLET	Withdrawn	3/26/2007
LOPINAVIR 100 MG, RITONAVIR 25 MG	07P-0437	TABLETS	Pending	11/13/2007
LORATADINE 10 MG	06P-0208	CAPSULES, SOFT GELATIN	Withdrawn	2/1/2010
LORATADINE 5 MG, 10 MG	07P-0037	ORALLY- DISSOLVING STRIPS	Pending	2/6/2007
LORAZEPAM 0.5 MG, 1 MG OR 2 MG	85P-0515	TABLET (FAST- DISSOLVING)	Withdrawn	3/26/2007
LORAZEPAM 0.5 MG, 1 MG, 2 MG	87P-0037	SOFT GELATIN CAPSULE	Withdrawn	3/26/2007
LORAZEPAM 1 MG/5 ML	86P-0292	ORAL SOLUTION	Withdrawn	3/26/2007
LOSARTAN POTASSIUM 10 MG/ML	05P-0351	ORAL SOLUTION	Denied	9/25/2007
MAGNESIUM SULFATE 20 ML AND 50 ML	09P-0091	INJECTION	Withdrawn	2/26/2009
MAGNESIUM SULFATE 50 ML	12P-1004	INJECTION	Withdrawn	11/9/2012
MAGNESIUM SULFATE 50% 20 ML, 50 ML FIL	09P-0397	INJECTION	Approved	9/7/2010
MEFENAMIC ACID 250 MG	97P-0155	TABLET; ORAL	Withdrawn	3/26/2007
MEFENAMIC ACID 500 MG	12P-1058	CAPSULES	Denied	3/16/2015
MELOXICAM 7.5MG, 15MG	05P-0480 (OLD 2005p-0329)	ORALLY DISINTEGRATING TABLETS	Pending	12/5/2005
MEMANTINE HYDROCHLORIDE 5 MG, 10 MG	07P-0203	ORALLY DISINTEGRATING TABLETS	Approved	3/7/2011
MEPERIDINE HYDROCHLORIDE 75 MG, 150 MG	04P-0500	TABLETS	Approved	3/31/2005
MERCAPTOPYRINE 100 MG	00P-1645	TABLET; ORAL	Approved	4/17/2001
MERCAPTOPYRINE 25 MG	10P-0582	TABLET	Approved	3/27/2012
METFORMIN HYDROCHLORIDE 1000 MG	03P-0388	EXTENDED RELEASE TABLETS	Approved	12/23/2003
METFORMIN HYDROCHLORIDE 500 MG, 850 MG, 1 G	11P-0558	CHEWABLE TABLETS	Approved	9/27/2012
METFORMIN HYDROCHLORIDE 500 MG, 850 MG, 1 G	10P-0533	POWDER FOR SOLUTION	Approved	9/27/2012

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METFORMIN HYDROCHLORIDE 500mg, 850mg, 1000mg	02P-0499	TABLETS FOR ORAL SOLUTION	Approved	2/11/2004
METHACHOLINE CHLORIDE 1280 MG/VIAL	04P-0511	POWDER, METERED	Withdrawn	3/21/2006
METHACHOLINE CHLORIDE 1280 MG/VIAL	04P-0359	ORAL INHALATION	Withdrawn	3/21/2006
METHADONE HYDROCHLORIDE 15mg, 20mg, 30mg	02P-0481	TABLETS (DISPERSIBLE)	Approved	3/4/2003
METHADONE HYDROCHLORIDE 15MG,20MG,30MG,40MG	01P-0377	TABLET; ORAL	Withdrawn	11/11/2002
METHIMAZOLE 15 MG AND 20 MG	00P-1308	TABLET; ORAL	Approved	9/9/2000
METHOCARBAMOL 1000 MG	06P-0002	TABLETS	Approved	12/3/2010
METHOTREXATE 100 MG/ML	06P-0177	INJECTION	Withdrawn	3/23/2007
METHOTREXATE 1000 MG/ML, 10 ML VIAL	06P-0507	INJECTION	Pending	1/11/2007
METHOTREXATE DISODIUM 2.5 MG/ML	99P-2078	FOR ORAL SOLUTION	Withdrawn	10/18/1999
METHOTREXATE SODIUM 2.5 MG/ML	99P-2078	FOR ORAL SOLUTION	Withdrawn	3/29/2000
METHOTREXATE SODIUM 5 mg/mL	02P-0226	ORAL SOLUTION	Approved	2/3/2004
METHYLPHENIDATE HYDROCHLORIDE 2.5 MG	99P-1418	TABLET; ORAL	Denied	2/29/2000
METHYLPHENIDATE HYDROCHLORIDE 5 MG & 10 MG	99P-1417	TABLET; CHEWABLE	Denied	2/29/2000
METHYLPHENIDATE HYDROCHLORIDE 5 MG/5 ML	99P-1416	SOLUTION; ORAL	Denied	2/29/2000
METHYLPHENIDATE HYDROCHLORIDE 72 MG	05P-0257	TABLET; EXTENDED- RELEASE; ORAL	Approved	11/14/2005
