

## 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) in markets 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.

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](mailto:genericdrugs@fda.hhs.gov). Sponsors may be referred to the Office of New Drugs if the product is a biological product and/or if the product is not eligible for submission and/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 their inquiry.

- Some products in Part II of the list may not be eligible for submission and/or approval as an ANDA via the 505(j) pathway; 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 provision 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 overcome with additional information exchange between FDA and a prospective ANDA sponsor (e.g., there is no applicable product-specific guidance, 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 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](mailto: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	N204767	SOLUTION
ACETYLCHOLINE CHLORIDE	N020213	FOR SOLUTION
ACRIVASTINE; PSEUDOEPHEDRINE HYDROCHLORIDE	N019806	CAPSULE
ACYCLOVIR	N021478	CREAM
ALBENDAZOLE	N020666	TABLET
ALBUTEROL SULFATE	N020503	AEROSOL, METERED
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	N021559	INJECTABLE
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	INJECTABLE
ALPROSTADIL	N020700	SUPPOSITORY
AMINO ACIDS	N020015	INJECTABLE
AMINO ACIDS	N017766	INJECTABLE
AMINO ACIDS	N019438	INJECTABLE
AMINO ACIDS	N019374	INJECTABLE
AMINO ACIDS	N019492	INJECTABLE
AMINO ACIDS	N018429	INJECTABLE
AMINO ACIDS	N019398	INJECTABLE
AMINO ACIDS	N019018	INJECTABLE
AMINO ACIDS	N018931	INJECTABLE
AMINO ACIDS	N020849	INJECTABLE
AMINO ACIDS	N020041	INJECTABLE
AMINO ACIDS; CALCIUM ACETATE; GLYCERIN; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE	N018582	INJECTABLE
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N020678	INJECTABLE
AMINO ACIDS; DEXTROSE	N020734	INJECTABLE
AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; POTASSIUM CHLORIDE; SODIUM ACETATE	N016822	INJECTABLE
AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE	N019437	INJECTABLE

AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE	N017673	INJECTABLE
AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE	N017789	INJECTABLE
AMINOCAPROIC ACID	N015197	TABLET
AMOXICILLIN; CLARITHROMYCIN; OMEPRAZOLE	N050824	CAPSULE, TABLET, CAPSULE, DELAYED RELEASE
AMPHOTERICIN B	N050740	INJECTABLE, LIPOSOMAL
APOMORPHINE HYDROCHLORIDE	N021264	INJECTABLE
APRACLONIDINE HYDROCHLORIDE	N019779	SOLUTION/DROPS
ARGATROBAN	N206769	INJECTABLE
ARGATROBAN	N203049	INJECTABLE
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
ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL ACETATE; VITAMIN A; VITAMIN K	N021646	INJECTABLE
ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E	N018920	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	N021625	INJECTABLE
ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E; VITAMIN K	N021643	INJECTABLE
ASPIRIN	N200671	CAPSULE, EXTENDED RELEASE
ASPIRIN; CAFFEINE; DIHYDROCODEINE BITARTRATE	N011483	CAPSULE
ATROPINE SULFATE	N208151	SOLUTION/DROPS

ATROPINE SULFATE	N206289	SOLUTION/DROPS
ATROPINE SULFATE	N021146	SOLUTION
ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE	N017744	TABLET
ATROPINE SULFATE; EDROPHONIUM CHLORIDE	N019678	INJECTABLE
AURANOFIN	N018689	CAPSULE
AZELAIC ACID	N020428	CREAM
AZTREONAM	N050632	INJECTABLE
BARIUM SULFATE	N208036	FOR SUSPENSION
BARIUM SULFATE	N208143	SUSPENSION
BARIUM SULFATE	N208844	PASTE
BENZOYL PEROXIDE; ERYTHROMYCIN	N050769	GEL
BENZYLPENICILLOYL POLYLYSINE	N050114	INJECTABLE
BETAINE HYDROCHLORIDE	N020576	FOR SOLUTION
BETAXOLOL HYDROCHLORIDE	N019845	SUSPENSION/DROPS
BOSENTAN	N021290	TABLET
BRINZOLAMIDE	N020816	SUSPENSION/DROPS
BUPRENORPHINE	N021306	FILM, EXTENDED RELEASE
BUSULFAN	N009386	TABLET
BUTENAFINE HYDROCHLORIDE	N020524	CREAM
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	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	N020000	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
CAPREOMYCIN SULFATE	N050095	INJECTABLE
CARBOPROST TROMETHAMINE	N017989	INJECTABLE
CARGLUMIC ACID	N022562	TABLET
CEFAZOLIN SODIUM	N207131	SOLUTION
CEFAZOLIN SODIUM	N050779	INJECTABLE
CEFEPIME HYDROCHLORIDE	N050817	INJECTABLE
CEFIXIME	N203195	CAPSULE
CEFTAZIDIME	N050823	INJECTABLE

