

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 |
|---|--------------|-----------------------|
| ACETYLCHOLINE CHLORIDE | N020213 | FOR SOLUTION |
| 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 |
| AMISULPRIDE | N209510 | SOLUTION |
| AMPHOTERICIN B | N050740 | INJECTABLE, LIPOSOMAL |
| APOMORPHINE HYDROCHLORIDE | N021264 | INJECTABLE |
| APRACLONIDINE HYDROCHLORIDE | N019779 | SOLUTION/DROPS |
| 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 ACETATE; VITAMIN A; VITAMIN K | N021265 | INJECTABLE |

RX List Part I

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| 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 | N206289 | SOLUTION/DROPS |
| ATROPINE SULFATE | N208151 | SOLUTION/DROPS |
| ATROPINE SULFATE | N214652 | 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; FLUORESCHEIN SODIUM | N208582 | SOLUTION/DROPS |
| BETAINE | N020576 | FOR SOLUTION |
| BETAXOLOL HYDROCHLORIDE | N019845 | SUSPENSION/DROPS |
| BEXAROTENE | N021056 | GEL |
| BISMUTH SUBCITRATE POTASSIUM; METRONIDAZOLE; TETRACYCLINE HYDROCHLORIDE | N050786 | CAPSULE |
| BIVALIRUDIN | N208374 | SOLUTION |
| BIVALIRUDIN | N211215 | SOLUTION |
| BORTEZOMIB | N206927 | POWDER |
| 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 |

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|---|---------|------------------------------------|
| 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 |
| 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 |
| CHLOROPROCAINE HYDROCHLORIDE | N009435 | INJECTABLE |
| CHLOROTHIAZIDE | N011870 | SUSPENSION |
| CHLORTHALIDONE | N019574 | TABLET |
| 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 | N050767 | SUPPOSITORY |
| CLINDAMYCIN PHOSPHATE | N208083 | SOLUTION |
| CLINDAMYCIN PHOSPHATE; TRETINOIN | N050803 | GEL |
| 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 |
| DES Loratadine; Pseudoephedrine Sulfate | N021313 | TABLET, EXTENDED RELEASE |
| DESVENLAFAXINE | N204150 | TABLET, EXTENDED RELEASE |
| DEXAMETHASONE; TOBRAMYCIN | N050616 | OINTMENT |

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| DEXMEDETOMIDINE HYDROCHLORIDE | N021038 | INJECTABLE |
| 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 | N019308 | INJECTABLE |
| DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE | N019630 | INJECTABLE |
| DEXTROSE; SODIUM CHLORIDE | N019631 | INJECTABLE |
| DIAZEPAM | N020648 | GEL |
| DICLOFENAC EPOLAMINE | N021234 | SYSTEM |
| 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 |

