

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 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 drug products for which FDA could immediately accept an ANDA without prior discussion.

Part II identifies 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 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 a biological product, or 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.
- Some products in Part II of the list are biological products that are subject to the transition provisions described in section 7002(e) of the Biologics Price Competition and Innovation Act of 2009.
- 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 will 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 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.

Part I

Ingredient	Approved NDA	Dosage Form
ACETAMINOPHEN	204767	SOLUTION
ACETYLCHOLINE CHLORIDE	020213	FOR SOLUTION
ACRIVASTINE; PSEUDOEPHEDRINE HYDROCHLORIDE	019806	CAPSULE
ACYCLOVIR	021478	CREAM
ALBUTEROL SULFATE	020503	AEROSOL, METERED
ALENDRONATE SODIUM; CHOLECALCIFEROL	021762	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	021163	SOLUTION
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	021559	SOLUTION
ALPROSTADIL	020700	SUPPOSITORY
AMINO ACIDS	017673	INJECTABLE
AMINO ACIDS	019438	INJECTABLE
AMINO ACIDS	020015	INJECTABLE
AMINO ACIDS	019492	INJECTABLE
AMINO ACIDS	016822	INJECTABLE
AMINO ACIDS	019018	INJECTABLE
AMINO ACIDS	018931	INJECTABLE
AMINO ACIDS	020041	INJECTABLE
AMINO ACIDS	020849	INJECTABLE
AMINO ACIDS	017789	INJECTABLE
AMINO ACIDS	018429	INJECTABLE
AMINO ACIDS	017766	INJECTABLE
AMINO ACIDS	019374	INJECTABLE
AMINO ACIDS	019398	INJECTABLE
AMINO ACIDS; CALCIUM ACETATE; GLYCERIN; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE	018582	INJECTABLE

AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	020678	INJECTABLE
AMINO ACIDS; DEXTROSE	020734	INJECTABLE
AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; POTASSIUM CHLORIDE; SODIUM ACETATE	016822	INJECTABLE
AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; SODIUM CHLORIDE	017789	INJECTABLE
AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE	016822	INJECTABLE
AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE	019437	INJECTABLE
AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC	017673	INJECTABLE
AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC	019437	INJECTABLE
AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE	017789	INJECTABLE
AMINOCAPROIC ACID	015197	TABLET
AMOXICILLIN; CLARITHROMYCIN; OMEPRAZOLE	050824	CAPSULE, TABLET, CAPSULE, DELAYED RELEASE
AMOXICILLIN; CLAVULANATE POTASSIUM	050575	FOR SUSPENSION
AMPHOTERICIN B	050740	INJECTABLE, LIPOSOMAL
APOMORPHINE HYDROCHLORIDE	021264	INJECTABLE
APRACLONIDINE HYDROCHLORIDE	019779	SOLUTION/DROPS
ARGATROBAN	203049	INJECTABLE
ARGATROBAN	206769	INJECTABLE
ARGININE HYDROCHLORIDE	016931	INJECTABLE
ARTEMETHER; LUMEFANTRINE	022268	TABLET

ARTICAINE HYDROCHLORIDE; EPINEPHRINE BITARTRATE	022466	INJECTABLE
ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL ACETATE; VITAMIN A; VITAMIN K	021265	INJECTABLE
ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL ACETATE; VITAMIN A; VITAMIN K	021646	INJECTABLE
ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E	018920	FOR SOLUTION
ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E; VITAMIN K	021643	INJECTABLE
ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E; VITAMIN K	021625	INJECTABLE
ASPIRIN	200671	CAPSULE, EXTENDED RELEASE

ATROPINE SULFATE	206289	SOLUTION/DROPS
ATROPINE SULFATE	208151	SOLUTION/DROPS
ATROPINE SULFATE	021146	SOLUTION
ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE	017744	TABLET
AURANOFIN	018689	CAPSULE
AZELAIC ACID	020428	CREAM
AZITHROMYCIN	050693	FOR SUSPENSION
AZTREONAM	050632	INJECTABLE
BARIUM SULFATE	208036	FOR SUSPENSION
BARIUM SULFATE	208844	PASTE
BARIUM SULFATE	208143	SUSPENSION
BENOXINATE HYDROCHLORIDE; FLUORESCEIN SODIUM	208582	SOLUTION/DROPS
BENZOYL PEROXIDE; ERYTHROMYCIN	050769	GEL
BENZYLPENICILLOYL POLYLYSINE	050114	INJECTABLE
BETAINE	020576	FOR SOLUTION
BETAXOLOL HYDROCHLORIDE	019845	SUSPENSION/DROPS
BIVALIRUDIN	208374	SOLUTION
BRINZOLAMIDE	020816	SUSPENSION/DROPS
BUDESONIDE	021949	POWDER, METERED
BUPRENORPHINE	021306	FILM, EXTENDED RELEASE
BUSULFAN	009386	TABLET
BUTENAFINE HYDROCHLORIDE	020524	CREAM
CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE	018469	SOLUTION
CALCIUM CHLORIDE; DEXTROSE; LACTIC ACID; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE	021703	INJECTABLE
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	020183	SOLUTION
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	017512	SOLUTION

CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	020577	INJECTABLE
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	019634	INJECTABLE
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	019367	INJECTABLE
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE	018895	INJECTABLE
CALCIUM GLUCONATE	208418	SOLUTION
CARBOPROST TROMETHAMINE	017989	INJECTABLE
CARGLUMIC ACID	022562	TABLET
CEFAZOLIN SODIUM	050779	INJECTABLE
CEFAZOLIN SODIUM	207131	SOLUTION
CEFEPIME HYDROCHLORIDE	050817	INJECTABLE
CEFTAZIDIME	050823	INJECTABLE
CHLORAMBUCIL	010669	TABLET
CHLORDIAZEPOXIDE HYDROCHLORIDE; CLIDINIUM BROMIDE	012750	CAPSULE
CHLOROPROCAINE HYDROCHLORIDE	009435	INJECTABLE
CHROMIC CHLORIDE	018961	INJECTABLE
CITRIC ACID; GLUCONOLACTONE; MAGNESIUM CARBONATE	019481	SOLUTION
CITRIC ACID; UREA C-13	021314	FOR SOLUTION, TABLET, FOR
CLINDAMYCIN PHOSPHATE	050635	INJECTABLE
CLINDAMYCIN PHOSPHATE	208083	SOLUTION
CLINDAMYCIN PHOSPHATE; TRETINOIN	050803	GEL
CLOCORTOLONE PIVALATE	017765	CREAM
CLOZAPINE	203479	SUSPENSION
CROTAMITON	006927	CREAM
CUPRIC CHLORIDE	018960	INJECTABLE
CYCLOSPORINE	050625	CAPSULE
DALFOPRISTIN; QUINUPRISTIN	050748	INJECTABLE
DALTEPARIN SODIUM	020287	INJECTABLE
DAPTOMYCIN	208385	POWDER
DAPTOMYCIN	209949	POWDER
DECITABINE	205582	POWDER

DELAVIRDINE MESYLATE	020705	TABLET
DESVENLAFAXINE	204150	TABLET, EXTENDED RELEASE
DESVENLAFAXINE	204683	TABLET, EXTENDED RELEASE
DEXAMETHASONE; TOBRAMYCIN	050616	OINTMENT
DEXMEDETOMIDINE HYDROCHLORIDE	206628	SOLUTION
DEXTROSE	018564	INJECTABLE
DEXTROSE	019445	INJECTABLE
DEXTROSE	019345	INJECTABLE
DEXTROSE	018562	INJECTABLE
DEXTROSE; MAGNESIUM ACETATE; POTASSIUM ACETATE; SODIUM CHLORIDE	017610	INJECTABLE
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE	019873	INJECTABLE
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM LACTATE	017484	INJECTABLE
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM LACTATE; SODIUM PHOSPHATE, MONOBASIC ANHYDROUS	019513	INJECTABLE
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	017609	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE	018371	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE	017634	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	019630	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	018365	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	018876	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	018008	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	019308	INJECTABLE
DEXTROSE; SODIUM CHLORIDE	019631	INJECTABLE
DEXTROSE; SODIUM CHLORIDE	017606	INJECTABLE
DEXTROSE; SODIUM CHLORIDE	017799	INJECTABLE

