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 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).

The Biologics Price Competition and Innovation Act of 2009 (BPCI Act) requires that, on March 23, 2020, an approved application for a biological product under section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) shall be deemed to be a license for the biological product (i.e., an approved biologics license application (BLA)) under section 351 of the Public Health Service Act (PHS Act) (see section 7002(e)(4) of the BPCI Act). Accordingly, on March 23, 2020, subject to a limited exception described in section 7002(e)(4)(B) of the BPCI Act, FDA removed from Approved Drug Products with Therapeutic Equivalence Evaluations (the Orange Book) the listings for biological products that had been approved in applications under section 505 of the FD&C Act because these products are no longer "listed drugs." The June 2020 update to the Off-Patent, Off-Exclusivity List is the first update after the March 23, 2020, transition date. In this update, we have removed biological products that had previously been included on the list because they are no longer listed drugs. Starting on March 23, 2020, a marketing application for a biological product must be submitted under section 351 of the PHS Act. Therefore, the inclusion of biological products on the list (or in the Appendix to the list) is no longer appropriate. Sponsors interested in pursuing licensure for proposed biosimilars or interchangeable biosimilars under section 351(k) of the PHS Act are encouraged to enroll in

the Biosimilar Product Development program and submit a request for a meeting with FDA (https://www.fda.gov/files/drugs/published/Formal-Meetings-Between-the-FDA-and-Sponsors-or-Applicants-of-BsUFA-Products-Guidance-for-Industry.pdf) to discuss the requirements for licensure under the 351(k) pathway.

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
ACETYLCHOLINE CHLORIDE	N020213	FOR SOLUTION
ACRIVASTINE; PSEUDOEPHEDRINE HYDROCHLORIDE	N019806	CAPSULE
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	N016822	INJECTABLE
AMINO ACIDS	N017766	INJECTABLE
AMINO ACIDS	N018931	INJECTABLE
AMINO ACIDS	N019398	INJECTABLE
AMINO ACIDS	N020849	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 ACETATE; PHOSPHORIC ACID; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE	N016822	INJECTABLE
AMOXICILLIN; CLARITHROMYCIN; OMEPRAZOLE	N050824	CAPSULE, TABLET, CAPSULE, DELAYED RELEASE
AMPHOTERICIN B	N050740	INJECTABLE, LIPOSOMAL
APOMORPHINE HYDROCHLORIDE	N021264	INJECTABLE
APRACLONIDINE HYDROCHLORIDE	N019779	SOLUTION/DROPS
ARGATROBAN	N203049	INJECTABLE
ARGATROBAN	N209552	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

ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL HYDROCHLORIDE; VITAMIN A; VITAMIN K	N021265	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
ATROPINE SULFATE	N021146	SOLUTION
ATROPINE SULFATE	N206289	SOLUTION/DROPS
ATROPINE SULFATE	N208151	SOLUTION/DROPS
ATROPINE SULFATE	N209260	SOLUTION
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
BENOXINATE HYDROCHLORIDE; FLUORESCEIN SODIUM	N208582	SOLUTION/DROPS
BENZYLPENICILLOYL POLYLYSINE	N050114	INJECTABLE
BETAINE	N020576	FOR SOLUTION
BETAXOLOL HYDROCHLORIDE	N019845	SUSPENSION/DROPS
BEXAROTENE	N021056	GEL
BISMUTH SUBCITRATE POTASSIUM; METRONIDAZOLE; TETRACYCLINE HYDROCHLORIDE	N050786	CAPSULE
BIVALIRUDIN	N208374	SOLUTION
BRINZOLAMIDE	N020816	SUSPENSION/DROPS
BUDESONIDE	N021949	POWDER, METERED
BUDESONIDE	N205613	AEROSOL, FOAM
BUSULFAN	N009386	TABLET