CEFUROXIME SODIUM	N050643	INJECTABLE
CHLORAMBUCIL	N010669	TABLET
CHLORDIAZEPOXIDE HYDROCHLORIDE; CLIDINIUM BROMIDE	N012750	CAPSULE
CHLOROPROCAINE HYDROCHLORIDE	N009435	INJECTABLE
CHROMIC CHLORIDE	N018961	INJECTABLE
CITRIC ACID; GLUCONOLACTONE; MAGNESIUM CARBONATE	N019481	SOLUTION
CITRIC ACID; UREA C-13	N021314	FOR SOLUTION, TABLET, FOR SOLUTION
CLINDAMYCIN PHOSPHATE	N050635	INJECTABLE
CLINDAMYCIN PHOSPHATE; TRETINOIN	N050803	GEL
CLOCORTOLONE PIVALATE	N017765	CREAM
CLOZAPINE	N203479	SUSPENSION
CROTAMITON	N006927	CREAM
CUPRIC CHLORIDE	N018960	INJECTABLE
CYCLOPHOSPHAMIDE	N203856	CAPSULE
CYCLOSPORINE	N050625	CAPSULE
DALFOPRISTIN; QUINUPRISTIN	N050748	INJECTABLE
DALTEPARIN SODIUM	N020287	INJECTABLE
DAPSONE	N021794	GEL
DECITABINE	N205582	POWDER
DELAVIRDINE MESYLATE	N020705	TABLET
DESFLURANE	N020118	LIQUID
DESVENLAFAXINE	N204683	TABLET, EXTENDED RELEASE
DESVENLAFAXINE	N204150	TABLET, EXTENDED RELEASE
DESVENLAFAXINE FUMARATE	N205583	TABLET, EXTENDED RELEASE
DEXAMETHASONE; TOBRAMYCIN	N050616	OINTMENT
DEXMETETOMIDINE HYDROCHLORIDE	N206628	SOLUTION
DEXTROSE	N019445	INJECTABLE
DEXTROSE; MAGNESIUM ACETATE TETRAHYDRATE; POTASSIUM ACETATE; SODIUM CHLORIDE	N017385	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; SODIUM CHLORIDE	N019630	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018365	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018876	INJECTABLE
DEXTROSE; SODIUM CHLORIDE	N017606	INJECTABLE
DEXTROSE; SODIUM CHLORIDE	N017799	INJECTABLE
DEXTROSE; SODIUM CHLORIDE	N019631	INJECTABLE
DIATRIZOATE MEGLUMINE; IODIPAMIDE MEGLUMINE	N011324	SOLUTION
DIAZEPAM	N020648	GEL
DIAZOXIDE	N017453	SUSPENSION
DIGOXIN	N021648	ELIXIR
DIGOXIN	N020405	TABLET
DIMERCAPROL	N005939	INJECTABLE
DINOPROSTONE	N020411	INSERT, EXTENDED RELEASE
DINOPROSTONE	N017810	SUPPOSITORY
DINOPROSTONE	N019617	GEL
DISOPYRAMIDE PHOSPHATE	N018655	CAPSULE, EXTENDED RELEASE
DOCETAXEL	N022234	INJECTABLE
DOCETAXEL	N201195	INJECTABLE
DOCETAXEL	N203551	INJECTABLE
DOLASETRON MESYLATE	N020624	INJECTABLE
DOLASETRON MESYLATE	N020623	TABLET
DOPAMINE HYDROCHLORIDE	N019615	INJECTABLE
DOPAMINE HYDROCHLORIDE	N019099	INJECTABLE
DOXAZOSIN MESYLATE	N021269	TABLET, EXTENDED RELEASE
DOXORUBICIN HYDROCHLORIDE	N050629	INJECTABLE
DOXYCYCLINE HYCLATE	N208253	CAPSULE
DROSPIRENONE; ESTRADIOL	N021355	TABLET
ECHOTHIOPHATE IODIDE	N011963	FOR SOLUTION
EDETATE CALCIUM DISODIUM	N008922	INJECTABLE
EFLORNITHINE HYDROCHLORIDE	N021145	CREAM
EMEDASTINE DIFUMARATE	N020706	SOLUTION/DROPS
ENFUVRTIDE	N021481	INJECTABLE
ENTECAVIR	N021798	SOLUTION
ERYTHROMYCIN ETHYLSUCCINATE	N050207	GRANULE
ESOMEPRAZOLE STRONTIUM	N202342	CAPSULE, DELAYED RELEASE
ESTRAMUSTINE PHOSPHATE SODIUM	N018045	CAPSULE
ESTROGENS, CONJUGATED	N004782	TABLET
ESTROGENS, CONJUGATED	N010402	INJECTABLE
ETHANOLAMINE OLEATE	N019357	INJECTABLE
ETHIONAMIDE	N013026	TABLET
ETOPOSIDE PHOSPHATE	N020457	INJECTABLE