METHYLPREDNISOLONE 16 MG	94P-0432	TABLET; CHEWABLE	Withdrawn	3/26/2007
METHYLPREDNISOLONE 4 MG & 16 MG	98P-0911	TABLET; SUBLINGUAL	Denied	6/14/1999
METHYLTESTOSTERONE 25 MG	93P-0459	CAPSULE	Withdrawn	3/26/2007
METHYLTESTOSTERONE 25 MG	85P-0067	CAPSULE	Withdrawn	3/26/2007
METOCLOPRAMIDE HYDROCHLORIDE 5 MG, 10 MG	04P-0409	ORALLY DISINTEGRATING TABLETS	Withdrawn	10/17/2005



Drug/Strength	Petition No	Dosage Form	Status	Status Date
METOPROLOL SUCCINATE 12.5 MG	12P-0698	TABLET; EXTENDED- RELEASE; ORAL	Approved	11/20/2014
METOPROLOL TARTRATE 12.5 MG	06P-0395	TABLETS	Withdrawn	8/27/2008
METOPROLOL TARTRATE 12.5 MG	03P-0441	TABLETS	Denied	10/15/2004
METOPROLOL TARTRATE 25 mg	02P-0460	TABLETS	Approved	2/13/2003
METOPROLOL TARTRATE 25 mg	02P-0459	TABLETS	Approved	2/13/2003
METOPROLOL TARTRATE 37.5 MG, 75 MG	07P-0072	TABLETS	Approved	3/18/2010
Metoprolol tartrate tablet, 100mg	14P-0647	Tablet, Oral	Pending	5/19/2014
METRONIDAZOLE 0.75%	95P-0328	LOTION; TOPICAL	Withdrawn	3/26/2007
METRONIDAZOLE 50 MG	09P-0121	TABLETS	Pending	3/4/2009
MIDAZOLAM 5 MG/ML-10 ML VIALS	01P-0136	INJECTION	Approved	8/5/2002
MIDAZOLAM HYDROCHLORIDE 500 MG/100 ML	10P-0460	INJECTION	Approved	7/7/2012
MIDODRINE HYDROCHLORIDE 15 MG	01P-0081	TABLET; ORAL	Approved	5/8/2001
MINOCYCLINE HYDROCHLORIDE 70 MG, 95 MG	11P-0347	TABLET; EXTENDED- RELEASE; ORAL	Approved	1/28/2013
MINOCYCLINE HYDROCHLORIDE 70 MG, 95 MG	11P-0347	TABLET; EXTENDED- RELEASE; ORAL	Approved	1/28/2013
MINOXIDIL 2%, 5% W/W	08P-0643	CREAM; TOPICAL	Pending	12/18/2008
MIRTAZAPINE 7.5 mg	02P-0249	TABLETS	Approved	2/27/2003
MORPHINE SULFATE 15MG,60MG,90MG,100MG	93P-0446	EXTENDED- RELEASE CAPSULE	Withdrawn	3/26/2007
MORPHINE SULFATE 20 MG/ML	09P-0388	SOLUTION (CONCENTRATE)	Withdrawn	12/2/2013
MORPHINE SULFATE 200 MG	97P-0225	CAPSULE, EXTENDED RELEASE; ORAL	Approved	4/14/2000
MORPHINE SULFATE 25 MG/ML, 50 ML & 100 ML VIALS	10P-0012	INJECTION	Withdrawn	12/29/2011

Drug/Strength	Petition No	Dosage Form	Status	Status Date
MORPHINE SULFATE 30 MG	89P-0071	EXTENDED- RELEASE CAPSULE	Withdrawn	3/26/2007
MORPHINE SULFATE 5 MG, 10 MG, 20 MG	08P-0401	TABLETS	Pending	7/17/2008
MORPHINE SULFATE 5 MG/ML	12P-1251	INJECTION	Pending	1/8/2013
MULTIVITAMIN SINGLE DOSE PHARMACY BULK PKG	09P-0417	FOR INJECTION	Withdrawn	11/15/2010
NABUMETONE 1000 MG	07P-0275	TABLETS	Approved	3/18/2010
NAFCILLIN SODIUM 200 GRAM	03P-0184	INJECTION	Approved	8/18/2003
NALTREXONE HYDROCHLORIDE 25MG, 100MG & 150MG	99P-4775	TABLET; ORAL	Approved	4/13/2000
NAPROXEN SODIUM 220 mg	02P-0473	SOFT GELATIN CAPSULES	Withdrawn	4/13/2005
NIACIN 375 MG, 500 MG	08P-0340	CAPSULE, EXTENDED RELEASE	Pending	6/18/2008
NICOTINE BASE 2 MG/240 ML, 4 MG/240 ML	04P-0281	ORAL SOLUTION	Denied	10/29/2010
NICOTINE BITARTRATE 2 MG/240 ML, 4 MG/240 ML	04P-0282	ORAL SOLUTION	Denied	10/29/2010