DIAZEPAM	020648	GEL
DIAZOXIDE	017453	SUSPENSION
DIGOXIN	021648	ELIXIR
DIGOXIN	020405	TABLET
DIMERCAPROL	005939	INJECTABLE
DINOPROSTONE	019617	GEL
DINOPROSTONE	020411	INSERT, EXTENDED RELEASE
DINOPROSTONE	017810	SUPPOSITORY
DISOPYRAMIDE PHOSPHATE	018655	CAPSULE, EXTENDED RELEASE
DOCETAXEL	203551	INJECTABLE
DOCETAXEL	022234	INJECTABLE
DOPAMINE HYDROCHLORIDE	019099	INJECTABLE
DOPAMINE HYDROCHLORIDE	019615	INJECTABLE
DOXAZOSIN MESYLATE	021269	TABLET, EXTENDED RELEASE
DOXORUBICIN HYDROCHLORIDE	050629	INJECTABLE
DROSPIRENONE; ESTRADIOL	021355	TABLET
ECHOTHIOPHATE IODIDE	011963	FOR SOLUTION
EDETATE CALCIUM DISODIUM	008922	INJECTABLE
EFLORNITHINE HYDROCHLORIDE	021145	CREAM
EMEDASTINE DIFUMARATE	020706	SOLUTION/DROPS
ENFUVIRTIDE	021481	INJECTABLE
ENTECAVIR	021798	SOLUTION
EPHEDRINE SULFATE	208943	SOLUTION
EPINEPHRINE	207534	SOLUTION
ERYTHROMYCIN ETHYLSUCCINATE	050207	GRANULE
ESOMEPRAZOLE STRONTIUM	202342	CAPSULE, DELAYED RELEASE
ESTRADIOL	021674	FILM, EXTENDED RELEASE
ESTRAMUSTINE PHOSPHATE SODIUM	018045	CAPSULE
ESTROGENS, CONJUGATED	010402	INJECTABLE
ESTROGENS, CONJUGATED	004782	TABLET
ETHANOLAMINE OLEATE	019357	INJECTABLE
ETHINYL ESTRADIOL; ETONOGESTREL	021187	RING
ETHIONAMIDE	013026	TABLET
ETOPOSIDE PHOSPHATE	020457	INJECTABLE
FENOFIBRATE	021612	CAPSULE
FENOPROFEN CALCIUM	017604	CAPSULE
FENTANYL	019813	FILM, EXTENDED RELEASE
FLUORESCEIN SODIUM	022186	INJECTABLE
FLUOROURACIL	016988	CREAM
FOSAMPRENAVIR CALCIUM	022116	SUSPENSION
FOSFOMYCIN TROMETHAMINE	050717	FOR SOLUTION
GEMCITABINE HYDROCHLORIDE	209604	SOLUTION
HALCINONIDE	017556	CREAM
HALCINONIDE	017824	OINTMENT
HEPARIN SODIUM	018916	INJECTABLE

HEPARIN SODIUM	019339	INJECTABLE
HYDROCHLOROTHIAZIDE; METOPROLOL SUCCINATE	021956	TABLET, EXTENDED RELEASE
HYDROCHLOROTHIAZIDE; SPIRONOLACTONE	012616	TABLET
HYDROXYAMPHETAMINE HYDROBROMIDE; TROPICAMIDE	019261	SOLUTION/DROPS
HYDROXYPROGESTERONE CAPROATE	021945	SOLUTION
HYDROXYUREA	016295	CAPSULE
ILOPROST	021779	SOLUTION
INDOMETHACIN	022536	INJECTABLE
IOBENGUANE SULFATE I-123	022290	SOLUTION
IODIXANOL	020351	INJECTABLE
IOFLUPANE I-123	022454	SOLUTION
LAMIVUDINE	021004	SOLUTION
LEFLUNOMIDE	020905	TABLET
LEUPROLIDE ACETATE	020708	INJECTABLE
LEUPROLIDE ACETATE	020263	INJECTABLE
LEUPROLIDE ACETATE	020517	INJECTABLE
LEUPROLIDE ACETATE	020011	INJECTABLE
LEUPROLIDE ACETATE	019732	INJECTABLE
LEVOLEUCOVORIN CALCIUM	208723	POWDER
L-GLUTAMINE	021667	FOR SOLUTION
LINEZOLID	206473	SOLUTION
LODOXAMIDE TROMETHAMINE	020191	SOLUTION/DROPS
LOMUSTINE	017588	CAPSULE
LOTEPREDNOL ETABONATE; TOBRAMYCIN	050804	SUSPENSION/DROPS
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	019696	INJECTABLE
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	017586	INJECTABLE
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	017378	INJECTABLE

MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	019711	INJECTABLE
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	017637	SOLUTION
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	019024	SOLUTION
MAGNESIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE	021910	SOLUTION
MAGNESIUM SULFATE	019316	SOLUTION
MAGNESIUM SULFATE	020488	INJECTABLE
MAGNESIUM SULFATE; POTASSIUM SULFATE; SODIUM SULFATE	204553	POWDER
MANGANESE CHLORIDE	018962	INJECTABLE
MECHLORETHAMINE HYDROCHLORIDE	006695	INJECTABLE
MEDROXYPROGESTERONE ACETATE	012541	INJECTABLE
MEROPENEM	202106	POWDER
MESALAMINE	020049	CAPSULE, EXTENDED RELEASE
MESNA	020855	TABLET
METHACHOLINE CHLORIDE	019193	FOR SOLUTION
METHOHEXITAL SODIUM	011559	INJECTABLE
METHYLPREDNISOLONE	011153	TABLET
METRONIDAZOLE	020743	CREAM
MIFEPRISTONE	020687	TABLET
MITOTANE	016885	TABLET
MOMETASONE FUROATE	205641	AEROSOL, METERED
MOMETASONE FUROATE	021067	POWDER
MORPHINE SULFATE	020616	CAPSULE, EXTENDED RELEASE
MORPHINE SULFATE	202515	INJECTABLE
MORPHINE SULFATE	019916	INJECTABLE
MORPHINE SULFATE	201517	SOLUTION
MORPHINE SULFATE	022207	TABLET
MOXIFLOXACIN HYDROCHLORIDE	205572	SOLUTION
NABILONE	018677	CAPSULE
NAFCILLIN SODIUM	050655	INJECTABLE
NAFTIFINE HYDROCHLORIDE	019356	GEL
NELARABINE	021877	INJECTABLE
NELFINAVIR MESYLATE	020779	TABLET
NELFINAVIR MESYLATE	021503	TABLET
NEOSTIGMINE METHYLSULFATE	203629	SOLUTION
NICARDIPINE HYDROCHLORIDE	022276	INJECTABLE

NICOTINE	020385	SPRAY, METERED
NITAZOXANIDE	021497	TABLET
NITROGLYCERIN	021780	AEROSOL, METERED
NITROGLYCERIN	020145	FILM, EXTENDED RELEASE
OCTREOTIDE ACETATE	021008	INJECTABLE
OLANZAPINE PAMOATE	022173	SUSPENSION, EXTENDED RELEASE
OLSALAZINE SODIUM	019715	CAPSULE
ORLISTAT	020766	CAPSULE
OXACILLIN SODIUM	050640	INJECTABLE
OXICONAZOLE NITRATE	020209	LOTION
OXYMETHOLONE	016848	TABLET
PALONOSETRON HYDROCHLORIDE	207963	SOLUTION
PALONOSETRON HYDROCHLORIDE	208109	SOLUTION
PENICILLAMINE	019853	CAPSULE
PENICILLAMINE	019854	TABLET
PENICILLIN G BENZATHINE; PENICILLIN G PROCAINE	050138	INJECTABLE
PENICILLIN G POTASSIUM	050638	INJECTABLE
PENTAMIDINE ISETHIONATE	019887	FOR SOLUTION
PENTETATE CALCIUM TRISODIUM	021749	SOLUTION
PENTETATE ZINC TRISODIUM	021751	SOLUTION
PENTOSAN POLYSULFATE SODIUM	020193	CAPSULE
PHENYLEPHRINE HYDROCHLORIDE	207926	SOLUTION/DROPS
PODOFILOX	020529	GEL
POLIDOCANOL	021201	SOLUTION
POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE ANHYDROUS	019011	FOR SOLUTION
POVIDONE-IODINE	018634	SOLUTION/DROPS
PRALIDOXIME CHLORIDE	014134	INJECTABLE
PRALIDOXIME CHLORIDE	018986	INJECTABLE
PROCARBAZINE HYDROCHLORIDE	016785	CAPSULE
PROGESTERONE	020701	GEL
PYRIDOSTIGMINE BROMIDE	015193	SYRUP
PYRIMETHAMINE	008578	TABLET
RABEPRAZOLE SODIUM	204736	CAPSULE, DELAYED RELEASE
RITONAVIR	020659	SOLUTION
SAQUINAVIR MESYLATE	020628	CAPSULE
SAQUINAVIR MESYLATE	021785	TABLET
SELEGILINE	021336	FILM, EXTENDED RELEASE
SELEGILINE HYDROCHLORIDE	021479	TABLET, ORALLY DISINTEGRATING
SILDENAFIL CITRATE	203109	FOR SUSPENSION
SODIUM ACETATE	018893	INJECTABLE
SODIUM CHLORIDE	021569	INJECTABLE
SODIUM CHLORIDE	018897	INJECTABLE
SODIUM CHLORIDE	019635	INJECTABLE

