

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 or imaging agent).

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
ACETAMINOPHEN	N204957	SOLUTION
ACETIC ACID, GLACIAL	N017656	SOLUTION
ACETIC ACID, GLACIAL	N018161	SOLUTION
ACETIC ACID, GLACIAL	N018523	SOLUTION
ACETYLCHOLINE CHLORIDE	N020213	FOR SOLUTION
ACYCLOVIR; HYDROCORTISONE	N022436	CREAM
ALENDRONATE SODIUM; CHOLECALCIFEROL	N021762	TABLET
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
ALPROSTADIL	N020700	SUPPOSITORY
AMINO ACIDS	N018931	INJECTABLE
AMINO ACIDS	N019398	INJECTABLE
AMINO ACIDS	N020849	INJECTABLE
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N020678	INJECTABLE
AMINO ACIDS; DEXTROSE	N020734	INJECTABLE
APRACLONIDINE HYDROCHLORIDE	N019779	SOLUTION/DROPS
ARGATROBAN	N209552	SOLUTION
ARGATROBAN	N212035	SOLUTION
ARGININE HYDROCHLORIDE	N016931	INJECTABLE
ARTEMETHER; LUMEFANTRINE	N022268	TABLET
ARTICAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE	N022466	INJECTABLE
ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL ACETATE; VITAMIN A; VITAMIN K	N021265	INJECTABLE
ASPIRIN	N200671	CAPSULE, EXTENDED RELEASE
ATROPINE SULFATE	N208151	SOLUTION/DROPS
ATROPINE SULFATE	N213581	SOLUTION/DROPS
ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE	N017744	TABLET
AURANOFIN	N018689	CAPSULE
AZELAIC ACID	N020428	CREAM
AZITHROMYCIN	N050693	FOR SUSPENSION
AZITHROMYCIN	N050810	SOLUTION/DROPS
BARIUM SULFATE	N208036	FOR SUSPENSION
BARIUM SULFATE	N208143	SUSPENSION
BARIUM SULFATE	N208844	PASTE

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BENOXINATE HYDROCHLORIDE; FLUORESCHEIN SODIUM	N208582	SOLUTION/DROPS
BETAXOLOL HYDROCHLORIDE	N019845	SUSPENSION/DROPS
BIVALIRUDIN	N211215	SOLUTION
BORTEZOMIB	N206927	POWDER
BORTEZOMIB	N209191	POWDER
BUDESONIDE	N021949	POWDER, METERED
BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE	N016964	INJECTABLE
BUPIVACAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE	N018304	INJECTABLE
BUSULFAN	N009386	TABLET
BUTENAFINE HYDROCHLORIDE	N020524	CREAM
CABAZITAXEL	N207949	SOLUTION
CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE	N018469	SOLUTION
CALCIUM CHLORIDE; DEXTROSE; LACTIC ACID; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE	N021703	INJECTABLE
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N017512	SOLUTION
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N018883	SOLUTION
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N020183	SOLUTION
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	N020577	INJECTABLE
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N019367	INJECTABLE
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N019634	INJECTABLE
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE	N018895	INJECTABLE
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE	N207026	INJECTABLE
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N016693	INJECTABLE
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018251	INJECTABLE
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N020002	INJECTABLE