NICOTINE POLACRILEX 2 MG/240 ML, 4 MG/240 ML	04P-0280	ORAL SOLUTION	Denied	5/26/2005
NIFEDIPINE 10 MG OR 20 MG	87P-0340	TABLET	Withdrawn	3/26/2007
NIFEDIPINE 30 MG, 60 MG, 90 MG	95P-0326	CAPSULE, EXTENDED RELEASE; ORAL	Withdrawn	3/26/2007
NIFEDIPINE 30 MG, 60 MG, 90 MG	90P-0436	EXTENDED- RELEASE CAPSULE	Withdrawn	3/26/2007
NIZATIDINE 75 MG	00P-1245	CAPSULE; ORAL	Approved	4/17/2001
olmesartan medoxomil, 40mg	15P-0596	Tablet; oral	Pending	2/25/2015
OLSALAZINE SODIUM 500 MG	08P-0422	CAPSULES	Approved	3/18/2010
OMEPRAZOLE 10 MG, 20 MG	98P-0225	TABLET; DELAYED RELEASE; ORAL	Denied	9/16/1999
OMEPRAZOLE 20 MG	06P-0211 (old 2006-0117)	DELAYED- RELEASE TABLET; ORAL	Pending	3/15/2006

Drug/Strength	Petition No	Dosage Form	Status	Status Date
OMEPRAZOLE 40 MG	99P-1087	TABLET; DELAYED- RELEASE, ORAL	Approved	4/18/2000
OMEPRAZOLE MAGNESIUM 20 MG BASE	04P-0373	DELAYED RELEASE CAPSULE	Approved	7/5/2005
ONDANSETRON 16 MG, 24 MG	04P-0056	ORALLY DISINTEGRATING TABLETS	Approved	7/7/2004
ONDANSETRON 16 MG/25 ML	12P-1068	INJECTION	Withdrawn	2/15/2013
ONDANSETRON 4 MG, 8 MG	11P-0166	EFFERVESCENT TABLETS	Denied	6/19/2012
ONDANSETRON 4 MG, 8 MG, 16 MG, 24 MG	07P-0043	ORALLY DISSOLVING STRIPS	Withdrawn	4/30/2009
ONDANSETRON HYDROCHLORIDE 16 MG	01P-0492	TABLET; ORAL	Approved	4/12/2002
ONDANSETRON HYDROCHLORIDE 8 MG/4 ML	04P-0544	INJECTION	Denied	6/19/2012
ONDANSETRON HYDROCHLORIDE 8 MG/4 ML	04P-0048	INJECTION	Withdrawn	4/12/2004
ONDANSETRON HYDROCHLORIDE 8, 12, 16, 20, 24MG, IN 50 ML 5% DEXTROSE	03P-0519	INJECTION	Withdrawn	4/12/2004
OXALIPLATIN 200 MG/VIAL	07P-0450	INJECTION	Approved	9/1/2010
OXAZEPAM 15 MG OR 30 MG	85P-0516	TABLET	Withdrawn	3/26/2007
OXYCODONE 2.5 MG, 5 MG/ ACETAMINOPHEN 325 MG	06P-0278 (2006- 0167)	ORALLY DISINTEGRATING TABLET	Pending	4/26/2006
OXYCODONE 2.5, 5, 7.5, 10 MG, ACETAMINOPHEN 400 MG	04P-0243	TABLETS	Withdrawn	6/10/2004
OXYCODONE 5mg, 7.5mg, 10mg, ACETAMINOPHEN 300mg	02P-0105	TABLETS	Approved	8/6/2002
OXYCODONE 7.5 MG, 10 MG, ACETAMINOPHEN 325 MG	06P-0278	ORALLY DISINTEGRATING TABLET	Pending	4/26/2006
oxycodone and acetaminophen USP, in strengths of 2.5 mg/300 mg, and 10 mg/300 mg	15P-2344	Oral	Pending	7/2/2015

Drug/Strength	Petition No	Dosage Form	Status	Status Date
OXYCODONE HYDROCHLORIDE 10 MG/5 ML, ACETAMINOPHEN 300 MG/5 ML	06P-0007	ORAL SOLUTION	Approved	1/16/2007
OXYCODONE HYDROCHLORIDE 10,15, 20, 30, 40, 60, 80 MG	12P-1180	CAPSULE, EXTENDED RELEASE; ORAL	Pending	12/18/2012
OXYCODONE HYDROCHLORIDE 15 mg, 20 mg, ACETAMINOPHEN 325 mg	02P-0285	TABLETS	Denied	2/12/2003
OXYCODONE HYDROCHLORIDE 15 MG, 20 MG; ACETAMINOPHEN 325 MG	02P-0285	TABLETS	Denied	7/30/2004
OXYCODONE HYDROCHLORIDE 15 MG, 20 MG; ACETAMINOPHEN 325MG, 325 MG	02P-0285	TABLET; ORAL	Denied	7/30/2004
OXYCODONE HYDROCHLORIDE 2.5 MG	09P-0399	TABLETS	Approved	11/16/2010
OXYCODONE HYDROCHLORIDE 2.5 MG, 5 MG, ACETAMINOPHEN 325 MG	04P-0149	ORALLY DISINTEGRATING TABLETS	Withdrawn	5/4/2006