SODIUM CHLORIDE	202832	INJECTABLE
SODIUM CHLORIDE	019319	SOLUTION FOR SLUSH
SODIUM IODIDE I-131	021305	CAPSULE
SODIUM IODIDE I-131	021305	SOLUTION
SODIUM LACTATE	018947	INJECTABLE
SODIUM NITROPRUSSIDE	209387	SOLUTION
SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE; SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS	018892	INJECTABLE
SORBITOL	016741	SOLUTION
SORBITOL	017863	SOLUTION
SOTALOL HYDROCHLORIDE	022306	SOLUTION
STREPTOZOCIN	050577	INJECTABLE
SUCRALFATE	019183	SUSPENSION
TAMOXIFEN CITRATE	021807	SOLUTION
TAZAROTENE	021184	CREAM
TAZAROTENE	020600	GEL
TECHNETIUM TC-99M EXAMETAZIME KIT	019829	INJECTABLE
TECHNETIUM TC-99M PENTETATE KIT	018511	INJECTABLE
TENOFOVIR DISOPROXIL FUMARATE	022577	POWDER
TESTOSTERONE	020489	FILM, EXTENDED RELEASE
TETRACAINE HYDROCHLORIDE	208135	SOLUTION
THEOPHYLLINE	019826	INJECTABLE
THIOGUANINE	012429	TABLET
TIOPRONIN	019569	TABLET
TOREMIFENE CITRATE	020497	TABLET
TRAMADOL HYDROCHLORIDE	022370	CAPSULE, EXTENDED RELEASE
TRETINOIN	020475	GEL
TRIAMCINOLONE HEXACETONIDE	016466	INJECTABLE
TRIAMTERENE	013174	CAPSULE
TRIMETHOPRIM HYDROCHLORIDE	074973	SOLUTION
TRIPTORELIN PAMOATE	021288	INJECTABLE
TRIPTORELIN PAMOATE	022437	INJECTABLE
TRIPTORELIN PAMOATE	020715	INJECTABLE
TROMETHAMINE	013025	INJECTABLE
TRYPAN BLUE	022278	SOLUTION
VANCOMYCIN HYDROCHLORIDE	050671	INJECTABLE
VERAPAMIL HYDROCHLORIDE	019614	CAPSULE, EXTENDED RELEASE
VERTEPORFIN	021119	INJECTABLE
VIGABATRIN	020427	TABLET
VORICONAZOLE	208562	POWDER
ZILEUTON	020471	TABLET
ZIPRASIDONE MESYLATE	020919	INJECTABLE