EZOGABINE	N022345	TABLET
FENOFIBRATE	N021612	CAPSULE
FENOPROFEN CALCIUM	N017604	CAPSULE
FLUORESCEIN SODIUM	N022186	INJECTABLE
FLUOROURACIL	N016988	CREAM
FLUOXETINE HYDROCHLORIDE	N202133	TABLET
FLUTICASONE PROPIONATE; SALMETEROL XINAFOATE	N021077	POWDER
FOSFOMYCIN TROMETHAMINE	N050717	FOR SUSPENSION
GUAIFENESIN; HYDROCODONE BITARTRATE	N022424	SOLUTION
GUAIFENESIN; HYDROCODONE BITARTRATE; PSEUDOEPHEDRINE HYDROCHLORIDE	N022279	SOLUTION
HALCINONIDE	N017556	CREAM
HALCINONIDE	N017824	OINTMENT
HEPARIN SODIUM	N019339	INJECTABLE
HEPARIN SODIUM	N018916	INJECTABLE
HYDROCHLOROTHIAZIDE; METOPROLOL SUCCINATE	N021956	TABLET, EXTENDED RELEASE
HYDROCHLOROTHIAZIDE; SPIRONOLACTONE	N012616	TABLET
HYDROXYAMPHETAMINE HYDROBROMIDE; TROPICAMIDE	N019261	SOLUTION/DROPS
HYDROXYUREA	N016295	CAPSULE
ILOPROST	N021779	SOLUTION
INDOMETHACIN	N022536	INJECTABLE
IODIXANOL	N020351	INJECTABLE
IOFLUPANE I-123	N022454	SOLUTION
LEUPROLIDE ACETATE	N019732	INJECTABLE
LEUPROLIDE ACETATE	N020011	INJECTABLE
LEUPROLIDE ACETATE	N020263	INJECTABLE
LEUPROLIDE ACETATE	N020708	INJECTABLE
LEUPROLIDE ACETATE	N020517	INJECTABLE
LEVOLEUCOVORIN CALCIUM	N208723	POWDER
L-GLUTAMINE	N021667	FOR SOLUTION
LINEZOLID	N206473	SOLUTION
LODOXAMIDE TROMETHAMINE	N020191	SOLUTION/DROPS
LOMUSTINE	N017588	CAPSULE
LOTEPREDNOL ETABONATE; TOBRAMYCIN	N050804	SUSPENSION/DROPS
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	N017637	SOLUTION
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	N017586	INJECTABLE