BUTENAFINE HYDROCHLORIDE	N020524	CREAM
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 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 GLUCONATE	N208418	SOLUTION
CARGLUMIC ACID	N022562	TABLET
CEFAZOLIN SODIUM	N050779	INJECTABLE
CEFAZOLIN SODIUM	N207131	SOLUTION
CEFEPIME HYDROCHLORIDE	N050817	INJECTABLE
CEFOTETAN DISODIUM	N065430	INJECTABLE
CEFTAZIDIME	N050823	INJECTABLE
CETRORELIX	N021197	INJECTABLE
CHLORAMBUCIL	N010669	TABLET
CHLORDIAZEPOXIDE HYDROCHLORIDE; CLIDINIUM BROMIDE	N012750	CAPSULE
CHLOROPROCAINE HYDROCHLORIDE	N009435	INJECTABLE
CHLOROTHIAZIDE	N011870	SUSPENSION
CHROMIC CHLORIDE	N018961	INJECTABLE
CIPROFLOXACIN HYDROCHLORIDE	N020369	OINTMENT
CIPROFLOXACIN HYDROCHLORIDE; HYDROCORTISONE	N020805	SUSPENSION/DROPS
CITRIC ACID; GLUCONOLACTONE; MAGNESIUM CARBONATE	N019481	SOLUTION
CITRIC ACID; UREA C-13	N021314	FOR SOLUTION, TABLET, FOR SOLUTION
CLINDAMYCIN PHOSPHATE	N050635	INJECTABLE
CLINDAMYCIN PHOSPHATE	N208083	SOLUTION
CLINDAMYCIN PHOSPHATE; TRETINOIN	N050803	GEL
CLOCORTOLONE PIVALATE	N017765	CREAM
CONIVAPTAN HYDROCHLORIDE	N021697	INJECTABLE
CUPRIC CHLORIDE	N018960	INJECTABLE
CYCLOSPORINE	N050625	CAPSULE
CYSTEAMINE HYDROCHLORIDE	N200740	SOLUTION/DROPS

DALFOPRISTIN; QUINUPRISTIN	N050748	INJECTABLE
DAPTOMYCIN	N209949	POWDER
DECITABINE	N205582	POWDER
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; 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	N018008	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018365	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019308	INJECTABLE
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N019630	INJECTABLE
DEXTROSE; SODIUM CHLORIDE	N017606	INJECTABLE
DEXTROSE; SODIUM CHLORIDE	N017799	INJECTABLE
DEXTROSE; SODIUM CHLORIDE	N019631	INJECTABLE
DIAZEPAM	N020648	GEL
DICLOFENAC EPOLAMINE	N021234	SYSTEM
DIFLUPREDNATE	N022212	EMULSION
DIGOXIN	N020405	TABLET
DIMERCAPROL	N005939	INJECTABLE
DINOPROSTONE	N017810	SUPPOSITORY
DINOPROSTONE	N019617	GEL
DINOPROSTONE	N020411	INSERT, EXTENDED RELEASE
DISOPYRAMIDE PHOSPHATE	N018655	CAPSULE, EXTENDED RELEASE
DOCETAXEL	N022234	INJECTABLE

DOCETAXEL	N203551	INJECTABLE
DOPAMINE HYDROCHLORIDE	N019099	INJECTABLE
DOPAMINE HYDROCHLORIDE	N019615	INJECTABLE
DOXAZOSIN MESYLATE	N021269	TABLET, EXTENDED RELEASE
DOXEPIN HYDROCHLORIDE	N020126	CREAM
DOXORUBICIN HYDROCHLORIDE	N050629	INJECTABLE
DOXYCYCLINE CALCIUM	N050480	SUSPENSION
DROSPIRENONE; ESTRADIOL	N021355	TABLET
ECHOTHIOPHATE IODIDE	N011963	FOR SOLUTION
EDETATE CALCIUM DISODIUM	N008922	INJECTABLE
EFAVIRENZ; LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE	N022142	TABLET
EFAVIRENZ; LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE	N208255	TABLET
EFLORNITHINE HYDROCHLORIDE	N021145	CREAM
ENFUVIRTIDE	N021481	INJECTABLE
ENTECAVIR	N021798	SOLUTION
EPINEPHRINE	N207534	SOLUTION
ESOMEPRAZOLE MAGNESIUM	N021957	FOR SUSPENSION, DELAYED RELEASE
ESTRADIOL	N021674	FILM, EXTENDED RELEASE
ESTRADIOL	N022038	GEL
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; NORETHINDRONE ACETATE	N204426	CAPSULE
ETHIONAMIDE	N013026	TABLET
ETOPOSIDE PHOSPHATE	N020457	INJECTABLE
EVEROLIMUS	N021560	TABLET
FENOFIBRATE	N021612	CAPSULE
FENOPROFEN CALCIUM	N017604	CAPSULE
FLUORESCEIN SODIUM	N022186	INJECTABLE
FLUOROURACIL	N016988	CREAM
FOSAMPRENAVIR CALCIUM	N022116	SUSPENSION
FOSFOMYCIN TROMETHAMINE	N050717	FOR SOLUTION
GEMCITABINE HYDROCHLORIDE	N209604	SOLUTION
GLYCOPYRROLATE	N210997	SOLUTION
HALCINONIDE	N017824	OINTMENT
HEPARIN SODIUM	N018916	INJECTABLE
HEPARIN SODIUM	N019339	INJECTABLE
HYDROCHLOROTHIAZIDE; METOPROLOL SUCCINATE	N021956	TABLET, EXTENDED RELEASE
HYDROCHLOROTHIAZIDE; SPIRONOLACTONE	N012616	TABLET

