

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 no competition, FDA is publishing a list of approved new drug application (NDA) drug products which 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 involving potential legal, regulatory, or scientific issues which should be addressed with the Agency prior to submission of an ANDA.

Sponsors wishing to pursue approval of drug products identified in Part II of this list should submit an initial inquiry to the Office of Generic Drugs at genericdrugs@fda.hhs.gov. 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 as an ANDA via the 505(j) pathway; 505(b)(2) may be an appropriate abbreviated approval pathway.
- For others, there is either no applicable product-specific guidance, the product is a complex mixture or imaging agent, or there are other regulatory complexities that may be overcome with additional information exchange between FDA and a prospective ANDA sponsor.
- A drug product marked with an asterisk is a protein that may be a transition product pursuant to the Biologics Price Competition and Innovation Act of 2009.

We have excluded any NDA drug products that have been approved within the past year, as it is too soon to tell whether ANDAs will be submitted.

The list shows active ingredients that lack generic competition. FDA will update this list every six months. We intend to develop it into a list of individual NDA drug products that lack competition. The current methodology is set forth at the bottom of the list. We welcome suggestions concerning the methodology, as well as any NDA drug products (active ingredient, dosage form, and strengths) that should be added to the list. Please direct correspondence to genericdrugs@fda.hhs.gov, providing your name, email address, phone number, NDA number, established name, and dosage form and strength(s) of any NDA drug product that should be added or, in limited cases, removed from the list.

Part I

Ingredient	Approved NDA
ACETYLCHOLINE CHLORIDE	N020213
ACRIVASTINE; PSEUDOEPHEDRINE HYDROCHLORIDE	N019806
ALBENDAZOLE	N020666
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; N021559
AMINO ACIDS; CALCIUM ACETATE; GLYCERIN; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE	N018582
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N020678
AMINO ACIDS; DEXTROSE	N020734
AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; POTASSIUM CHLORIDE; SODIUM ACETATE	N016822
AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM ACETATE; SODIUM CHLORIDE	N017789
AMINO ACIDS; MAGNESIUM ACETATE; PHOSPHORIC ACID; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE	N016822
AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE	N019437
AMINO ACIDS; MAGNESIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM CHLORIDE	N017673; N017789
AMOXICILLIN; CLARITHROMYCIN; OMEPRAZOLE	N050824
A POMORPHINE HYDROCHLORIDE	N021264
ARGININE HYDROCHLORIDE	N016931
ARTEMETHER; LUMEFANTRINE	N022268
ASCORBIC ACID; BIOTIN; CHOLECALCIFEROL; CYANOCOBALAMIN; DEXPANTHENOL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE; RIBOFLAVIN; THIAMINE; TOCOPHEROL ACETATE; VITAMIN A; VITAMIN K	N021265; N021646
ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PHYTONADIONE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E	N018920

ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E	N008809
ASCORBIC ACID; BIOTIN; CYANOCOBALAMIN; DEXPANTHENOL; ERGOCALCIFEROL; FOLIC ACID; NIACINAMIDE; PYRIDOXINE HYDROCHLORIDE; RIBOFLAVIN 5'-PHOSPHATE SODIUM; THIAMINE HYDROCHLORIDE; VITAMIN A; VITAMIN E; VITAMIN K	N021625; N021643
ASPIRIN; CAFFEINE; DIHYDROCODEINE BITARTRATE	N011483
ATROPINE SULFATE	N021146; N206289
ATROPINE SULFATE; DIFENOXIN HYDROCHLORIDE	N017744
ATROPINE SULFATE; EDROPHONIUM CHLORIDE	N019678
AURANOFIN	N018689
BARIUM SULFATE	N208036; N208143; N208844
BENTOQUATAM	N020532
BENZYLPENICILLOYL POLYLYSINE	N050114
BETAINE HYDROCHLORIDE	N020576
BOSENTAN	N021290
BRINZOLAMIDE	N020816
BUTENAFINE HYDROCHLORIDE	N020524; N021307
CALCIUM CHLORIDE	N021117
CALCIUM CHLORIDE; DEXTROSE; GLUTATHIONE DISULFIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE	N018469; N020079
CALCIUM CHLORIDE; DEXTROSE; LACTIC ACID; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE	N021703
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N017512; N018883; N020163; N020171; N020183
CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM BICARBONATE; SODIUM CHLORIDE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	N020577
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018254; N020000
CALCIUM CHLORIDE; DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N016679; N017608; N019367; N019634; N019685
CALCIUM CHLORIDE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE	N018895
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N016693; N017635; N018156; N018251; N018495; N020002
CALCIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM CHLORIDE; SODIUM LACTATE	N016682; N017641; N018494; N018681; N018921; N019416; N019632
CAPREOMYCIN SULFATE	N050095
CARBOPROST TROMETHAMINE	N017989
CARMUSTINE	N017422
CHLORAMBUCIL	N010669