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CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N017635	SOLUTION
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018156	SOLUTION
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018495	SOLUTION
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N018494	SOLUTION
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N018681	SOLUTION
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N018921	SOLUTION
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N019416	SOLUTION
CALCIUM GLUCONATE	N208418	SOLUTION
CARBIDOPA; LEVODOPA	N203952	SUSPENSION
CARMUSTINE	N215000	POWDER
CEFAZOLIN SODIUM	N207131	SOLUTION
CEFEPIME HYDROCHLORIDE	N050817	INJECTABLE
CHLORAMBUCIL	N010669	TABLET
CHLOROPROCAINE HYDROCHLORIDE	N009435	INJECTABLE
CHLOROTHIAZIDE	N011870	SUSPENSION
CHLORTHALIDONE	N019574	TABLET
CHOLIC ACID	N205750	CAPSULE
CHROMIC CHLORIDE	N018961	INJECTABLE
CIPROFLOXACIN HYDROCHLORIDE	N020369	OINTMENT
CIPROFLOXACIN HYDROCHLORIDE; HYDROCORTISONE	N020805	SUSPENSION/DROPS
CITALOPRAM HYDROBROMIDE	N215428	CAPSULE
CITRIC ACID; GLUCONOLACTONE; MAGNESIUM CARBONATE	N019481	SOLUTION
CITRIC ACID; UREA C-13	N021314	FOR SOLUTION, TABLET, FOR SOLUTION
CLINDAMYCIN PHOSPHATE	N050635	INJECTABLE
CLINDAMYCIN PHOSPHATE	N050767	SUPPOSITORY
CLINDAMYCIN PHOSPHATE	N208083	SOLUTION
COCAINE HYDROCHLORIDE	N209575	SOLUTION
CONIVAPTAN HYDROCHLORIDE	N021697	INJECTABLE
CYCLOSPORINE	N050625	CAPSULE
CYSTEAMINE HYDROCHLORIDE	N200740	SOLUTION/DROPS
DALFOPRISTIN; QUINUPRISTIN	N050748	INJECTABLE
DALTEPARIN SODIUM	N020287	INJECTABLE
DAPTOMYCIN	N209949	POWDER
DECITABINE	N205582	POWDER
DESLORATADINE; PSEUDOEPHEDRINE SULFATE	N021313	TABLET, EXTENDED RELEASE

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DESVENLAFAXINE	N204150	TABLET, EXTENDED RELEASE
DEXAMETHASONE; TOBRAMYCIN	N050616	OINTMENT
DEXMEDETOMIDINE HYDROCHLORIDE	N206628	SOLUTION
DEXTROSE	N018562	INJECTABLE
DEXTROSE	N018564	INJECTABLE
DEXTROSE	N019345	INJECTABLE
DEXTROSE	N019445	INJECTABLE
DEXTROSE	N016673	INJECTABLE
DEXTROSE	N016730	INJECTABLE
DEXTROSE	N018563	INJECTABLE
DEXTROSE	N018561	INJECTABLE
DEXTROSE	N019466	INJECTABLE
DEXTROSE	N019479	INJECTABLE
DEXTROSE	N019626	INJECTABLE
DEXTROSE	N019893	INJECTABLE
DEXTROSE	N020179	INJECTABLE
DEXTROSE	N020047	INJECTABLE
DEXTROSE; MAGNESIUM ACETATE; POTASSIUM ACETATE; SODIUM CHLORIDE	N017610	INJECTABLE
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE	N019873	INJECTABLE
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM LACTATE	N017484	INJECTABLE
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM LACTATE; SODIUM PHOSPHATE, MONOBASIC ANHYDROUS	N019513	INJECTABLE
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	N017609	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE	N017634	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE	N018371	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE	N019699	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018008	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019308	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018037	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018629	INJECTABLE
DEXTROSE; SODIUM CHLORIDE	N019631	INJECTABLE