HYDROCORTISONE ACETATE	N017351	AEROSOL, METERED
HYDROXYAMPHETAMINE HYDROBROMIDE; TROPICAMIDE	N019261	SOLUTION/DROPS
HYDROXYUREA	N016295	CAPSULE
ILOPROST	N021779	SOLUTION
INDOMETHACIN	N022536	INJECTABLE
IOBENGUANE SULFATE I-123	N022290	SOLUTION
IODIXANOL	N020351	INJECTABLE
IOFLUPANE I-123	N022454	SOLUTION
ISOCARBOXAZID	N011961	TABLET
ISONIAZID; PYRAZINAMIDE; RIFAMPIN	N050705	TABLET
ISOSORBIDE DINITRATE	N019790	CAPSULE, EXTENDED RELEASE
KETOROLAC TROMETHAMINE	N022382	SPRAY, METERED
LAMIVUDINE	N021004	SOLUTION
LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE	N022141	TABLET
LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE	N211284	TABLET
LEFLUNOMIDE	N020905	TABLET
LEUPROLIDE ACETATE	N019732	INJECTABLE
LEUPROLIDE ACETATE	N020011	INJECTABLE
LEUPROLIDE ACETATE	N020263	INJECTABLE
LEUPROLIDE ACETATE	N020517	INJECTABLE
LEUPROLIDE ACETATE	N020708	INJECTABLE
LEVOLEUCOVORIN	N211226	POWDER
LINEZOLID	N206473	SOLUTION
LODOXAMIDE TROMETHAMINE	N020191	SOLUTION/DROPS
LOMUSTINE	N017588	CAPSULE
LOPINAVIR; RITONAVIR	N021906	TABLET
LOTEPREDNOL ETABONATE	N020803	SUSPENSION/DROPS
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	N017378	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
MANGANESE CHLORIDE	N018962	INJECTABLE
MEDROXYPROGESTERONE ACETATE	N012541	INJECTABLE
MEROPENEM	N202106	POWDER
MESALAMINE	N020049	CAPSULE, EXTENDED RELEASE
MESNA	N020855	TABLET
METHACHOLINE CHLORIDE	N019193	FOR SOLUTION
METHOHEXITAL SODIUM	N011559	INJECTABLE
METHSUXIMIDE	N010596	CAPSULE
METRONIDAZOLE	N020743	CREAM
METYROSINE	N017871	CAPSULE
MITOTANE	N016885	TABLET
MOMETASONE FUROATE	N021067	POWDER
MOMETASONE FUROATE	N205641	AEROSOL, METERED
MORPHINE SULFATE	N020616	CAPSULE, EXTENDED RELEASE
MORPHINE SULFATE	N202515	INJECTABLE
MOXIFLOXACIN HYDROCHLORIDE	N205572	SOLUTION
NABILONE	N018677	CAPSULE
NAFCILLIN SODIUM	N050655	INJECTABLE
NELARABINE	N021877	INJECTABLE
NELFINAVIR MESYLATE	N020779	TABLET
NELFINAVIR MESYLATE	N021503	TABLET
NEOSTIGMINE METHYLSULFATE	N203629	SOLUTION
NICOTINE	N020385	SPRAY, METERED
NIMODIPINE	N203340	SOLUTION
NITAZOXANIDE	N021497	TABLET
NITROGLYCERIN	N020145	FILM, EXTENDED RELEASE
NITROGLYCERIN	N021780	AEROSOL, METERED
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
OXYMETHOLONE	N016848	TABLET
PALONOSETRON HYDROCHLORIDE	N207963	SOLUTION
PALONOSETRON HYDROCHLORIDE	N208109	SOLUTION
PENICILLIN G BENZATHINE; PENICILLIN G PROCAINE	N050138	INJECTABLE
PENICILLIN G POTASSIUM	N050638	INJECTABLE
PENTETATE CALCIUM TRISODIUM	N021749	SOLUTION
PENTETATE ZINC TRISODIUM	N021751	SOLUTION
PENTOSAN POLYSULFATE SODIUM	N020193	CAPSULE
PHENDIMETRAZINE TARTRATE	N018074	CAPSULE, EXTENDED RELEASE
PHENYLEPHRINE HYDROCHLORIDE	N207926	SOLUTION/DROPS
PODOFILOX	N020529	GEL
POLIDOCANOL	N021201	SOLUTION
POTASSIUM CHLORIDE	N018279	TABLET, EXTENDED RELEASE
POTASSIUM CHLORIDE	N019904	INJECTABLE
POVIDONE-IODINE	N018634	SOLUTION/DROPS
PRALIDOXIME CHLORIDE	N014134	INJECTABLE
PRALIDOXIME CHLORIDE	N018986	INJECTABLE
PROCARBAZINE HYDROCHLORIDE	N016785	CAPSULE
PROGESTERONE	N020701	GEL
PROGESTERONE	N022057	INSERT
PROPYLTHIOURACIL	N006188	TABLET
RABEPRAZOLE SODIUM	N204736	CAPSULE, DELAYED RELEASE
RIFAPENTINE	N021024	TABLET
RITONAVIR	N020659	SOLUTION
RITONAVIR	N209512	POWDER
SAQUINAVIR MESYLATE	N021785	TABLET
SELEGILINE	N021336	FILM, EXTENDED RELEASE
SELEGILINE HYDROCHLORIDE	N021479	TABLET, ORALLY DISINTEGRATING
SODIUM ACETATE	N018893	INJECTABLE
SODIUM CHLORIDE	N018897	INJECTABLE
SODIUM CHLORIDE	N019319	SOLUTION FOR SLUSH
SODIUM CHLORIDE	N019635	INJECTABLE
SODIUM CHLORIDE	N021569	INJECTABLE
SODIUM CHLORIDE	N202832	INJECTABLE
SODIUM IODIDE I-131	N021305	CAPSULE
SODIUM LACTATE	N018947	INJECTABLE
SODIUM NITROPRUSSIDE	N209387	SOLUTION
SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE; SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS	N018892	INJECTABLE
SORBITOL	N016741	SOLUTION
SORBITOL	N017863	SOLUTION