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|---|---------|------------------------------------|
| DROSPIRENONE; ESTRADIOL | N021355 | TABLET |
| ECHOTHIOPHATE IODIDE | N011963 | FOR SOLUTION |
| EDETATE CALCIUM DISODIUM | N008922 | INJECTABLE |
| EFLORNITHINE HYDROCHLORIDE | N021145 | CREAM |
| EMTRICITABINE | N021896 | SOLUTION |
| ENFUVRTIDE | N021481 | INJECTABLE |
| ENTECAVIR | N021798 | SOLUTION |
| EPINEPHRINE | N207534 | SOLUTION |
| EPINEPHRINE | N209359 | SOLUTION |
| ERAVACYCLINE DIHYDROCHLORIDE | N211109 | POWDER |
| ESMOLOL HYDROCHLORIDE | N019386 | INJECTABLE |
| ESOMEPRAZOLE MAGNESIUM | N021957 | FOR SUSPENSION, DELAYED RELEASE |
| ESTRADIOL | N021674 | SYSTEM |
| 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; LEVONORGESTREL | N208612 | TABLET |
| ETHIODIZED OIL | N009190 | OIL |
| ETHIONAMIDE | N013026 | TABLET |
| ETOPOSIDE PHOSPHATE | N020457 | INJECTABLE |
| EVEROLIMUS | N021560 | TABLET |
| FENOFIBRATE | N021350 | TABLET |
| FENOFIBRATE | N021612 | CAPSULE |
| FENOPROFEN CALCIUM | N017604 | CAPSULE |
| FLUORESCIN SODIUM | N022186 | INJECTABLE |
| FORMOTEROL FUMARATE; MOMETASONE FUROATE | N022518 | AEROSOL, METERED |
| FOSAMPRENAVIR CALCIUM | N022116 | SUSPENSION |
| GADOXETATE DISODIUM | N022090 | SOLUTION |
| GEMCITABINE HYDROCHLORIDE | N209604 | SOLUTION |
| GLYCOPYRROLATE | N210997 | SOLUTION |
| HALCINONIDE | N017824 | OINTMENT |
| HEPARIN SODIUM | N018609 | INJECTABLE |
| HEPARIN SODIUM | N018916 | INJECTABLE |
| HEPARIN SODIUM | N019339 | INJECTABLE |
| HYDRALAZINE HYDROCHLORIDE; ISOSORBIDE DINITRATE | N020727 | TABLET |
| HYDROCHLOROTHIAZIDE; SPIRONOLACTONE | N012616 | TABLET |
| HYDROCORTISONE ACETATE | N017351 | AEROSOL, METERED |
| HYDROMORPHONE HYDROCHLORIDE | N019034 | INJECTABLE |
| HYDROXYAMPHETAMINE HYDROBROMIDE; TROPICAMIDE | N019261 | SOLUTION/DROPS |
| HYDROXYUREA | N016295 | CAPSULE |

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| ILOPROST | N021779 | SOLUTION |
| INDOMETHACIN | N022536 | INJECTABLE |
| IOBENGUANE SULFATE I-123 | N022290 | SOLUTION |
| IODIXANOL | N020351 | INJECTABLE |
| IOFLUPANE I-123 | N022454 | SOLUTION |
| ISOCARBOXAZID | N011961 | TABLET |
| KETOCONAZOLE | N021946 | GEL |
| KETOROLAC TROMETHAMINE | N022382 | SPRAY, METERED |
| LABETALOL HYDROCHLORIDE | N213330 | SOLUTION |
| LAMIVUDINE | N021004 | SOLUTION |
| LAMIVUDINE; TENOFOVIR DISOPROXIL FUMARATE | N022141 | TABLET |
| LEFLUNOMIDE | N020905 | TABLET |
| LEUPROLIDE ACETATE | N019732 | INJECTABLE |
| LEUPROLIDE ACETATE | N020011 | INJECTABLE |
| LEUPROLIDE ACETATE | N020263 | POWDER |
| LEUPROLIDE ACETATE | N020517 | INJECTABLE |
| LEUPROLIDE ACETATE | N020708 | INJECTABLE |
| LEVAMLODIPINE MALEATE | N212895 | TABLET |
| LEVOLEUCOVORIN | N211226 | POWDER |
| LINEZOLID | N206473 | SOLUTION |
| LODOXAMIDE TROMETHAMINE | N020191 | SOLUTION/DROPS |
| LOMUSTINE | N017588 | CAPSULE |
| 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 |