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DEXTROSE; SODIUM CHLORIDE	N016687	INJECTABLE
DEXTROSE; SODIUM CHLORIDE	N016689	INJECTABLE
DIAZEPAM	N020648	GEL
DICLOFENAC EPOLAMINE	N021234	SYSTEM
DIMERCAPROL	N005939	INJECTABLE
DINOPROSTONE	N019617	GEL
DINOPROSTONE	N020411	INSERT, EXTENDED RELEASE
DISOPYRAMIDE PHOSPHATE	N018655	CAPSULE, EXTENDED RELEASE
DOBUTAMINE HYDROCHLORIDE	N020201	INJECTABLE
DOBUTAMINE HYDROCHLORIDE	N020255	INJECTABLE
DOCETAXEL	N022234	INJECTABLE
DOCETAXEL	N203551	INJECTABLE
DOCETAXEL	N022534	SOLUTION
DOLASETRON MESYLATE	N020623	TABLET
DOPAMINE HYDROCHLORIDE	N019099	INJECTABLE
DOPAMINE HYDROCHLORIDE	N019615	INJECTABLE
DOPAMINE HYDROCHLORIDE	N018132	INJECTABLE
DOPAMINE HYDROCHLORIDE	N018826	INJECTABLE
DOXAZOSIN MESYLATE	N021269	TABLET, EXTENDED RELEASE
DOXORUBICIN HYDROCHLORIDE	N050629	INJECTABLE
DOXYCYCLINE CALCIUM	N050480	SUSPENSION
DROSPIRENONE; ESTRADIOL	N021355	TABLET
ECHOTHIOPHATE IODIDE	N011963	FOR SOLUTION
EMTRICITABINE	N021896	SOLUTION
ENFUVRTIDE	N021481	INJECTABLE
ENTECAVIR	N021798	SOLUTION
EPHEDRINE HYDROCHLORIDE	N213536	SOLUTION
EPHEDRINE SULFATE	N208289	SOLUTION
EPINEPHRINE	N209359	SOLUTION
EPINEPHRINE	N205029	SOLUTION
ESMOLOL HYDROCHLORIDE	N019386	INJECTABLE
ESOMEPRAZOLE MAGNESIUM	N021957	FOR SUSPENSION, DELAYED RELEASE
ESTRADIOL	N021674	SYSTEM
ESTRADIOL	N021813	GEL, METERED
ESTRADIOL	N022014	SPRAY
ESTRADIOL; LEVONORGESTREL	N021258	FILM, EXTENDED RELEASE
ESTRADIOL; NORETHINDRONE ACETATE	N020870	FILM, EXTENDED RELEASE
ESTRAMUSTINE PHOSPHATE SODIUM	N018045	CAPSULE
ESTROGENS, CONJUGATED	N004782	TABLET
ESTROGENS, CONJUGATED	N010402	INJECTABLE
ETHANOLAMINE OLEATE	N019357	INJECTABLE
ETHINYL ESTRADIOL; LEVONORGESTREL	N209405	TABLET
ETHIODIZED OIL	N009190	OIL
ETHIONAMIDE	N013026	TABLET

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ETOPOSIDE PHOSPHATE	N020457	INJECTABLE
FENOFIBRATE	N021612	CAPSULE
FENOFIBRATE	N021350	TABLET
FINASTERIDE; TADALAFIL	N215423	CAPSULE
FLUORESCEIN SODIUM	N021980	INJECTABLE
FLUORESCEIN SODIUM	N022186	INJECTABLE
FORMOTEROL FUMARATE; MOMETASONE FUROATE	N022518	AEROSOL, METERED
FOSAMPRENAVIR CALCIUM	N022116	SUSPENSION
GADOBUTROL	N201277	SOLUTION
GADOXETATE DISODIUM	N022090	SOLUTION
GEMCITABINE HYDROCHLORIDE	N209604	SOLUTION
GLYCINE	N016784	SOLUTION
GLYCINE	N017865	SOLUTION
GLYCINE	N018315	SOLUTION
GLYCOPYRROLATE	N210997	SOLUTION
GLYCOPYRROLATE	N215019	TABLET, ORALLY DISINTEGRATING
GLYCOPYRROLATE	N214919	SOLUTION
HALCINONIDE	N017824	OINTMENT
HEPARIN SODIUM	N018609	INJECTABLE
HEPARIN SODIUM	N018916	INJECTABLE
HEPARIN SODIUM	N019339	INJECTABLE
HEPARIN SODIUM	N019952	INJECTABLE
HYDROCHLOROTHIAZIDE; SPIRONOLACTONE	N012616	TABLET
HYDROCORTISONE ACETATE	N017351	AEROSOL, METERED
HYDROMORPHONE HYDROCHLORIDE	N019034	INJECTABLE
HYDROMORPHONE HYDROCHLORIDE	N200403	INJECTABLE
HYDROXYCHLOROQUINE SULFATE	N214581	TABLET
HYDROXYUREA	N016295	CAPSULE
ILOPROST	N021779	SOLUTION
INDOMETHACIN	N022536	INJECTABLE
IOBENGUANE SULFATE I-123	N022290	SOLUTION
IOHEXOL	N018956	SOLUTION
IOHEXOL	N018956	INJECTABLE
IOHEXOL	N020608	SOLUTION
ISOCARBOXAZID	N011961	TABLET
KETOROLAC TROMETHAMINE	N022382	SPRAY, METERED
LABETALOL HYDROCHLORIDE	N213330	SOLUTION
LAMIVUDINE	N021004	SOLUTION
LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE	N022141	TABLET
LANREOTIDE ACETATE	N215395	SOLUTION
LEFLUNOMIDE	N020905	TABLET
LEUPROLIDE ACETATE	N020263	POWDER
LEUPROLIDE ACETATE	N020517	INJECTABLE
LEUPROLIDE ACETATE	N020708	INJECTABLE
LEUPROLIDE ACETATE	N020011	INJECTABLE
LEUPROLIDE ACETATE	N019732	INJECTABLE