STREPTOZOCIN	N050577	INJECTABLE
SUCCIMER	N019998	CAPSULE
TACROLIMUS	N204096	CAPSULE, EXTENDED RELEASE
TAMOXIFEN CITRATE	N021807	SOLUTION
TAZAROTENE	N020600	GEL
TAZAROTENE	N021184	CREAM
TECHNETIUM TC-99M EXAMETAZIME KIT	N019829	INJECTABLE
TECHNETIUM TC-99M PENTETATE KIT	N018511	INJECTABLE
TESTOSTERONE	N020489	FILM, EXTENDED RELEASE
TETRACAINE HYDROCHLORIDE	N208135	SOLUTION
TETRACAINE HYDROCHLORIDE	N210821	SOLUTION
THEOPHYLLINE	N019826	INJECTABLE
THIOGUANINE	N012429	TABLET
TIMOLOL MALEATE	N019463	SOLUTION/DROPS
TIPRANAVIR	N021814	CAPSULE
TIPRANAVIR	N022292	SOLUTION
TRAMADOL HYDROCHLORIDE	N022370	CAPSULE, EXTENDED RELEASE
TRANEXAMIC ACID	N212020	SOLUTION
TRETINOIN	N020475	GEL
TRETINOIN	N021108	CREAM
TRIAMCINOLONE HEXACETONIDE	N016466	INJECTABLE
TRIMETHOPRIM HYDROCHLORIDE	N074973	SOLUTION
TRIPTORELIN PAMOATE	N020715	INJECTABLE
TRIPTORELIN PAMOATE	N021288	INJECTABLE
TRYPAN BLUE	N021670	SOLUTION
TRYPAN BLUE	N022278	SOLUTION
VANCOMYCIN HYDROCHLORIDE	N050671	INJECTABLE
VANCOMYCIN HYDROCHLORIDE	N209481	POWDER
VERAPAMIL HYDROCHLORIDE	N019614	CAPSULE, EXTENDED RELEASE
VERTEPORFIN	N021119	INJECTABLE
ZILEUTON	N020471	TABLET
ZOLEDRONIC ACID	N204016	SOLUTION