OXYCODONE HYDROCHLORIDE 2.5 mg, ACETAMINOPHEN 300 mg	02P-0465	TABLETS	Approved	2/13/2003
OXYCODONE HYDROCHLORIDE 2.5, 5, 7.5 10 MG, ACETAMINOPHEN 650 MG	09P-0203-0003	TABLETS; EFFERVESCENT	Withdrawn	3/23/2011
OXYCODONE HYDROCHLORIDE 2.5, 5, 7.5, 10 MG, ACETAMINOPHEN 500 MG	09P-0203-0001	TABLETS; EFFERVESCENT	Withdrawn	3/23/2011
OXYCODONE HYDROCHLORIDE 20 MG/ML	05P-0144	ORAL SOLUTION	Denied	3/28/2006
OXYCODONE HYDROCHLORIDE 30 MG, 60 MG	05P-0225	TABLET; CONTROLLED- RELEASE; ORAL	Approved	7/15/2005
OXYCODONE HYDROCHLORIDE 5 MG	08P-0598	CAPSULES	Withdrawn	5/7/2012
OXYCODONE HYDROCHLORIDE 5 MG	06P-0481	CAPSULES	Pending	12/11/2006

Drug/Strength	Petition No	Dosage Form	Status	Status Date
OXYCODONE HYDROCHLORIDE 5 MG, 10 MG, 20 MG	04P-0148	TABLETS	Approved	9/28/2004
OXYCODONE HYDROCHLORIDE 5, 10, 15, 20, 30 MG	04P-0153	CAPSULES	Denied	5/17/2005
OXYCODONE HYDROCHLORIDE 7.5 MG	05P-0140	TABLETS	Approved	7/14/2005
OXYCODONE HYDROCHLORIDE 7.5 MG, 10.0 MG, ACETAMINOPHEN 325 MG	04P-0150	ORALLY DISINTEGRATING TABLETS	Withdrawn	5/4/2006
OXYCODONE HYDROCHLORIDE 9.25 MG, AND 7.0 MG; OXYCODONE TEREPHTHALATE 0.85 MG, AND 0.57 MG	99P-5105	TABLET; ORAL	Denied	5/7/2001
OXYTOCIN 1000 USP UNITS/100ML	10P-0112	INJECTION	Pending	3/2/2010
PAMIDRONATE DISODIUM 3 MG/ML, 10 ML, 9 MG/ML, 10 ML	99P-1653	INJECTION	Withdrawn	10/14/1999
PAMIDRONATE DISODIUM 3MG/ML - 10 ML VIALS, 9MG/ML - 10 ML VIALS	00P-0091	INJECTION	Approved	4/18/2000
PAMIDRONATE DISODIUM 3mg/mL - 10 mL, 6mg/mL - 10 mL	99P-2252	INJECTION	Approved	4/18/2000
PAROXETINE 20 MG & 40 MG	01P-0241	CAPSULE; ORAL	Withdrawn	2/12/2004
PEMETREXED 1000 MG	11P-0052	INJECTION	Approved	3/27/2012
PEMETREXED DISODIUM 750 MG/VIAL	12P-1259	INJECTION	Pending	1/8/2013
PENICILLAMINE 500 MG	08P-0463	CAPSULES	Approved	3/18/2010
PENTAMIDINE ISETHIONATE 100 MG/ML	89P-0435	INJECTION	Withdrawn	3/26/2007
PENTAZOCINE HYDROCHLORIDE 12.5 MG, 25 MG, ACETAMINOPHEN 325 MG	11P-0459	TABLETS	Approved	12/19/2013
PENTETATE ZINC TRISODIUM 1055 MG/5 ML	09P-0258	INJECTION; SOLUTION	Pending	6/9/2009
PENTOXIFYLLINE 500 MG	01P-0283	TABLET; EXTENDED- RELEASE; ORAL	Denied	7/3/2002

Drug/Strength	Petition No	Dosage Form	Status	Status Date
PENTOXIFYLLINE 400 MG	96P-0079	EXTENDED- RELEASE PACKET (MICROPARTICL E)	Withdrawn	3/26/2007
Phenylephrine Hydrochloride, USP, size of the vial (2 mL vs. 5 mL).	14P-0311		Pending	3/14/2014
PHENYTOIN SODIUM 100 MG; 250 MG/VIAL	87P-0367	FOR INJECTION	Withdrawn	3/26/2007
PHENYTOIN SODIUM 200 MG, 300 MG	00P-1462	CAPSULE, EXTENDED RELEASE; ORAL	Approved	2/13/2000
PHYTONADIONE 2.5 MG,7.5 MG, 10 MG	08P-0421	TABLETS	Approved	3/18/2010
PIPERACILLIN 12 GRAMS, TAZOBACTAM 1.5 GRAMS	06P-0095	INJECTION	Approved	5/6/2011
PIPERACILLIN SODIUM 300 & 360 G, TAZOBACTAM SODIUM 37.5 & 45 G	11P-0031	INJECTION	Approved	2/25/2015