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	N020488	INJECTABLE
MAGNESIUM SULFATE	N019316	SOLUTION
MAGNESIUM SULFATE; POTASSIUM SULFATE; SODIUM SULFATE	N204553	POWDER
MANGANESE CHLORIDE	N018962	INJECTABLE
MECHLORETHAMINE HYDROCHLORIDE	N006695	INJECTABLE
MEDROXYPROGESTERONE ACETATE	N012541	INJECTABLE
MEROPENEM	N202106	POWDER
MESALAMINE	N020049	CAPSULE, EXTENDED RELEASE
MESNA	N020855	TABLET
METHACHOLINE CHLORIDE	N019193	FOR SOLUTION
METHADONE HYDROCHLORIDE	N006383	POWDER
METHADONE HYDROCHLORIDE	N021624	INJECTABLE
METHOHEXITAL SODIUM	N011559	INJECTABLE
METHOTREXATE	N204824	SOLUTION
METRONIDAZOLE	N020743	CREAM
MIGLUSTAT	N021348	CAPSULE
MITOTANE	N016885	TABLET
MIVACURIUM CHLORIDE	N020098	SOLUTION
MOMETASONE FUROATE	N205641	AEROSOL, METERED
MORPHINE SULFATE	N019916	INJECTABLE
MORPHINE SULFATE	N201517	SOLUTION
MORPHINE SULFATE	N202515	INJECTABLE
MORPHINE SULFATE	N022207	TABLET
MORPHINE SULFATE	N020616	CAPSULE, EXTENDED RELEASE
MOXIFLOXACIN HYDROCHLORIDE	N205572	SOLUTION
MUPIROCIIN CALCIUM	N050703	OINTMENT
NABILONE	N018677	CAPSULE
NAFCILLIN SODIUM	N050655	INJECTABLE
NAFTIFINE HYDROCHLORIDE	N019356	GEL
NELARABINE	N021877	INJECTABLE
NELFINAVIR MESYLATE	N020779	TABLET
NELFINAVIR MESYLATE	N021503	TABLET
NEOSTIGMINE METHYLSULFATE	N203629	SOLUTION
NICARDIPINE HYDROCHLORIDE	N022276	INJECTABLE
NICOTINE	N020385	SPRAY, METERED
NITAZOXANIDE	N021497	TABLET
NITROGLYCERIN	N020145	FILM, EXTENDED RELEASE
NITROGLYCERIN	N021780	AEROSOL, METERED



OCTREOTIDE ACETATE	N021008	INJECTABLE
OLSALAZINE SODIUM	N019715	CAPSULE
OXACILLIN SODIUM	N050640	INJECTABLE
OXICONAZOLE NITRATE	N020209	LOTION
OXYMETHOLONE	N016848	TABLET
PALONOSETRON HYDROCHLORIDE	N207963	SOLUTION
PENICILLAMINE	N019854	TABLET
PENICILLAMINE	N019853	CAPSULE
PENICILLIN G BENZATHINE; PENICILLIN G PROCAINE	N050138	INJECTABLE
PENICILLIN G POTASSIUM	N050638	INJECTABLE
PENTAMIDINE ISETHIONATE	N019887	FOR SOLUTION
PENTAZOCINE LACTATE	N016194	INJECTABLE
PENTETATE CALCIUM TRISODIUM	N021749	SOLUTION
PENTETATE ZINC TRISODIUM	N021751	SOLUTION
PENTOSAN POLYSULFATE SODIUM	N020193	CAPSULE
PHENYLEPHRINE HYDROCHLORIDE	N204300	SOLUTION
PHENYLEPHRINE HYDROCHLORIDE	N207926	SOLUTION/DROPS
PHENYLEPHRINE HYDROCHLORIDE	N203826	SOLUTION
PHYTONADIONE	N010104	TABLET
PODOFILOX	N020529	GEL
POLIDOCANOL	N021201	SOLUTION
POLYETHYLENE GLYCOL 3350; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM SULFATE ANHYDROUS	N019011	FOR SOLUTION
POTASSIUM CHLORIDE	N206814	SOLUTION
POTASSIUM CHLORIDE	N208019	FOR SOLUTION
POTASSIUM CHLORIDE; SODIUM CHLORIDE	N017648	INJECTABLE
POVIDONE-IODINE	N018634	SOLUTION/DROPS
PRALIDOXIME CHLORIDE	N018986	INJECTABLE
PRALIDOXIME CHLORIDE	N014134	INJECTABLE
PRAZIQUANTEL	N018714	TABLET
PROCARBAZINE HYDROCHLORIDE	N016785	CAPSULE
PROGESTERONE	N020701	GEL
PYRIDOSTIGMINE BROMIDE	N015193	SYRUP
PYRIMETHAMINE	N008578	TABLET
QUINIDINE GLUCONATE	N007529	INJECTABLE
RABEPRAZOLE SODIUM	N204736	CAPSULE, DELAYED RELEASE
RITONAVIR	N020659	SOLUTION
ROPIVACAINE HYDROCHLORIDE	N020533	SOLUTION
SAQUINAVIR MESYLATE	N020628	CAPSULE
SAQUINAVIR MESYLATE	N021785	TABLET
SELEGILINE HYDROCHLORIDE	N021479	TABLET, ORALLY
SILDENAFIL CITRATE	N203109	FOR SUSPENSION
SODIUM ACETATE ANHYDROUS	N018893	INJECTABLE
SODIUM CHLORIDE	N202832	INJECTABLE
SODIUM CHLORIDE	N019319	SOLUTION FOR SLUSH
SODIUM CHLORIDE	N018897	INJECTABLE