Part II

Ingredient	Approved NDA	Dosage Form
ACETOHYDROXAMIC ACID	N018749	TABLET
ALITRETINOIN	N020886	GEL
ALPROSTADIL	N020649	INJECTABLE
ALPROSTADIL	N021212	INJECTABLE
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM GLYCEROPHOSPHATE; SOYBEAN OIL	N200656	EMULSION
AMINOLEVULINIC ACID HYDROCHLORIDE	N208081	GEL
AMPHOTERICIN B	N050724	INJECTABLE, LIPID COMPLEX
ATAZANAVIR SULFATE	N206352	POWDER
ATROPINE	N017106	SOLUTION
ATROPINE; PRALIDOXIME CHLORIDE	N021983	INJECTABLE
BECLOMETHASONE DIPROPIONATE MONOHYDRATE	N019389	SPRAY, METERED
CALCITRIOL	N022087	OINTMENT
CARMUSTINE	N020637	IMPLANT
CHLORHEXIDINE GLUCONATE	N020774	TABLET
CIPROFLOXACIN HYDROCHLORIDE	N021918	SOLUTION/DROPS
COLISTIN SULFATE; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; THONZONIUM BROMIDE	N050356	SUSPENSION/DROPS
COPPER	N018680	INTRAUTERINE DEVICE
CORTICOTROPIN	N008372	INJECTABLE
CYSTEAMINE BITARTRATE	N020392	CAPSULE
DESMOPRESSIN ACETATE	N020355	SPRAY, METERED
DIATRIZOATE MEGLUMINE	N010040	SOLUTION
DOXYCYCLINE HYCLATE	N050751	SYSTEM, EXTENDED RELEASE
ESTRADIOL	N020472	INSERT, EXTENDED RELEASE
ESTRADIOL	N020655	FILM, EXTENDED RELEASE
ESTRADIOL	N021166	GEL, METERED
ESTRADIOL ACETATE	N021367	INSERT, EXTENDED RELEASE
ESTROGENS, CONJUGATED	N020216	CREAM
ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE	N020527	TABLET
ETHOTOIN	N010841	TABLET
EXENATIDE SYNTHETIC	N021773	INJECTABLE
FERRIC HEXACYANOFERRATE(II)	N021626	CAPSULE
FLUOCINOLONE ACETONIDE	N020001	SHAMPOO
FLUOCINOLONE ACETONIDE	N021737	IMPLANT
FLUOROMETHOLONE	N017760	OINTMENT
FLUOROMETHOLONE	N019216	SUSPENSION/DROPS
FLUOROMETHOLONE ACETATE	N019079	SUSPENSION/DROPS
FLURANDRENOLIDE	N012806	CREAM