PIROXICAM 5 MG	13P-0666	CAPSULES	Withdrawn	6/25/2013
POTASSIUM ACETATE 100 ML/100 CC PBP	09P-0068	INJECTION	Approved	6/22/2011
POTASSIUM ACETATE 200 MEQ	12P-0983	INJECTION	Withdrawn	11/9/2012
POTASSIUM ACETATE 50 ML	09P-0108	INJECTION	Approved	6/22/2011
POTASSIUM ACETATE 50 ML	09P-0102	INJECTION	Approved	6/29/2015
POTASSIUM CHLORIDE 10 mEq	96P-0054	FOR ORAL SUSPENSION EXTENDED- RELEASE	Withdrawn	3/26/2007
POTASSIUM CHLORIDE 10%, 20%	06P-0011	ORAL SOLUTION	Pending	12/11/2006
POTASSIUM CHLORIDE 15 mEq	01P-0108	TABLET; EXTENDED- RELEASE; ORAL	Approved	7/9/2001
POTASSIUM CHLORIDE 20 mEq	96P-0018	EXTENDED- RELEASE CAPSULES	Withdrawn	3/26/2007
POTASSIUM CITRATE 10, 20, 25 MEQ	13P-0506	TABLET; EFFERVESCENT	Pending	5/16/2013
POTASSIUM IODIDE 65 MG	00P-1574	TABLET; ORAL	Approved	7/25/2001
POTASSIUM IODIDE 65 MG/ML	04P-0092	ORAL SOLUTION	Approved	3/3/2004
POTASSIUM PHOSPHATES 5 ML/10 CC, 15 ML/30 CC	09P-0082	INJECTION	Withdrawn	3/10/2009

Drug/Strength	Petition No	Dosage Form	Status	Status Date
PRAVASTATIN SODIUM 30 MG	04P-0216	TABLETS	Approved	9/28/2004
PRAVASTATIN SODIUM 60 MG	04P-0213	TABLETS	Approved	9/28/2004
PREDNISOLONE 10 MG, 15 MG, 30 MG	09P-0180	TABLETS	Approved	10/6/2010
PREDNISOLONE SODIUM PHOSPHATE 10 MG (BASE)	96P-0498	TABLET; CHEWABLE	Withdrawn	4/5/2000
PREDNISOLONE SODIUM PHOSPHATE 10 MG/5 ML	06P-0072	ORAL SOLUTION	Withdrawn	4/11/2006
PREDNISOLONE SODIUM PHOSPHATE 10MG/5ML; 20MG/5ML; 25MG/5ML	05P-0080	SOLUTION	Approved	4/8/2005
PREDNISOLONE SODIUM PHOSPHATE 15 MG/5 ML	96P-0499	LIQUID; ORAL	Withdrawn	4/5/2000
PREDNISOLONE SODIUM PHOSPHATE 30 MG/5ML	08P-0584	SOLUTION	Approved	5/6/2011
PREDNISONE 1,2.5,20,50 MG	93P-0333	CHEWABLE TABLET	Withdrawn	3/26/2007
PREDNISONE 1,2.5,5,10,20,25,50	88P-0391	CAPSULE	Withdrawn	3/26/2007
PREDNISONE 5 MG OR 10 MG	92P-0336	CHEWABLE TABLET	Withdrawn	3/26/2007
PRIMIDONE 25 MG,100 MG, 125 MG	09P-0482	TABLETS	Approved	11/15/2012
PRIMIDONE 50, 100, 125, 250 MG	09P-0481	TABLETS ORALLY DISINTEGRATING	Approved	1/16/2013
PRIMIDONE 50, 100, 125, 250 MG	09P-0477	CAPSULES	Approved	1/16/2013
PROGESTERONE 100 MG & 200 MG	01P-0209	TABLET; ORAL	Approved	7/3/2002
PROMETHAZINE HYDROCHLORIDE 25 MG, 50 MG	09P-0249	TABLETS; EFFERVESCENT	Withdrawn	4/7/2011
PROMETHAZINE HYDROCHLORIDE 6.25 MG, HYDROCODONE BITARTRATE 2.5 MG, 1.67 MG	07P-0076	SYRUP	Pending	3/15/2007
PROPOFOL 100 MG/10 ML (1%)	00P-1289	INJECTION	Approved	9/9/2000
PROPOFOL 2%:20MG/ML:10ML,50ML	00P-1471	INJECTION	Denied	4/30/2001
PROPOXYPHENE HYDROCHLORIDE 65 mg	02P-0297	CAPSULES	Denied	2/3/2004

Drug/Strength	Petition No	Dosage Form	Status	Status Date
PROPOXYPHENE HYDROCHLORIDE 65 MG, ACETAMINOPHEN 325 MG	06P-0510	TABLETS	Approved	3/5/2009
PROPOXYPHENE NAPSYLATE 100 mg, ACETAMINOPHEN 325 mg, 500 mg	02P-0422	ORAL TABLETS	Withdrawn	3/7/2003
PROPOXYPHENE NAPSYLATE 100 MG, ACETAMINOPHEN 400 MG	06P-0503	TABLETS	Approved	3/5/2009