ZOLEDRONIC ACID	204016	SOLUTION
-----------------	--------	----------

Part II

Ingredient	Approved NDA	Dosage Form
ACETOHYDROXAMIC ACID	018749	TABLET
ALBUMIN IODINATED I-125 SERUM	017836	INJECTABLE
ALBUMIN IODINATED I-131 SERUM	017837	INJECTABLE
ALITRETINOIN	020886	GEL
ALPROSTADIL	021212	INJECTABLE
ALPROSTADIL	020649	INJECTABLE
ALTRETAMINE	019926	CAPSULE
AMIKACIN SULFATE	207356	SUSPENSION, LIPOSOMAL
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM GLYCEROPHOSPHATE; SOYBEAN OIL	200656	EMULSION
ATROPINE SULFATE	017106	SOLUTION
ATROPINE; PRALIDOXIME CHLORIDE	021983	INJECTABLE
BECLOMETHASONE DIPROPIONATE MONOHYDRATE	019389	SPRAY, METERED
BERACTANT	020032	SUSPENSION
BEXAROTENE	021056	GEL
BUDESONIDE	205613	AEROSOL, FOAM
CALCITRIOL	022087	OINTMENT
CALFACTANT	020521	SUSPENSION
CARMUSTINE	020637	IMPLANT
CHLORHEXIDINE GLUCONATE	020774	TABLET
CHLOROTHIAZIDE	011870	SUSPENSION
CIPROFLOXACIN HYDROCHLORIDE	020369	OINTMENT
CIPROFLOXACIN HYDROCHLORIDE	021918	SOLUTION/DROPS
CIPROFLOXACIN HYDROCHLORIDE; HYDROCORTISONE	020805	SUSPENSION/DROPS
COLESTIPOL HYDROCHLORIDE	017563	GRANULE
COLISTIN SULFATE; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; THONZONIUM BROMIDE	050356	SUSPENSION/DROPS
COPPER	018680	INTRAUTERINE DEVICE
CORTICORELIN OVINE TRIFLUTATE	020162	INJECTABLE
CORTICOTROPIN	008372	INJECTABLE
CYSTEAMINE BITARTRATE	020392	CAPSULE
DESMOPRESSIN ACETATE	020355	SPRAY, METERED
DIATRIZOATE MEGLUMINE	010040	SOLUTION
DIHYDROERGOTAMINE MESYLATE	020148	SPRAY, METERED
DOXEPIN HYDROCHLORIDE	020126	CREAM
DOXYCYCLINE CALCIUM	050480	SUSPENSION
DOXYCYCLINE HYCLATE	050751	SYSTEM, EXTENDED RELEASE
ESTRADIOL	020655	FILM, EXTENDED RELEASE
ESTRADIOL	021166	GEL, METERED
ESTRADIOL	022038	GEL
ESTRADIOL	020472	INSERT, EXTENDED RELEASE
ESTRADIOL ACETATE	021367	INSERT, EXTENDED RELEASE
ESTRADIOL; LEVONORGESTREL	021258	FILM, EXTENDED RELEASE

ESTRADIOL; NORETHINDRONE ACETATE	020870	FILM, EXTENDED RELEASE
ESTROGENS, CONJUGATED	020216	CREAM
ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE	020527	TABLET
ETHOTOIN	010841	TABLET
FERRIC HEXACYANOFERRATE(II)	021626	CAPSULE
FERRIC PYROPHOSPHATE CITRATE	208551	FOR SOLUTION
FLUNISOLIDE	021247	AEROSOL, METERED
FLUOCINOLONE ACETONIDE	020001	SHAMPOO
FLUOROMETHOLONE	017760	OINTMENT
FLUOROMETHOLONE	019216	SUSPENSION/DROPS
FLUOROMETHOLONE ACETATE	019079	SUSPENSION/DROPS
FLURANDRENOLIDE	012806	CREAM
FLURANDRENOLIDE	016455	TAPE
FLUTICASONE PROPIONATE	020833	POWDER
FOLLITROPIN ALFA/BETA	021765	INJECTABLE
GADOBENATE DIMEGLUMINE	021357	INJECTABLE
GADOBENATE DIMEGLUMINE	021358	INJECTABLE
GADOBUTROL	201277	SOLUTION
GADODIAMIDE	022066	INJECTABLE
GADODIAMIDE	020123	INJECTABLE
GADOPENTETATE DIMEGLUMINE	019596	INJECTABLE
GADOPENTETATE DIMEGLUMINE	021037	INJECTABLE
GADOTERIDOL	020131	INJECTABLE
GADOTERIDOL	021489	INJECTABLE
GALLIUM CITRATE GA-67	017478	INJECTABLE
GALLIUM CITRATE GA-67	018058	INJECTABLE
GANCICLOVIR	022211	GEL
GENTAMICIN SULFATE; PREDNISOLONE ACETATE	050612	OINTMENT
GENTAMICIN SULFATE; PREDNISOLONE ACETATE	050586	SUSPENSION/DROPS
GLUCAGON	020928	INJECTABLE
GLUCAGON HYDROCHLORIDE	020918	INJECTABLE
GLUCAGON HYDROCHLORIDE	201849	POWDER
GONADOTROPIN, CHORIONIC	017016	INJECTABLE
GUANIDINE HYDROCHLORIDE	001546	TABLET
HISTRELIN ACETATE	021732	IMPLANT
HYALURONIDASE	021665	INJECTABLE
HYALURONIDASE	021640	INJECTABLE
HYDROCORTISONE ACETATE	017351	AEROSOL, METERED
HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE	050218	CREAM
HYDROCORTISONE PROBUTATE	020453	CREAM
HYDROXOCOBALAMIN	022041	INJECTABLE
HYDROXYPROPYL CELLULOSE	018771	INSERT
ICODEXTRIN	021321	SOLUTION
IMIGLUCERASE	020367	INJECTABLE
INDIUM IN-111 CHLORIDE	019862	INJECTABLE