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| MAGNESIUM SULFATE | N019316 | SOLUTION |
| MAGNESIUM SULFATE | N020488 | INJECTABLE |
| MANGANESE CHLORIDE | N018962 | INJECTABLE |
| MERCAPTOPYRINE | N205919 | SUSPENSION |
| MEROPENEM | N202106 | POWDER |
| MESALAMINE | N020049 | CAPSULE, EXTENDED RELEASE |
| MESNA | N020855 | TABLET |
| METHACHOLINE CHLORIDE | N019193 | FOR SOLUTION |
| METHOHEXITAL SODIUM | N011559 | INJECTABLE |
| METHOTREXATE | N210737 | SOLUTION |
| METHSUXIMIDE | N010596 | CAPSULE |
| METRONIDAZOLE | N020743 | CREAM |
| MILTEFOSINE | N204684 | CAPSULE |
| 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 |
| NELARABINE | N021877 | INJECTABLE |
| NELFINAVIR MESYLATE | N020779 | TABLET |
| NELFINAVIR MESYLATE | N021503 | TABLET |
| NEOSTIGMINE METHYLSULFATE | N203629 | SOLUTION |
| NICARDIPINE HYDROCHLORIDE | N022276 | INJECTABLE |
| NICOTINE | N020385 | SPRAY, METERED |
| NITISINONE | N021232 | CAPSULE |
| 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 |
| PALONOSETRON HYDROCHLORIDE | N207963 | SOLUTION |
| PENCICLOVIR | N020629 | CREAM |
| PENICILLIN G BENZATHINE; PENICILLIN G PROCAINE | N050138 | INJECTABLE |
| PENICILLIN G POTASSIUM | N050638 | INJECTABLE |
| PENTOSAN POLYSULFATE SODIUM | N020193 | CAPSULE |
| PHENDIMETRAZINE TARTRATE | N018074 | CAPSULE, EXTENDED RELEASE |

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| PHENYLEPHRINE HYDROCHLORIDE | N207926 | SOLUTION/DROPS |
| PHENYLEPHRINE HYDROCHLORIDE | N212909 | SOLUTION |
| PODOFILOX | N020529 | GEL |
| POLIDOCANOL | N021201 | SOLUTION |
| POTASSIUM CHLORIDE | N018279 | TABLET, EXTENDED RELEASE |
| POTASSIUM CHLORIDE | N019904 | 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 |
| RIFAPENTINE | N021024 | TABLET |
| RITONAVIR | N020659 | SOLUTION |
| RITONAVIR | N209512 | POWDER |
| ROMIDEPSIN | N022393 | POWDER |
| ROMIDEPSIN | N208574 | SOLUTION |
| SAQUINAVIR MESYLATE | N021785 | TABLET |
| SELEGILINE | N021336 | FILM, EXTENDED RELEASE |
| SELEGILINE HYDROCHLORIDE | N021479 | TABLET, ORALLY DISINTEGRATING |
| SODIUM CHLORIDE | N018897 | SOLUTION |
| 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 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 |
| TAMOXIFEN CITRATE | N021807 | SOLUTION |
| TAZAROTENE | N020600 | GEL |
| TAZAROTENE | N021184 | CREAM |
| TECHNETIUM TC-99M EXAMETAZIME KIT | N019829 | INJECTABLE |
| TECHNETIUM TC-99M PENTETATE KIT | N018511 | INJECTABLE |
| TERIPARATIDE | N211939 | SOLUTION |
| TESTOSTERONE | N020489 | FILM, EXTENDED RELEASE |
| TETRACAINE HYDROCHLORIDE | N208135 | SOLUTION |
| TETRACAINE HYDROCHLORIDE | N210821 | SOLUTION |

RX List Part I

| | | |
|----------------------------|---------|---------------------------|
| THALIDOMIDE | N020785 | CAPSULE |
| THEOPHYLLINE | N019826 | INJECTABLE |
| THIOGUANINE | N012429 | TABLET |
| TIMOLOL MALEATE | N019463 | SOLUTION/DROPS |
| TIOPRONIN | N211843 | TABLET, DELAYED RELEASE |
| TIPRANAVIR | N021814 | CAPSULE |
| TIPRANAVIR | N022292 | SOLUTION |
| TRANEXAMIC ACID | N212020 | SOLUTION |
| TRETINOIN | N020475 | GEL |
| TRETINOIN | N021108 | CREAM |
| TRIAMCINOLONE HEXACETONIDE | N016466 | INJECTABLE |
| TRIPTORELIN PAMOATE | N020715 | INJECTABLE |
| TRIPTORELIN PAMOATE | N021288 | INJECTABLE |
| TROMETHAMINE | N013025 | SOLUTION |
| TRYPAN BLUE | N021670 | SOLUTION |
| TRYPAN BLUE | N022278 | SOLUTION |
| VANCOMYCIN HYDROCHLORIDE | N050671 | INJECTABLE |
| VANCOMYCIN HYDROCHLORIDE | N209481 | POWDER |
| VASOPRESSIN | N212593 | SOLUTION |
| VERAPAMIL HYDROCHLORIDE | N019614 | CAPSULE, EXTENDED RELEASE |
| VERTEPORFIN | N021119 | INJECTABLE |
| ZILEUTON | N020471 | TABLET |
| ZINC SULFATE | N209377 | SOLUTION |
| ZOLEDRONIC ACID | N204016 | SOLUTION |