SODIUM CHLORIDE	N019635	INJECTABLE
SODIUM CHLORIDE	N021569	INJECTABLE
SODIUM IODIDE I-131	N021305	CAPSULE
SODIUM IODIDE I-131	N021305	SOLUTION
SODIUM IODIDE I-131	N016515	SOLUTION
SODIUM IODIDE I-131	N016517	CAPSULE
SODIUM LACTATE	N018947	INJECTABLE
SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE; SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS	N018892	INJECTABLE
SORBITOL	N017863	SOLUTION
SORBITOL	N016741	SOLUTION
SOTALOL HYDROCHLORIDE	N022306	SOLUTION
STREPTOZOCIN	N050577	INJECTABLE
SUCRALFATE	N019183	SUSPENSION
TAZAROTENE	N021184	CREAM
TAZAROTENE	N020600	GEL
TESTOSTERONE	N020489	FILM, EXTENDED RELEASE
TETRACAINE HYDROCHLORIDE	N208135	SOLUTION
THIOGUANINE	N012429	TABLET
TIAGABINE HYDROCHLORIDE	N020646	TABLET
TIOPRONIN	N019569	TABLET
TOREMIFENE CITRATE	N020497	TABLET
TRAMADOL HYDROCHLORIDE	N022370	CAPSULE, EXTENDED RELEASE
TRETINOIN	N020475	GEL
TRIAMCINOLONE HEXACETONIDE	N016466	INJECTABLE
TRIAMTERENE	N013174	CAPSULE
TRIENTINE HYDROCHLORIDE	N019194	CAPSULE
TRIMETHOPRIM HYDROCHLORIDE	N074973	SOLUTION
TRIPTORELIN PAMOATE	N021288	INJECTABLE
TRIPTORELIN PAMOATE	N022437	INJECTABLE
TRIPTORELIN PAMOATE	N020715	INJECTABLE
TROMETHAMINE	N013025	INJECTABLE
TRYPAN BLUE	N022278	SOLUTION
TRYPAN BLUE	N021670	SOLUTION
VANCOMYCIN HYDROCHLORIDE	N050671	INJECTABLE
VERAPAMIL HYDROCHLORIDE	N019614	CAPSULE, EXTENDED RELEASE
VERTEPORFIN	N021119	INJECTABLE
VIGABATRIN	N020427	TABLET
ZILEUTON	N020471	TABLET
ZIPRASIDONE MESYLATE	N020919	INJECTABLE
ZOLEDRONIC ACID	N204016	SOLUTION

## Part II

Ingredient	Approved NDA	Dosage Form
ACETOHYDROXAMIC ACID	N018749	TABLET
ALBUMIN IODINATED I-125 SERUM	N017836	INJECTABLE
ALBUMIN IODINATED I-131 SERUM	N017837	INJECTABLE
ALITRETINOIN	N020886	GEL
ALPROSTADIL	N020649	INJECTABLE
ALPROSTADIL	N021212	INJECTABLE
ALPROSTADIL	N020379	INJECTABLE
ALTRETAMINE	N019926	CAPSULE
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM GLYCEROPHOSPHATE; SOYBEAN OIL	N200656	EMULSION
ATROPINE	N017106	INJECTABLE
ATROPINE; PRALIDOXIME CHLORIDE	N021983	INJECTABLE
BACLOFEN	N022462	INJECTABLE
BECLOMETHASONE DIPROPIONATE MONOHYDRATE	N019389	SPRAY, METERED
BERACTANT	N020032	SUSPENSION
BEXAROTENE	N021056	GEL
BUDESONIDE	N205613	AEROSOL, FOAM
CALCITRIOL	N022087	OINTMENT
CALFACTANT	N020521	SUSPENSION
CARMUSTINE	N020637	IMPLANT
CARMUSTINE	N017422	INJECTABLE
CHLORHEXIDINE GLUCONATE	N020774	TABLET
CHLOROTHIAZIDE	N011870	SUSPENSION
CIPROFLOXACIN HYDROCHLORIDE	N020369	OINTMENT
CIPROFLOXACIN HYDROCHLORIDE	N021918	SOLUTION/DROPS
CIPROFLOXACIN HYDROCHLORIDE; HYDROCORTISONE	N020805	SUSPENSION/DROPS
COLESTIPOL HYDROCHLORIDE	N017563	GRANULE
COLISTIN SULFATE; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; THONZONIUM BROMIDE	N050356	SUSPENSION/DROPS
COPPER	N018680	INTRAUTERINE DEVICE
CORTICORELIN OVINE TRIFLUTATE	N020162	INJECTABLE
CORTICOTROPIN	N008372	INJECTABLE
CYSTEAMINE BITARTRATE	N020392	CAPSULE
CYTARABINE	N021041	INJECTABLE, LIPOSOMAL
DESIRUDIN RECOMBINANT	N021271	INJECTABLE
DESMOPRESSIN ACETATE	N020355	SPRAY, METERED
DIATRIZOATE MEGLUMINE	N010040	INJECTABLE
DIATRIZOATE MEGLUMINE	N010040	SOLUTION
DIHYDROERGOTAMINE MESYLATE	N020148	SPRAY, METERED
DOXEPIN HYDROCHLORIDE	N020126	CREAM
DOXYCYCLINE CALCIUM	N050480	SUSPENSION
DOXYCYCLINE HYCLATE	N050751	SYSTEM, EXTENDED RELEASE
ERYTHROMYCIN	N050584	OINTMENT