FLURANDRENOLIDE	N016455	TAPE
FLUTICASONE PROPIONATE	N020833	POWDER
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
GENTAMICIN SULFATE; PREDNISOLONE ACETATE	N050586	SUSPENSION/DROPS
GENTAMICIN SULFATE; PREDNISOLONE ACETATE	N050612	OINTMENT
GLUCAGON	N020928	INJECTABLE
GLUCAGON HYDROCHLORIDE	N020918	INJECTABLE
GLUCAGON HYDROCHLORIDE	N201849	POWDER
GUANIDINE HYDROCHLORIDE	N001546	TABLET
HALCINONIDE	N017823	SOLUTION
HISTRELIN ACETATE	N021732	IMPLANT
HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE	N050218	CREAM
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
IODIXANOL	N020808	INJECTABLE
IOHEXOL	N018956	INJECTABLE
IOHEXOL	N018956	SOLUTION
IOHEXOL	N020608	SOLUTION
IOHEXOL	N205383	FOR SOLUTION
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
IRON DEXTRAN	N017441	INJECTABLE
IRON SUCROSE	N021135	INJECTABLE
LEUPROLIDE ACETATE	N021343	INJECTABLE
LEUPROLIDE ACETATE; NORETHINDRONE ACETATE	N203696	INJECTABLE, TABLET
LIDOCAINE; PRILOCAINE	N021451	GEL
MAFENIDE ACETATE	N016763	CREAM
MANNITOL	N016772	SOLUTION

MANNITOL	N022368	POWDER
MEDROXYPROGESTERONE ACETATE	N021583	INJECTABLE
METHOXSALEN	N020969	INJECTABLE
METYRAPONE	N012911	CAPSULE
MINOCYCLINE HYDROCHLORIDE	N209269	TABLET, EXTENDED RELEASE
MORPHINE SULFATE	N019999	INJECTABLE
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
PEGAPTANIB SODIUM	N021756	INJECTABLE
PENICILLIN G BENZATHINE	N050141	INJECTABLE
POLIDOCANOL	N205098	SOLUTION
PORFIMER SODIUM	N020451	INJECTABLE
PRAMLINTIDE ACETATE	N021332	INJECTABLE
PREDNISOLONE ACETATE	N017100	SUSPENSION/DROPS
PREDNISOLONE ACETATE; SULFACETAMIDE SODIUM	N012813	SUSPENSION
RISPERIDONE	N021346	INJECTABLE
RUBIDIUM CHLORIDE RB-82	N019414	INJECTABLE
RUBIDIUM CHLORIDE RB-82	N202153	SOLUTION
SALMETEROL XINAFOATE	N020692	POWDER
SAMARIUM SM-153 LEXIDRONAM PENTASODIUM	N020570	INJECTABLE
SECRETIN SYNTHETIC HUMAN	N021256	FOR SOLUTION
SERTACONAZOLE NITRATE	N021385	CREAM
SOYBEAN OIL	N019942	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	N018124	INJECTABLE
TECHNETIUM TC-99M OXIDRONATE KIT	N018321	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 SULFUR COLLOID KIT	N017858	SOLUTION

TEGASEROD MALEATE	N021200	TABLET
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
ZINC CHLORIDE	N018959	INJECTABLE

Appendix

Ingredient	Approved NDA	Dosage Form
ALBUTEROL SULFATE	N020503	AEROSOL, METERED
DIAZOXIDE	N017453	SUSPENSION
DIHYDROERGOTAMINE MESYLATE	N020148	SPRAY, METERED
ETHINYL ESTRADIOL; ETONOGESTREL	N021187	RING
PENICILLAMINE	N019854	TABLET
PYRIMETHAMINE	N008578	TABLET
SODIUM IODIDE I-131	N021305	SOLUTION
SUCRALFATE	N019183	SUSPENSION
ZIPRASIDONE MESYLATE	N020919	INJECTABLE

Methodology[1]

1. The list is based on the Orange Book Data Files, accessed April 17, 2020.

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 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,[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.

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[1] FDA notes that the methodology used to compile the original list (posted in June 2017) was updated in December 2017. Under the updated methodology, the list is organized based on drug products, not active ingredients. 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.