RX List Part II

| Ingredient | Approved NDA | Dosage Form |
|--|--------------|---------------------------|
| ACETOHYDROXAMIC ACID | N018749 | TABLET |
| ALBUMIN HUMAN | N020899 | INJECTABLE |
| 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 |
| CARMUSTINE | N020637 | IMPLANT |
| CHLORHEXIDINE GLUCONATE | N020774 | TABLET |
| 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 |
| 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 |
| EXENATIDE SYNTHETIC | N021773 | INJECTABLE |
| FERRIC HEXACYANOFERRATE(II) | N021626 | CAPSULE |
| FERRIC OXYHYDROXIDE | N017441 | INJECTABLE |
| FERRIC OXYHYDROXIDE | N021135 | INJECTABLE |
| FISH OIL; MEDIUM CHAIN TRIGLYCERIDES; OLIVE OIL; SOYBEAN OIL | N207648 | EMULSION |
| FLUOCINOLONE ACETONIDE | N020001 | SHAMPOO |
| FLUOCINOLONE ACETONIDE | N021737 | IMPLANT |
| FLUOROMETHOLONE | N017760 | OINTMENT |
| FLUOROMETHOLONE | N019216 | SUSPENSION/DROPS |
| FLUOROMETHOLONE ACETATE | N019079 | SUSPENSION/DROPS |
| FLURANDRENOLIDE | N016455 | TAPE |
| FLUTICASONE PROPIONATE | N020833 | POWDER |
| FULVESTRANT | N210063 | SOLUTION |
| GADOBENATE DIMEGLUMINE | N021358 | INJECTABLE |

RX List Part II

| | | |
|--|---------|------------------|
| 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 HYDROCHLORIDE | N020918 | INJECTABLE |
| GLUCAGON HYDROCHLORIDE | N201849 | POWDER |
| HALCINONIDE | N017823 | SOLUTION |
| 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 | SOLUTION |
| IOHEXOL | N018956 | INJECTABLE |
| 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 |
| LEUPROLIDE ACETATE | N021343 | POWDER |
| LIDOCAINE; PRILOCAINE | N021451 | GEL |
| LIDOCAINE; TETRACAINE | N021623 | PATCH |
| MAFENIDE ACETATE | N016763 | CREAM |
| MANNITOL | N016772 | SOLUTION |
| 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 |

RX List Part II

| | | |
|---|---------|-----------------------|
| OXYTOCIN | N018261 | 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 | N018107 | 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 |
| VINCRISTINE SULFATE | N202497 | INJECTABLE, LIPOSOMAL |
| 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 |
|---|---------------------|--------------------|
| ATROPINE SULFATE | N021146 | SOLUTION |
| CLINDAMYCIN PHOSPHATE | N050782 | GEL |
| DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE | N018365 | INJECTABLE |
| DIFLUPREDNATE | N022212 | EMULSION |
| LOPINAVIR; RITONAVIR | N021906 | TABLET |
| SODIUM ACETATE | N018893 | INJECTABLE |
| ZINC CHLORIDE | N018959 | INJECTABLE |
| ZOLMITRIPTAN | N021450 | SPRAY |

Methodology¹

1. The list is based on the [Orange Book Data Files](#), accessed October 8, 2021.
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.