ERYTHROMYCIN	N050611	TABLET, COATED PARTICLES
ESTRADIOL	N022038	GEL
ESTRADIOL	N020472	INSERT, EXTENDED RELEASE
ESTRADIOL	N021166	GEL, METERED
ESTRADIOL	N020655	FILM, EXTENDED RELEASE
ESTRADIOL ACETATE	N021367	INSERT, EXTENDED RELEASE
ESTRADIOL HEMIHYDRATE	N021371	EMULSION
ESTRADIOL; LEVONORGESTREL	N021258	FILM, EXTENDED RELEASE
ESTRADIOL; NORETHINDRONE ACETATE	N020870	FILM, EXTENDED RELEASE
ESTROGENS, CONJUGATED	N020216	CREAM
ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE	N020527	TABLET
ETHOTOIN	N010841	TABLET
FERRIC HEXACYANOFERRATE(II)	N021626	CAPSULE
FERRIC PYROPHOSPHATE CITRATE	N206317	SOLUTION
FERRIC PYROPHOSPHATE CITRATE	N208551	FOR SOLUTION
FLUNISOLIDE	N021247	AEROSOL, METERED
FLUOCINOLONE ACETONIDE	N020001	SHAMPOO
FLUOROMETHOLONE	N019216	SUSPENSION/DROPS
FLUOROMETHOLONE	N017760	OINTMENT
FLUOROMETHOLONE ACETATE	N019079	SUSPENSION/DROPS
FLURANDRENOLIDE	N012806	CREAM
FLURANDRENOLIDE	N012806	OINTMENT
FLURANDRENOLIDE	N016455	TAPE
FLUTICASONE PROPIONATE	N020833	POWDER
FOLLITROPIN ALFA/BETA	N021765	INJECTABLE
GADOBENATE DIMEGLUMINE	N021358	INJECTABLE
GADOBENATE DIMEGLUMINE	N021357	INJECTABLE
GADOBUTROL	N201277	SOLUTION
GADODIAMIDE	N020123	INJECTABLE
GADODIAMIDE	N022066	INJECTABLE
GADOPENTETATE DIMEGLUMINE	N021037	INJECTABLE
GADOPENTETATE DIMEGLUMINE	N019596	INJECTABLE
GADOTERIDOL	N020131	INJECTABLE
GADOTERIDOL	N021489	INJECTABLE
GADOVERSETAMIDE	N020975	INJECTABLE
GADOVERSETAMIDE	N020937	INJECTABLE
GADOVERSETAMIDE	N020976	INJECTABLE
GALLIUM CITRATE GA-67	N018058	INJECTABLE
GALLIUM CITRATE GA-67	N017478	INJECTABLE
GANCICLOVIR	N022211	GEL
GENTAMICIN SULFATE; PREDNISOLONE ACETATE	N050586	SUSPENSION/DROPS
GENTAMICIN SULFATE; PREDNISOLONE ACETATE	N050612	OINTMENT
GLUCAGON HYDROCHLORIDE	N201849	POWDER
GLUCAGON HYDROCHLORIDE RECOMBINANT	N020918	INJECTABLE
GLUCAGON RECOMBINANT	N020928	INJECTABLE
GONADOTROPIN, CHORIONIC	N017016	INJECTABLE