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LEUPROLIDE ACETATE	N205054	FOR SUSPENSION
LEVAMLODIPINE MALEATE	N212895	TABLET
LEVETIRACETAM	N202543	INJECTABLE
LIDOCAINE HYDROCHLORIDE	N018461	INJECTABLE
LIDOCAINE HYDROCHLORIDE	N019830	INJECTABLE
LINEZOLID	N206473	SOLUTION
LODOXAMIDE TROMETHAMINE	N020191	SOLUTION/DROPS
LOFEXIDINE HYDROCHLORIDE	N209229	TABLET
LOMUSTINE	N017588	CAPSULE
LOTEPREDNOL ETABONATE	N200738	OINTMENT
LOTEPREDNOL ETABONATE; TOBRAMYCIN	N050804	SUSPENSION/DROPS
LOVASTATIN	N021316	TABLET, EXTENDED RELEASE
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	N019696	INJECTABLE
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	N017586	INJECTABLE
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	N017637	SOLUTION
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	N019024	SOLUTION
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	N019711	INJECTABLE
MAGNESIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE	N021910	SOLUTION
MAGNESIUM SULFATE	N019316	SOLUTION
MAGNESIUM SULFATE	N020488	INJECTABLE
MAGNESIUM SULFATE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM PHOSPHATE	N018336	SOLUTION
MAGNESIUM SULFATE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM PHOSPHATE	N018508	SOLUTION
MANGANESE CHLORIDE	N018962	INJECTABLE
MANNITOL	N013684	INJECTABLE
MANNITOL	N019603	INJECTABLE
MANNITOL	N020006	INJECTABLE
MARAVIROC	N022128	TABLET
MELOXICAM	N021530	SUSPENSION
MERCAPTOPYRINE	N205919	SUSPENSION
MEROPENEM	N202106	POWDER

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MESALAMINE	N020049	CAPSULE, EXTENDED RELEASE
MESNA	N020855	TABLET
METAXALONE	N022503	TABLET
METHACHOLINE CHLORIDE	N019193	FOR SOLUTION
METHOHEXITAL SODIUM	N011559	INJECTABLE
METHOTREXATE	N210737	SOLUTION
METHSUXIMIDE	N010596	CAPSULE
METHYLENE BLUE	N204630	SOLUTION
METRONIDAZOLE	N020743	CREAM
MICAFUNGIN SODIUM	N212156	POWDER
MICONAZOLE	N022404	TABLET
MILTEFOSINE	N204684	CAPSULE
MINOCYCLINE HYDROCHLORIDE	N050781	POWDER, EXTENDED RELEASE
MITOTANE	N016885	TABLET
MOMETASONE FUROATE	N021067	POWDER
MOMETASONE FUROATE	N205641	AEROSOL, METERED
MORPHINE SULFATE	N202515	INJECTABLE
MOXIFLOXACIN HYDROCHLORIDE	N205572	SOLUTION
NABILONE	N018677	CAPSULE
NAFCILLIN SODIUM	N050655	INJECTABLE
NELFINAVIR MESYLATE	N020779	TABLET
NELFINAVIR MESYLATE	N021503	TABLET
NEOSTIGMINE METHYLSULFATE	N203629	SOLUTION
NICARDIPINE HYDROCHLORIDE	N022276	INJECTABLE
NICOTINE	N020385	SPRAY, METERED
NITROGLYCERIN	N020145	FILM, EXTENDED RELEASE
NITROGLYCERIN	N021780	AEROSOL, METERED
NOREPINEPHRINE BITARTRATE	N214313	SOLUTION
OCTREOTIDE ACETATE	N021008	INJECTABLE
OLANZAPINE PAMOATE	N022173	SUSPENSION, EXTENDED RELEASE
OLIVE OIL; SOYBEAN OIL	N204508	EMULSION
OLSALAZINE SODIUM	N019715	CAPSULE
OMEPRAZOLE MAGNESIUM	N022056	FOR SUSPENSION, DELAYED RELEASE
ORLISTAT	N020766	CAPSULE
OXACILLIN SODIUM	N050640	INJECTABLE
OXICONAZOLE NITRATE	N020209	LOTION
PALONOSETRON HYDROCHLORIDE	N207963	SOLUTION
PEMETREXED	N208419	SOLUTION
PEMETREXED DISODIUM	N214657	SOLUTION
PENICILLIN G BENZATHINE; PENICILLIN G PROCAINE	N050138	INJECTABLE
PENICILLIN G POTASSIUM	N050638	INJECTABLE
PENTOSAN POLYSULFATE SODIUM	N020193	CAPSULE