CHLORDIAZEPOXIDE HYDROCHLORIDE; CLIDINIUM BROMIDE	N012750
CHLORPHENIRAMINE MALEATE; IBUPROFEN; PHENYLEPHRINE HYDROCHLORIDE	N022113
CHROMIC CHLORIDE	N018961
CITRIC ACID; GLUCONOLACTONE; MAGNESIUM CARBONATE	N019481
CITRIC ACID; UREA C-13	N021314
CLOCORTOLONE PIVALATE	N017765
CUPRIC CHLORIDE	N018960
DALFOPRISTIN; QUINUPRISTIN	N050748
DALTEPARIN SODIUM	N020287
DESFLURANE	N020118
DESVENLAFAXINE	N204150; N204683
DESVENLAFAXINE FUMARATE	N205583
DEXTROSE; MAGNESIUM ACETATE TETRAHYDRATE; POTASSIUM ACETATE; SODIUM CHLORIDE	N017385
DEXTROSE; MAGNESIUM ACETATE; POTASSIUM ACETATE; SODIUM CHLORIDE	N017610
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE	N019873
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM LACTATE	N017484
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM LACTATE; SODIUM PHOSPHATE, MONOBASIC ANHYDROUS	N019513
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE	N019844
DEXTROSE; MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	N017609
DEXTROSE; POTASSIUM CHLORIDE	N017634; N018371; N019699
DEXTROSE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, DIBASIC; SODIUM ACETATE; SODIUM CHLORIDE	N019870
DEXTROSE; POTASSIUM CHLORIDE; SODIUM CHLORIDE	N018008; N018037; N018362; N018365; N018629; N018876; N019308; N019630; N019691
DEXTROSE; SODIUM CHLORIDE	N016678; N016683; N016687; N016689; N016696; N016697; N017585; N017606; N017607; N017799; N019631
DIATRIZOATE MEGLUMINE; IODIPAMIDE MEGLUMINE	N011324
DIMERCAPROL	N005939
DINOPROSTONE	N017810; N019617; N020411
DOLASETRON MESYLATE	N020623; N020624
ECHOTHIOPHATE IODIDE	N011963
EDETATE CALCIUM DISODIUM	N008922
EFLORNITHINE HYDROCHLORIDE	N021145
EMEDASTINE DIFUMARATE	N020706
ENFUVIRTIDE	N021481