INDIUM IN-111 CHLORIDE	019841	INJECTABLE
INDIUM IN-111 PENTETATE DISODIUM	017707	INJECTABLE
INDIUM IN-111 PENTETREOTIDE KIT	020314	INJECTABLE
INSULIN ASPART PROTAMINE RECOMBINANT; INSULIN ASPART RECOMBINANT	021172	INJECTABLE
INSULIN ASPART RECOMBINANT	020986	INJECTABLE
INSULIN HUMAN	018780	SOLUTION
INSULIN LISPRO PROTAMINE RECOMBINANT; INSULIN LISPRO RECOMBINANT	021018	INJECTABLE
INSULIN LISPRO PROTAMINE RECOMBINANT; INSULIN LISPRO RECOMBINANT	021017	INJECTABLE
INSULIN LISPRO RECOMBINANT	020563	INJECTABLE
IOHEXOL	205383	FOR SOLUTION
IOHEXOL	018956	INJECTABLE
IOHEXOL	018956	SOLUTION
IOHEXOL	020608	SOLUTION
IOPROMIDE	021425	INJECTABLE
IOPROMIDE	020220	INJECTABLE
IOTHALAMATE MEGLUMINE	013295	INJECTABLE
IOTHALAMATE MEGLUMINE	017057	SOLUTION
IOTHALAMATE SODIUM I-125	017279	INJECTABLE
IOVERSOL	019710	INJECTABLE
IOVERSOL	020923	INJECTABLE
IRON DEXTRAN	040024	INJECTABLE
IRON DEXTRAN	017441	INJECTABLE
IRON DEXTRAN	017807	INJECTABLE
IRON SUCROSE	021135	INJECTABLE
ISOCARBOXAZID	011961	TABLET
ISONIAZID; PYRAZINAMIDE; RIFAMPIN	050705	TABLET
ISOSORBIDE DINITRATE	019790	CAPSULE, EXTENDED RELEASE
LEUPROLIDE ACETATE; NORETHINDRONE ACETATE	203696	INJECTABLE, TABLET
LEVOTHYROXINE SODIUM	021924	CAPSULE
LIDOCAINE; PRILOCAINE	021451	GEL
LOTEPREDNOL ETABONATE	200738	OINTMENT
LOTEPREDNOL ETABONATE	020803	SUSPENSION/DROPS
LOTEPREDNOL ETABONATE	020583	SUSPENSION/DROPS
LOVASTATIN	021316	TABLET, EXTENDED RELEASE
MAFENIDE ACETATE	016763	CREAM
MANNITOL	016772	SOLUTION
MECASERMIN RECOMBINANT	021839	INJECTABLE
MENOTROPINS (FSH;LH)	021663	INJECTABLE
METHOXSALIN	020969	INJECTABLE
METHSUXIMIDE	010596	CAPSULE
METYRAPONE	012911	CAPSULE
METYROSINE	017871	CAPSULE
MORPHINE SULFATE	019999	INJECTABLE
MUPIROCIN	050788	OINTMENT