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PHENDIMETRAZINE TARTRATE	N018074	CAPSULE, EXTENDED RELEASE
PHENYLEPHRINE HYDROCHLORIDE	N212909	SOLUTION
PHENYLEPHRINE HYDROCHLORIDE	N203826	SOLUTION
PIPERACILLIN SODIUM; TAZOBACTAM SODIUM	N050750	INJECTABLE
PODOFILOX	N020529	GEL
POLIDOCANOL	N021201	SOLUTION
POTASSIUM CHLORIDE	N019904	INJECTABLE
POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019686	INJECTABLE
POTASSIUM PHOSPHATE, DIBASIC; POTASSIUM PHOSPHATE, MONOBASIC	N212832	SOLUTION
POVIDONE-IODINE	N018634	SOLUTION/DROPS
PRALIDOXIME CHLORIDE	N014134	INJECTABLE
PROCARBAZINE HYDROCHLORIDE	N016785	CAPSULE
PROGESTERONE	N020701	GEL
PROGESTERONE	N022057	INSERT
PROPRANOLOL HYDROCHLORIDE	N021438	CAPSULE, EXTENDED RELEASE
PROPYLTHIOURACIL	N006188	TABLET
PYRIDOSTIGMINE BROMIDE	N009830	INJECTABLE
PYRIDOSTIGMINE BROMIDE	N017398	INJECTABLE
RIFAPENTINE	N021024	TABLET
RITONAVIR	N209512	POWDER
SELEGILINE	N021336	FILM, EXTENDED RELEASE
SELEGILINE HYDROCHLORIDE	N021479	TABLET, ORALLY DISINTEGRATING
SERTRALINE HYDROCHLORIDE	N215133	CAPSULE
SILVER SULFADIAZINE	N017381	CREAM
SILVER SULFADIAZINE	N018578	CREAM
SILVER SULFADIAZINE	N018810	CREAM
SODIUM BENZOATE; SODIUM PHENYLACETATE	N215025	SOLUTION
SODIUM CHLORIDE	N019319	SOLUTION FOR SLUSH
SODIUM CHLORIDE	N019635	INJECTABLE
SODIUM CHLORIDE	N021569	INJECTABLE
SODIUM CHLORIDE	N202832	INJECTABLE
SODIUM CHLORIDE	N019022	INJECTABLE
SODIUM CHLORIDE	N016733	SOLUTION
SODIUM CHLORIDE	N017427	SOLUTION
SODIUM CHLORIDE	N017514	SOLUTION
SODIUM CHLORIDE	N017867	SOLUTION
SODIUM CHLORIDE	N018314	SOLUTION
SODIUM IODIDE I-131	N021305	CAPSULE
SORBITOL	N016741	SOLUTION
SORBITOL	N017863	SOLUTION
STERILE WATER FOR IRRIGATION	N016734	LIQUID
STERILE WATER FOR IRRIGATION	N017428	LIQUID
STERILE WATER FOR IRRIGATION	N017513	LIQUID