PROPOXYPHENE NAPSYLATE 50 MG, 100 MG, ACETAMINOPHEN 300 MG	06P-0087	TABLETS	Approved	12/18/2008
PROPOXYPHENE NAPSYLATE; 100 mg, ACETAMINOPHEN 325 mg	01P-0186	TABLET; ORAL	Approved	8/20/2001
PROPOXYPHENE NAPSYLATE; 100 MG; ACETAMINOPHEN 500 MG	00P-1551	TABLET; ORAL	Approved	1/16/2001
PROPOXYPHENE NAPSYLATE; 50 MG; ACETAMINOPHEN 500 MG	00P-1551	TABLET; ORAL	Approved	1/16/2001
PROPRANOLOL HYDROCHLORIDE 10, 20, 60, 80, 90MG	93P-0049	EFFERVESCENT TABLET	Withdrawn	3/26/2007
PROPRANOLOL HYDROCHLORIDE 10,20,40,60,80,90 MG	86P-0045	CAPSULE	Withdrawn	3/26/2007
PROPRANOLOL HYDROCHLORIDE 160 MG	85P-0129	EXTENDED- RELEASE TABLET	Withdrawn	3/26/2007
PROPRANOLOL HYDROCHLORIDE 40 MG	92P-0232	EFFERVESCENT TABLET	Withdrawn	3/26/2007
PROPRANOLOL HYDROCHLORIDE 40 MG OR 80 MG/5 ML	87P-0399	ORAL SOLUTION	Withdrawn	3/26/2007
PROPRANOLOL HYDROCHLORIDE 60, 80, 120, 160 MG	03P-0237	EXTENDED- RELEASE TABLETS	Approved	2/3/2004
PROPRANOLOL HYDROCHLORIDE 80 MG, 120 MG, 160MG	85P-0197	EXTENDED- RELEASE TABLET	Withdrawn	3/26/2007
PYRIDOXINE HYDROCHLORIDE 100 MG/ML, 10 ML FIL	09P-0185	INJECTION	Approved	10/6/2010
PYRIDOXINE HYDROCHLORIDE 3 G/30 ML	10P-0114	INJECTION	Approved	11/15/2012



Drug/Strength	Petition No	Dosage Form	Status	Status Date
QUINIDINE SULFATE 300 MG	88P-0277	EXTENDED- RELEASE CAPSULE	Withdrawn	3/26/2007
RAMIPRIL 1.25 MG, 2.5 MG, 5 MG AND 10 MG	05P-0460	TABLETS	Withdrawn	11/3/2009
RAMIPRIL 1.25, 2.50, 5, 10 MG	06P-0084	TABLETS	Withdrawn	2/1/2010
RAMIPRIL 1.25MG, 2.5MG, 5MG, 10MG	05P-0472	TABLETS	Withdrawn	5/1/2007
RAMIPRIL 2.5 MG & 10 MG	01P-0240	CAPSULE; ORAL	Withdrawn	7/31/2001
RANITIDINE HYDROCHLORIDE 15 MG BASE/ML	05P-0228	SUSPENSION	Withdrawn	5/24/2006
RIBAVIRIN 200 MG	02P-0436	TABLET	Withdrawn	9/29/2004
RIBAVIRIN 400 MG, 600 MG	04P-0196	TABLETS	Approved	9/28/2004
RIBAVIRIN USP 500 MG	05P-0179	TABLETS	Approved	7/14/2005
RIFAMPIN 50 MG/5 ML	08P-0662	SUSPENSION; ORAL	Pending	1/5/2009
RIFAXIMIN 200 MG	08P-0404	CAPSULES	Pending	7/18/2008
RISPERIDONE 0.25 MG	05P-0007	ORALLY DISINTEGRATING TABLETS	Approved	3/31/2005
RITONAVIR 100 MG	07P-0483	TABLETS	Pending	9/10/2007
SELEGILINE HYDROCHLORIDE 5 MG	04P-0514	ORALLY DISINTEGRATING TABLETS	Withdrawn	1/11/2012
SERTRALINE HYDROCHLORIDE 150 MG, 200 MG	04P-0125	TABLETS	Withdrawn	4/12/2004
SERTRALINE HYDROCHLORIDE 25MG, 50MG, 100MG	00P-1468	CAPSULE; ORAL	Approved	7/3/2002
SIMVASTATIN 10 MG & 40 MG	01P-0242	CAPSULE; ORAL	Withdrawn	7/31/2001
SITAGLIPTIN 50 MG, METFORMIN HYDROCHLORIDE 850 MG	12P-0826	TABLET; EXTENDED- RELEASE; ORAL	Denied	2/19/2015
SODIUM ACETATE 16.4% PBP	09P-0055	INJECTION	Approved	9/7/2010
SODIUM ACETATE 32.8% PBP	09P-0055	INJECTION	Approved	10/6/2010
SODIUM ACETATE 4 MEQ/ML	12P-0982	INJECTION	Withdrawn	11/9/2012
SODIUM ACETATE 50 ML SDV	09P-0109	INJECTION	Approved	6/22/2011