NAFARELIN ACETATE	019886	SPRAY, METERED
NATAMYCIN	050514	SUSPENSION
NESIRITIDE RECOMBINANT	020920	FOR SOLUTION
NICOTINE	020714	INHALANT
NITAZOXANIDE	021498	FOR SUSPENSION
NITISINONE	209449	TABLET
NITROGLYCERIN	021359	OINTMENT
NORGESTREL	017031	TABLET
OXYTOCIN	018248	INJECTABLE
OXYTOCIN	018261	INJECTABLE
PALIPERIDONE PALMITATE	207946	SUSPENSION, EXTENDED RELEASE
PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)	022175	CAPSULE, DELAYED RELEASE
PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)	022523	CAPSULE, DELAYED RELEASE
PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)	022222	CAPSULE, DELAYED RELEASE
PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)	022542	TABLET
PEGADEMASE BOVINE	019818	INJECTABLE
PEGAPTANIB SODIUM	021756	INJECTABLE
PEGVISOMANT	021106	INJECTABLE
PENICILLIN G BENZATHINE	050141	INJECTABLE
POLIDOCANOL	205098	SOLUTION
PORACTANT ALFA	020744	SUSPENSION
PORFIMER SODIUM	020451	INJECTABLE
PREDNISOLONE ACETATE	017100	SUSPENSION/DROPS
PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM	012813	SUSPENSION
RIFAPENTINE	021024	TABLET
RUBIDIUM CHLORIDE RB-82	019414	INJECTABLE
RUBIDIUM CHLORIDE RB-82	202153	SOLUTION
SALMETEROL XINAFOATE	020692	POWDER
SAMARIUM SM-153 LEXIDRONAM PENTASODIUM	020570	INJECTABLE
SECRETIN SYNTHETIC HUMAN	021256	FOR SOLUTION
SERTACONAZOLE NITRATE	021385	CREAM
SOMATROPIN	019774	INJECTABLE
SOMATROPIN RECOMBINANT	020280	INJECTABLE
SOMATROPIN RECOMBINANT	021426	INJECTABLE
SOMATROPIN RECOMBINANT	020522	INJECTABLE
SOMATROPIN RECOMBINANT	019640	INJECTABLE
SOMATROPIN RECOMBINANT	020604	INJECTABLE
SOMATROPIN RECOMBINANT	019764	INJECTABLE
SOMATROPIN RECOMBINANT	021597	INJECTABLE
SOYBEAN OIL	019942	INJECTABLE
SUCCIMER	019998	CAPSULE
SULCONAZOLE NITRATE	018737	CREAM
SULCONAZOLE NITRATE	018738	SOLUTION
SUMATRIPTAN SUCCINATE	208223	SOLUTION
TALC	020587	AEROSOL
TALC	021388	POWDER

TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT	017881	INJECTABLE
TECHNETIUM TC-99M BICISATE KIT	020256	INJECTABLE
TECHNETIUM TC-99M DISOFENIN KIT	018467	INJECTABLE
TECHNETIUM TC-99M EXAMETAZIME KIT	208870	POWDER
TECHNETIUM TC-99M MEDRONATE	018035	INJECTABLE
TECHNETIUM TC-99M MEDRONATE KIT	018124	INJECTABLE
TECHNETIUM TC-99M MERTIATIDE KIT	019882	INJECTABLE
TECHNETIUM TC-99M OXIDRONATE KIT	018321	INJECTABLE
TECHNETIUM TC-99M RED BLOOD CELL KIT	019981	INJECTABLE
TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR	017243	SOLUTION
TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR	017771	SOLUTION
TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR	017693	SOLUTION
TERCONAZOLE	021735	CREAM
THYROTROPIN ALFA	020898	INJECTABLE
TOBRAMYCIN	050555	OINTMENT
TRETINOIN	020400	GEL
TRIMETHADIONE	005856	TABLET
UREA, C-14	020617	CAPSULE
VALRUBICIN	020892	SOLUTION
VELAGLUCERASE ALFA	022575	INJECTABLE
XENON XE-133	017284	GAS
XENON XE-133	018327	GAS
ZANAMIVIR	021036	POWDER
ZINC ACETATE	020458	CAPSULE
ZINC CHLORIDE	018959	INJECTABLE

Appendix

Ingredient	Approved NDA	Dosage Form
ALBENDAZOLE	020666	TABLET
CARMUSTINE	017422	INJECTABLE
CEFIXIME	203195	CAPSULE
INDIUM IN-111 OXYQUINOLINE	019044	INJECTABLE
MIGLUSTAT	021348	CAPSULE
MORPHINE SULFATE	018565	INJECTABLE
PHENYLEPHRINE HYDROCHLORIDE	203826	SOLUTION
PHENYLEPHRINE HYDROCHLORIDE	204300	SOLUTION
PHYTONADIONE	010104	TABLET
POTASSIUM CHLORIDE	206814	SOLUTION
ROPIVACAINE HYDROCHLORIDE	020533	SOLUTION

Methodology¹

1. The list is based on the [Orange Book Data Files](#), accessed October 22, 2018.
2. The list includes Orange Book-listed drug products. 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 strength). 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,^{2,3} and
 - b. There are no approved ANDAs for the drug product,⁴ and
 - c. There are no unexpired patents or exclusivities listed in the Orange Book for the drug product.⁵
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 "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.

³ Drug products with only approved and Orange Book-listed ANDAs but no Orange Book-listed NDAs are not included on the list.

⁴ Drug products with an approved but discontinued ANDA are not included on the list.

⁵ Drug products that have at least one Orange Book-listed patent or exclusivity are not included on the list.