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STERILE WATER FOR IRRIGATION	N017866	LIQUID
STERILE WATER FOR IRRIGATION	N018313	LIQUID
STREPTOZOCIN	N050577	INJECTABLE
SUCCIMER	N019998	CAPSULE
SUCCINYLCHOLINE CHLORIDE	N215143	SOLUTION
TAMOXIFEN CITRATE	N021807	SOLUTION
TAZAROTENE	N021184	CREAM
TECHNETIUM TC-99M EXAMETAZIME KIT	N019829	INJECTABLE
TECHNETIUM TC-99M PENTETATE KIT	N018511	INJECTABLE
TENOFOVIR DISOPROXIL FUMARATE	N022577	POWDER
TERIPARATIDE	N211939	SOLUTION
TETRACAINE HYDROCHLORIDE	N208135	SOLUTION
TETRACAINE HYDROCHLORIDE	N210821	SOLUTION
THALIDOMIDE	N020785	CAPSULE
THEOPHYLLINE	N019826	INJECTABLE
THIOGUANINE	N012429	TABLET
TIPRANAVIR	N021814	CAPSULE
TIROFIBAN HYDROCHLORIDE	N020912	SOLUTION
TORSEMIDE	N213218	TABLET
TRAMADOL HYDROCHLORIDE	N022370	CAPSULE, EXTENDED RELEASE
TRANEXAMIC ACID	N212020	SOLUTION
TRETINOIN	N020475	GEL
TRETINOIN	N021108	CREAM
TRIPTORELIN PAMOATE	N020715	INJECTABLE
TRIPTORELIN PAMOATE	N021288	INJECTABLE
TROMETHAMINE	N013025	SOLUTION
TRYPAN BLUE	N021670	SOLUTION
VANCOMYCIN HYDROCHLORIDE	N050671	INJECTABLE
VANCOMYCIN HYDROCHLORIDE	N209481	POWDER
VASOPRESSIN	N212593	SOLUTION
VERAPAMIL HYDROCHLORIDE	N019614	CAPSULE, EXTENDED RELEASE
VERTEPORFIN	N021119	INJECTABLE
VORICONAZOLE	N208562	POWDER
ZILEUTON	N020471	TABLET
ZOLEDRONIC ACID	N204016	SOLUTION

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Ingredient	Approved NDA	Dosage Form
ACETOHYDROXAMIC ACID	N018749	TABLET
ALBUMIN HUMAN	N020899	INJECTABLE
ALITRETINOIN	N020886	GEL
ALPROSTADIL	N021212	INJECTABLE
ALPROSTADIL	N020649	INJECTABLE
ALPROSTADIL	N020379	INJECTABLE
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM GLYCEROPHOSPHATE; SOYBEAN OIL	N200656	EMULSION
AMPHOTERICIN B	N050724	INJECTABLE, LIPID COMPLEX
ATAZANAVIR SULFATE	N206352	POWDER
ATROPINE	N017106	SOLUTION
ATROPINE; PRALIDOXIME CHLORIDE	N021983	INJECTABLE
AZTREONAM	N050814	FOR SOLUTION
BECLOMETHASONE DIPROPIONATE MONOHYDRATE	N019389	SPRAY, METERED
CARMUSTINE	N020637	IMPLANT
CIPROFLOXACIN HYDROCHLORIDE	N021918	SOLUTION/DROPS
CLOBETASOL PROPIONATE	N213691	LOTION
COLISTIN SULFATE; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; THONZONIUM BROMIDE	N050356	SUSPENSION/DROPS
COPPER	N018680	INTRAUTERINE DEVICE
CORTICOTROPIN	N008372	INJECTABLE
CORTICOTROPIN	N008975	INJECTABLE
CYSTEAMINE BITARTRATE	N020392	CAPSULE
DIATRIZOATE MEGLUMINE	N010040	SOLUTION
ESTRADIOL	N020472	INSERT, EXTENDED RELEASE
ESTRADIOL	N021166	GEL, METERED
ESTRADIOL ACETATE	N021367	INSERT, EXTENDED RELEASE
ESTROGENS, CONJUGATED	N020216	CREAM
ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE	N020527	TABLET
FERRIC HEXACYANOFERRATE(II)	N021626	CAPSULE
FERRIC OXYHYDROXIDE	N017441	INJECTABLE
FERRIC OXYHYDROXIDE	N021135	INJECTABLE
FLUDEOXYGLUCOSE F-18	N021870	INJECTABLE
FLUOCINOLONE ACETONIDE	N020001	SHAMPOO
FLUOCINOLONE ACETONIDE	N021737	IMPLANT
FLUROMETHOLONE	N019216	SUSPENSION/DROPS
FLUROMETHOLONE ACETATE	N019079	SUSPENSION/DROPS
FLURANDRENOLIDE	N016455	TAPE
FLUTICASONE PROPIONATE	N020833	POWDER
FULVESTRANT	N210063	SOLUTION