SODIUM ACETATE 50 ML SDV	09P-0107	INJECTION	Pending	3/3/2009
SODIUM BICARBONATE 5 ML	09P-0085	INJECTION	Approved	3/30/2011

Drug/Strength	Petition No	Dosage Form	Status	Status Date
SODIUM BICARBONATE 8.4% 1 MEQ/ML 10 ML, 4.2% 0.5 MEQ/ML 5 ML	09P-0396	INJECTION	Approved	10/6/2010
SODIUM CHLORIDE 0.9%	11P-0846	INJECTION	Pending	1/10/2012
SODIUM CHLORIDE 0.9% 9 MG/ML	09P-0565	INJECTION	Approved	5/6/2011
SODIUM CHLORIDE 0.9%, 1 ML SYRINGE	06P-0302	INJECTION	Approved	8/22/2007
SODIUM CHLORIDE 100 ML	09P-0104	INJECTION	Withdrawn	3/10/2011
SODIUM CHLORIDE 100 ML/100 CC PBP, 200 ML/200 CC PBP	09P-0069	INJECTION	Pending	2/19/2009
SODIUM CHLORIDE 3 ML, 5 ML, 15 ML, 30 ML	06P-0272	INJECTION	Approved	8/22/2007
SODIUM FERRIC GLUCONATE 10 ML/125 MG, COMPLEX IN SUCROSE	04P-0360	INJECTION	Approved	3/15/2006
SODIUM FLUORIDE F 18 20-600 mCi/mL	12P-0103	INJECTION	Approved	2/29/2012
SODIUM IODIDE I 131 500 - 3500 MCI/ML	13P-0219	SOLUTION (CONCENTRATE)	Approved	12/8/2014
SODIUM PHOSPHATES 5 ML/10 CC, 50 ML/50 CC	09P-0080	INJECTION	Approved	3/30/2011
SODIUM TETRADECYL SULFATE 0.5% & 0.2%	01P-0351	INJECTION	Denied	4/12/2002
SPIRONOLACTONE 25 MG/5 ML	86P-0055	ORAL SUSPENSION	Withdrawn	3/26/2007
SPIRONOLACTONE 25 MG/5 ML	85P-0510	SYRUP	Withdrawn	3/26/2007
STERILE WATER 2000 ML, 3000 ML	11P-0551	INJECTION	Withdrawn	8/16/2012
STERILE WATER 5 ML/6 CC VIAL, 100 ML/100 CC VIAL	09P-0070	INJECTION	Approved	9/7/2010
SULFAMETHOXAZOLE 200 MG	94P-0186	CHEWABLE TABLET	Withdrawn	3/26/2007
SULINDAC 200 MG	08P-0647	CAPSULES	Withdrawn	3/9/2011
TACROLIMUS 0.5 MG/ML	13P-0767	ORAL SUSPENSION	Pending	7/5/2013
TADALAFIL 40 MG	12P-0935	TABLETS	Pending	8/31/2012
TEMAZEPAM 7.5 MG, 15 MG, 22.5 MG AND 30 MG	06P-0396 (2006P-0103 old)	ORALLY DISINTEGRATING TABLETS	Pending	3/21/2006
TERBUTALINE SULFATE 1 MG/ML 25 ML PHARMACY BULK	04P-0518 (old 2004P-0086)	INJECTION	Pending	11/19/2004

Drug/Strength	Petition No	Dosage Form	Status	Status Date
TERFENADINE 60 MG	93P-0367	EXTENDED- RELEASE CAPSULE	Withdrawn	3/26/2007
TESTOSTERONE 5%	01P-0302	GEL; TOPICAL	Denied	4/12/2002
Thiotepa for injection, 15mg/vial	14P-2140	Injection	Pending	12/8/2014
THIOTEPA, STERILE 30 MG/VIAL	00P-0092	FOR INJECTION	Approved	6/14/2000
TIZANIDINE HYDROCHLORIDE 8 MG	13P-0847	TABLETS	Pending	7/25/2013
TOBRAMYCIN 100 MG/ML	04P-0213 (old 04P-0131)	SOLUTION FOR INHALATION	Complete	2/9/2011
TOPOTECAN 1 MG/ML	08P-0348	SOLUTION; INJECTABLE	Withdrawn	12/3/2009
TOPOTECAN HYDROCHLORIDE 1 MG/1 ML; 3 MG/3 ML	08P-0591	SOLUTION	Approved	7/30/2012
TOPOTECAN HYDROCHLORIDE 1 MG/ML	09P-0077	INJECTION	Pending	2/19/2009
TRAMADOL HYDROCHLORIDE 100 MG	08P-0327	TABLETS	Approved	3/18/2010
TRAMADOL HYDROCHLORIDE 37.5 MG, ACETAMINOPHEN 300 MG	13P-0675	TABLETS	Pending	6/14/2013
TRAMADOL HYDROCHLORIDE 50 MG PER 5 ML	04P-0405	ORAL SOLUTION	Denied	7/28/2005