GUANIDINE HYDROCHLORIDE	N001546	TABLET
HISTRELIN ACETATE	N021732	IMPLANT
HYALURONIDASE	N021665	INJECTABLE
HYALURONIDASE	N021640	INJECTABLE
HYDROCORTISONE ACETATE	N017351	AEROSOL, METERED
HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE	N050218	CREAM
HYDROCORTISONE PROBUTATE	N020453	CREAM
HYDROXOCOBALAMIN	N022041	INJECTABLE
HYDROXYPROPYL CELLULOSE	N018771	INSERT
IMIGLUCERASE	N020367	INJECTABLE
INDIUM IN-111 CHLORIDE	N019862	INJECTABLE
INDIUM IN-111 CHLORIDE	N019841	INJECTABLE
INDIUM IN-111 OXYQUINOLINE	N019044	INJECTABLE
INDIUM IN-111 PENTETATE DISODIUM	N017707	INJECTABLE
INDIUM IN-111 PENTETREOTIDE KIT	N020314	INJECTABLE
INSULIN HUMAN	N018780	INJECTABLE; SOLUTION
INSULIN LISPRO PROTAMINE RECOMBINANT; INSULIN LISPRO RECOMBINANT	N021017	INJECTABLE
INSULIN LISPRO PROTAMINE RECOMBINANT; INSULIN LISPRO RECOMBINANT	N021018	INJECTABLE
INSULIN LISPRO RECOMBINANT	N020563	INJECTABLE
IOBENGUANE SULFATE I-123	N022290	SOLUTION
IOHEXOL	N018956	INJECTABLE
IOHEXOL	N018956	SOLUTION
IOHEXOL	N205383	FOR SOLUTION
IOHEXOL	N020608	SOLUTION
IOPROMIDE	N021425	INJECTABLE
IOPROMIDE	N020220	INJECTABLE
IOTHALAMATE MEGLUMINE	N013295	INJECTABLE
IOTHALAMATE MEGLUMINE	N017057	SOLUTION
IOTHALAMATE MEGLUMINE	N016983	INJECTABLE
IOTHALAMATE SODIUM I-125	N017279	INJECTABLE
IOVERSOL	N019710	INJECTABLE
IOVERSOL	N020923	INJECTABLE
IRON DEXTRAN	N040024	INJECTABLE
IRON DEXTRAN	N017441	INJECTABLE
IRON DEXTRAN	N017807	INJECTABLE
IRON SUCROSE	N021135	INJECTABLE
ISOCARBOXAZID	N011961	TABLET
ISONIAZID; PYRAZINAMIDE; RIFAMPIN	N050705	TABLET
ISOSORBIDE DINITRATE	N019790	CAPSULE, EXTENDED RELEASE
LEUPROLIDE ACETATE; NORETHINDRONE ACETATE	N203696	INJECTABLE, TABLET
LEVOTHYROXINE SODIUM	N021924	CAPSULE
LIDOCAINE; PRILOCAINE	N021451	GEL
LIOTRIX (T4;T3)	N016807	TABLET
LOTEPREDNOL ETABONATE	N020803	SUSPENSION/DROPS

LOTEPREDNOL ETABONATE	N202872	GEL
LOTEPREDNOL ETABONATE	N200738	OINTMENT
LOTEPREDNOL ETABONATE	N020583	SUSPENSION/DROPS
MAFENIDE ACETATE	N016763	CREAM
MANNITOL	N016772	SOLUTION
MECASERMIN RECOMBINANT	N021839	INJECTABLE
MENOTROPINS (FSH;LH)	N021663	INJECTABLE
METHOXSALEN	N020969	INJECTABLE
METHSUXIMIDE	N010596	CAPSULE
METYRAPONE	N012911	CAPSULE
METYROSINE	N017871	CAPSULE
MORPHINE SULFATE	N019999	INJECTABLE
MORPHINE SULFATE	N018565	INJECTABLE
NAFARELIN ACETATE	N019886	SPRAY, METERED
NATAMYCIN	N050514	SUSPENSION
NESIRITIDE RECOMBINANT	N020920	FOR SOLUTION
NICOTINE	N020714	INHALANT
NITAZOXANIDE	N021498	FOR SUSPENSION
NITISINONE	N021232	CAPSULE
NITROGLYCERIN	N021359	OINTMENT
OXYTOCIN	N018261	INJECTABLE
OXYTOCIN	N018248	INJECTABLE
PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)	N022175	CAPSULE, DELAYED RELEASE
PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)	N022222	CAPSULE, DELAYED RELEASE
PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)	N022523	CAPSULE, DELAYED RELEASE
PANCRELIPASE (AMYLASE;LIPASE;PROTEASE)	N022542	TABLET
PEGADEMASE BOVINE	N019818	INJECTABLE
PEGAPTANIB SODIUM	N021756	INJECTABLE
PEGVISOMANT	N021106	INJECTABLE
PENICILLIN G BENZATHINE	N050141	INJECTABLE
PORACTANT ALFA	N020744	SUSPENSION
PORFIMER SODIUM	N020451	INJECTABLE
PREDNISOLONE ACETATE	N017100	SUSPENSION/DROPS
PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM	N012813	SUSPENSION
RIFAPENTINE	N021024	TABLET
RUBIDIUM CHLORIDE RB-82	N202153	SOLUTION
RUBIDIUM CHLORIDE RB-82	N019414	INJECTABLE
SALMETEROL XINAFOATE	N020692	POWDER
SAMARIUM SM-153 LEXIDRONAM PENTASODIUM	N020570	INJECTABLE
SECRETIN SYNTHETIC HUMAN	N021256	FOR SOLUTION
SERTACONAZOLE NITRATE	N021385	CREAM
SILVER SULFADIAZINE	N018578	CREAM
SOMATROPIN RECOMBINANT	N019640	INJECTABLE
SOMATROPIN RECOMBINANT	N019764	INJECTABLE
SOMATROPIN RECOMBINANT	N021426	INJECTABLE
SOMATROPIN RECOMBINANT	N020604	INJECTABLE