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GADOBENATE DIMEGLUMINE	N021357	INJECTABLE
GADOBENATE DIMEGLUMINE	N021358	INJECTABLE
GADODIAMIDE	N020123	INJECTABLE
GADODIAMIDE	N022066	INJECTABLE
GADOTERIDOL	N020131	INJECTABLE
GADOTERIDOL	N021489	INJECTABLE
GALLIUM CITRATE GA-67	N017478	INJECTABLE
GALLIUM CITRATE GA-67	N018058	INJECTABLE
GANCICLOVIR	N022211	GEL
GLUCAGON HYDROCHLORIDE	N020918	INJECTABLE
GLUCAGON HYDROCHLORIDE	N201849	POWDER
GOSERELIN ACETATE	N020578	IMPLANT
GOSERELIN ACETATE	N019726	IMPLANT
HALCINONIDE	N017823	SOLUTION
HEXACHLOROPHENE	N017433	SPONGE
HYDROCORTISONE PROBUTATE	N020453	CREAM
HYDROXOCOBALAMIN	N022041	INJECTABLE
HYDROXYPROPYL CELLULOSE	N018771	INSERT
ICODEXTRIN	N021321	SOLUTION
INDIUM IN-111 CHLORIDE	N019841	INJECTABLE
INDIUM IN-111 PENTETATE DISODIUM	N017707	INJECTABLE
INDIUM IN-111 PENTETREOTIDE KIT	N020314	INJECTABLE
IOPROMIDE	N020220	INJECTABLE
IOPROMIDE	N021425	INJECTABLE
IOTHALAMATE MEGLUMINE	N013295	INJECTABLE
IOTHALAMATE MEGLUMINE	N017057	SOLUTION
IOTHALAMATE SODIUM I-125	N017279	INJECTABLE
IOVERSOL	N019710	INJECTABLE
IOVERSOL	N020923	INJECTABLE
LEUPROLIDE ACETATE	N021343	POWDER
LIDOCAINE; PRILOCAINE	N021451	GEL
MAFENIDE ACETATE	N016763	CREAM
MANNITOL	N022368	POWDER
MEDROXYPROGESTERONE ACETATE	N021583	INJECTABLE
METHOXSALEN	N020969	INJECTABLE
METYRAPONE	N012911	CAPSULE
MUPIROCIN	N050788	OINTMENT
NAFARELIN ACETATE	N019886	SPRAY, METERED
NATAMYCIN	N050514	SUSPENSION
NICOTINE	N020714	INHALANT
NITAZOXANIDE	N021498	FOR SUSPENSION
NITROGLYCERIN	N021359	OINTMENT
OXYTOCIN	N018248	INJECTABLE
OXYTOCIN	N018261	INJECTABLE
PENICILLIN G BENZATHINE	N050141	INJECTABLE
PORFIMER SODIUM	N020451	INJECTABLE
PRAMLINTIDE ACETATE	N021332	INJECTABLE