TRAMADOL HYDROCHLORIDE 75 MG, ACETAMINOPHEN 650 MG	09P-0429	TABLETS	Withdrawn	11/30/2011
Trazodone Tablet, 100mg	14P-0646	Tablet; Oral	Pending	5/19/2014
TRETINOIN 0.0375%, 0.075%	05P-0417	CREAM	Approved	5/9/2007
tretinoin cream	15P-1903	Topical	Pending	5/28/2015
TRIAMTERENE 50 MG	87P-0335	TABLET	Withdrawn	3/26/2007
TRIAMTERENE 50 MG, HYDROCHLOROTHIAZIDE 25 MG	12P-0061	CAPSULES	Withdrawn	2/10/2012
TRIAZOLAM 0.125 MG/5 ML	92P-0048	ORAL SOLUTION	Withdrawn	3/26/2007
TRIMETHOPRIM 25 MG/5 ML	92P-0500	ORAL SOLUTION	Withdrawn	3/26/2007
TRIPLENNAMINE HYDROCHLORIDE 25 MG/5 ML	95P-0345	SYRUP;ORAL	Withdrawn	3/23/2000
URSODIOL 100 MG/5 ML	00P-1568	SUSPENSION; ORAL	Denied	7/9/2002

Drug/Strength	Petition No	Dosage Form	Status	Status Date
URSODIOL 100, 200, 400 MG	06P-0505	CAPSULES	Approved	8/28/2007
URSODIOL 20 MG/ML	05P-0315	ORAL SUSPENSION	Pending	8/19/2005
URSODIOL 20 MG/ML	03P-0082	ORAL SUSPENSION	Withdrawn	2/3/2004
VALRUBICIN 800 MG/20 ML	12P-1029	SOLUTION	Pending	10/23/2012
VANCOMYCIN HYDROCHLORIDE 1.5 GRAMS VIAL	13P-1202	INJECTION	Pending	10/7/2013
VANCOMYCIN HYDROCHLORIDE 100 GRAM VIAL	05P-0242	FOR INJECTION	Approved	4/19/2006
VANCOMYCIN HYDROCHLORIDE 750 MG	06P-0534	INJECTION	Approved	8/22/2007
VANCOMYCIN HYDROCHLORIDE 750 MG	06P-0533	INJECTION	Approved	8/22/2007
VENLAFAXINE HYDROCHLORIDE 225 MG, 300 MG	08P-0247	TABLET; EXTENDED- RELEASE; ORAL	Withdrawn	11/21/2008
VENLAFAXINE HYDROCHLORIDE 37.5MG, 75MG, 150MG	03P-0159	TABLET; EXTENDED- RELEASE; ORAL	Withdrawn	6/10/2009
VENLAFAXINE HYDROCHLORIDE 37.5MG, 75MG, 150MG	03P-0159	TABLET; EXTENDED- RELEASE; ORAL	Withdrawn	6/10/2009
VENLAFAXINE HYDROCHLORIDE 37.5MG, 75MG, 150MG	03P-0159	EXTENDED RELEASE TABLETS	Approved	3/30/2005
VERAPAMIL HYDROCHLORIDE 120 MG OR 240 MG	87P-0233	EXTENDED- RELEASE CAPSULE	Withdrawn	3/26/2007
VERAPAMIL HYDROCHLORIDE 40MG/5ML OR 80MG/5ML	87P-0101	ORAL SOLUTION	Withdrawn	3/26/2007
VINCRISTINE SULFATE 2 MG	85P-0084	FOR INJECTION	Withdrawn	3/26/2007
Voriconazole Injection, 10 mg/mL; 20 mL	14P-1603	Injection	Pending	10/14/2014
WARFARIN SODIUM 0.5 mg	02P-0498	TABLETS	Approved	4/14/2003
WARFARIN SODIUM 1 MG/ML	05P-0307	ORAL SOLUTION	Pending	8/9/2005
WARFARIN SODIUM 1.5 MG	03P-0307	TABLETS	Approved	10/6/2003
WATER FOR INJECTION 3 ML, 5 ML, 15 ML, 30 ML	06P-0273	INJECTION	Approved	8/22/2007
WATER FOR INJECTION USP 0.5, 1.0, 1.5, 2.0, 2.5, 4.0, 6.0, 7.0	11P-0818	INJECTION	Pending	1/10/2012

Drug/Strength	Petition No	Dosage Form	Status	Status Date
ZALEPLON 7.5 MG	07P-0398	CAPSULES	Pending	10/23/2007
ZIDOVUDINE 100 MG	08P-0407	TABLETS	Pending	7/31/2008
ziprasidone mesylate, EQ 20MG BASE/ML [20 MG BASE Vial]	15P-0547	Injection	Pending	1/20/2015
ZOLPIDEM TARTRATE 5 MG, 10 MG	09P-0248	TABLET; EFFERVESCENT	Pending	6/1/2009
ZOLPIDEM TARTRATE 5 MG, 10 MG	07P-0042	ORALLY DISSOLVING STRIPS	Withdrawn	6/1/2009
ZOLPIDEM TARTRATE 7.5 MG	10P-0015	TABLETS	Denied	10/8/2013