SOMATROPIN RECOMBINANT	N021905	INJECTABLE
SOMATROPIN RECOMBINANT	N019774	INJECTABLE
SOMATROPIN RECOMBINANT	N021597	INJECTABLE
SOMATROPIN RECOMBINANT	N020522	INJECTABLE
SOMATROPIN RECOMBINANT	N020280	INJECTABLE
SOYBEAN OIL	N019942	INJECTABLE
SUCCIMER	N019998	CAPSULE
SULCONAZOLE NITRATE	N018738	SOLUTION
SULCONAZOLE NITRATE	N018737	CREAM
SUMATRIPTAN SUCCINATE	N208223	SOLUTION
TALC	N020587	AEROSOL, METERED
TALC	N021388	POWDER
TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT	N017881	INJECTABLE
TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT	N017776	INJECTABLE
TECHNETIUM TC-99M BICISATE KIT	N020256	INJECTABLE
TECHNETIUM TC-99M DISOFENIN KIT	N018467	INJECTABLE
TECHNETIUM TC-99M EXAMETAZIME KIT	N019829	INJECTABLE
TECHNETIUM TC-99M EXAMETAZIME KIT	N208870	POWDER
TECHNETIUM TC-99M MEDRONATE	N018035	INJECTABLE
TECHNETIUM TC-99M MERTIATIDE KIT	N019882	INJECTABLE
TECHNETIUM TC-99M OXIDRONATE KIT	N018321	INJECTABLE
TECHNETIUM TC-99M PENTETATE KIT	N018511	INJECTABLE
TECHNETIUM TC-99M RED BLOOD CELL KIT	N019981	INJECTABLE
TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR	N017771	SOLUTION
TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR	N017693	SOLUTION
TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR	N017243	SOLUTION
TECHNETIUM TC-99M TETROFOSMIN KIT	N020372	INJECTABLE
TERCONAZOLE	N021735	CREAM
TESTOSTERONE	N202763	GEL
THYROTROPIN ALFA	N020898	INJECTABLE
TOBRAMYCIN	N050555	OINTMENT
TRETINOIN	N020400	GEL
TRIMETHADIONE	N005856	TABLET
UREA, C-14	N020617	CAPSULE
UROFOLLITROPIN	N021289	INJECTABLE
VALRUBICIN	N020892	SOLUTION
VELAGLUCERASE ALFA	N022575	INJECTABLE
XENON XE-133	N017284	GAS
XENON XE-133	N018327	GAS
ZANAMIVIR	N021036	POWDER
ZINC ACETATE	N020458	CAPSULE
ZINC CHLORIDE	N018959	INJECTABLE

## Methodology<sup>1</sup>

1. The list is based on the [Orange Book Data Files](#), accessed October 30, 2017.
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,<sup>2,3</sup> and
  - b. There are no approved ANDAs for the drug product,<sup>4</sup> and
  - c. There are no unexpired patents or exclusivities listed in the Orange Book for the drug product.<sup>5</sup>
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.

---

<sup>1</sup> FDA notes that the methodology used to compile the June 2017 list has been updated for the December 2017 list. 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.

<sup>2</sup> "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.

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

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

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