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PREDNISOLONE ACETATE	N017100	SUSPENSION/DROPS
PREDNISOLONE ACETATE	N017011	SUSPENSION/DROPS
PREDNISOLONE ACETATE	N017469	SUSPENSION/DROPS
RADIUM RA-223 DICHLORIDE	N203971	SOLUTION
RISPERIDONE	N021346	INJECTABLE
RUBIDIUM CHLORIDE RB-82	N019414	INJECTABLE
RUBIDIUM CHLORIDE RB-82	N202153	SOLUTION
SALMETEROL XINAFOATE	N020692	POWDER
SECRETIN SYNTHETIC HUMAN	N021256	FOR SOLUTION
SERTACONAZOLE NITRATE	N021385	CREAM
SINCALIDE	N017697	INJECTABLE
SOYBEAN OIL	N019942	INJECTABLE
SOYBEAN OIL	N017643	INJECTABLE
SOYBEAN OIL	N018449	INJECTABLE
SOYBEAN OIL	N019531	INJECTABLE
SOYBEAN OIL	N020248	INJECTABLE
SULCONAZOLE NITRATE	N018737	CREAM
SULCONAZOLE NITRATE	N018738	SOLUTION
TALC	N020587	AEROSOL
TALC	N021388	POWDER
TECHNETIUM TC-99M BICISATE KIT	N020256	INJECTABLE
TECHNETIUM TC-99M EXAMETAZIME KIT	N208870	POWDER
TECHNETIUM TC-99M MEDRONATE	N018035	INJECTABLE
TECHNETIUM TC-99M MEDRONATE KIT	N018107	INJECTABLE
TECHNETIUM TC-99M MEDRONATE KIT	N018124	INJECTABLE
TECHNETIUM TC-99M OXIDRONATE KIT	N018321	INJECTABLE
TECHNETIUM TC-99M PYROPHOSPHATE KIT	N017538	INJECTABLE
TECHNETIUM TC-99M PYROPHOSPHATE KIT	N019039	INJECTABLE
TECHNETIUM TC-99M RED BLOOD CELL KIT	N019981	INJECTABLE
TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR	N017243	SOLUTION
TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR	N017771	SOLUTION
TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR	N202158	SOLUTION
TECHNETIUM TC-99M SUCCIMER	N214993	POWDER
TECHNETIUM TC-99M SULFUR COLLOID KIT	N017858	SOLUTION
TECHNETIUM TC-99M TETROFOSMIN KIT	N020372	INJECTABLE
TERCONAZOLE	N021735	CREAM
TOBRAMYCIN	N050555	OINTMENT
TRETINOIN	N020400	GEL
UREA, C-14	N020617	CAPSULE
XENON XE-133	N017284	GAS
XENON XE-133	N018327	GAS
ZANAMIVIR	N021036	POWDER
ZINC ACETATE	N020458	CAPSULE

RX List Appendix

Ingredient	Approved NDA	Dosage Form
BISMUTH SUBCITRATE POTASSIUM; METRONIDAZOLE; TETRACYCLINE HYDROCHLORIDE	N050786	CAPSULE
BUDESONIDE	N205613	AEROSOL, FOAM
CUPRIC CHLORIDE	N018960	INJECTABLE
DICHLORPHENAMIDE	N011366	TABLET
DOXEPIN HYDROCHLORIDE	N020126	CREAM
LOTEPREDNOL ETABONATE	N020803	SUSPENSION/DROPS
NITISINONE	N021232	CAPSULE
PENCICLOVIR	N020629	CREAM
PHENYLEPHRINE HYDROCHLORIDE	N207926	SOLUTION/DROPS
ZINC SULFATE	N209377	SOLUTION

Methodology¹

1. The list is based on the [Orange Book Data Files](#), accessed April 14, 2023.
2. The list includes Orange Book-listed drug products that are marketed as prescription drug products.² The list generally does not differentiate between different strengths of a given drug product. However, we have included a drug product of multiple strengths on the list if there is not an approved ANDA for one or more of the strengths (even if there is an approved ANDA for one or more other strengths). 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.

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. This means that an active and approved NDA for a particular active ingredient and dosage form will be included on the list if there are no approved ANDAs for at least one drug product for that active ingredient and dosage form approved in the NDA, even if there are approved ANDAs that reference a drug product in a different NDA with the same active ingredient and dosage form.

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.