ESOMEPRAZOLE STRONTIUM	N202342
ESTRAMUSTINE PHOSPHATE SODIUM	N018045
ESTROGENS, CONJUGATED	N004782; N010402
ETHANOLAMINE OLEATE	N019357
ETHIONAMIDE	N013026
ETOPOSIDE PHOSPHATE	N020457
EZOGABINE	N022345
FLUORESCHEIN SODIUM	N021980; N022186
FOSFOMYCIN TROMETHAMINE	N050717
GLUTAMINE	N021667
GLYCINE	N016784; N017865; N018315
GUAIFENESIN; HYDROCODONE BITARTRATE	N022424; N205474
GUAIFENESIN; HYDROCODONE BITARTRATE; PSEUDOEPHEDRINE HYDROCHLORIDE	N022279
HALCINONIDE	N017556; N017824
HYDROCHLOROTHIAZIDE; METOPROLOL SUCCINATE	N021956
HYDROXYAMPHETAMINE HYDROBROMIDE; TROPICAMIDE	N019261
IDOXURIDINE	N014169
ILOPROST	N021779
LODOXAMIDE TROMETHAMINE	N020191
LOMUSTINE	N017588
LOTEPREDNOL ETABONATE	N020583
LOTEPREDNOL ETABONATE; TOBRAMYCIN	N050804
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE; SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE	N019696
MAGNESIUM CHLORIDE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM CHLORIDE; SODIUM GLUCONATE	N017378; N017586; N017637; N019024; N019711
MAGNESIUM SULFATE; POTASSIUM CHLORIDE; POTASSIUM PHOSPHATE, MONOBASIC; SODIUM CHLORIDE; SODIUM PHOSPHATE	N018336; N018508
MAGNESIUM SULFATE; POTASSIUM SULFATE; SODIUM SULFATE	N204553
MANGANESE CHLORIDE	N018962
MANNITOL; SORBITOL	N018316
MESTRANOL; NORETHINDRONE	N016659
METHACHOLINE CHLORIDE	N019193
METHOHEXITAL SODIUM	N011559
MIGLUSTAT	N021348
MITOTANE	N016885
NABILONE	N018677
NELFINAVIR MESYLATE	N020779; N021503
OLSALAZINE SODIUM	N019715
OXYMETHOLONE	N016848
PENICILLAMINE	N019853; N019854
PENICILLIN G BENZATHINE; PENICILLIN G PROCAINE	N050138
PENTAZOCINE LACTATE	N016194
PENTETATE CALCIUM TRISODIUM	N021749
PENTETATE ZINC TRISODIUM	N021751

PENTOSAN POLYSULFATE SODIUM	N020193
POVIDONE-IODINE	N018634; N019522
PRALIDOXIME CHLORIDE	N014134; N018986
PRAZIQUANTEL	N018714
PROCARBAZINE HYDROCHLORIDE	N016785
PURIFIED WATER	N022305
PYRIMETHAMINE	N008578
SAQUINAVIR MESYLATE	N020628; N021785
SODIUM ACETATE ANHYDROUS	N018893
SODIUM LACTATE	N018947
SODIUM PHOSPHATE, DIBASIC, HEPTAHYDRATE; SODIUM PHOSPHATE, MONOBASIC, ANHYDROUS	N018892
SORBITOL	N016741; N017863
STERILE WATER FOR IRRIGATION	N016734; N017428; N017513; N017866; N018313
STREPTOZOCIN	N050577
TENIPOSIDE	N020119
TETRACAINE HYDROCHLORIDE	N208135
THIOGUANINE	N012429
TOREMIFENE CITRATE	N020497
TRIAMCINOLONE HEXACETONIDE	N016466
TRIAMTERENE	N013174
TRIENTINE HYDROCHLORIDE	N019194
TRIMETHOPRIM HYDROCHLORIDE	N074973
TRIPTORELIN PAMOATE	N020715; N021288; N022437
TROMETHAMINE	N013025
TRYPAN BLUE	N021670; N022278
VERTEPORFIN	N021119

Part II

Ingredient	Approved NDA
ACETOHYDROXAMIC ACID	N018749
ALBUMIN IODINATED I-125 SERUM	N017836
ALBUMIN IODINATED I-131 SERUM	N017837
ALCOHOL; CHLORHEXIDINE GLUCONATE	N021074
ALITRETINOIN	N020886
ALTRETAMINE	N019926
AMINO ACIDS; CALCIUM CHLORIDE; DEXTROSE; MAGNESIUM SULFATE; POTASSIUM CHLORIDE; SODIUM ACETATE; SODIUM GLYCEROPHOSPHATE; SOYBEAN OIL	N200656
ATROPINE; PRALIDOXIME CHLORIDE	N021983
AVOBENZONE; ECAMSULE; OCTOCRYLENE	N021501; N021502
AVOBENZONE; ECAMSULE; OCTOCRYLENE; TITANIUM DIOXIDE	N021471; N022009
AVOBENZONE; OCTINOXATE; OXYBENZONE	N020045
BECLOMETHASONE DIPROPIONATE MONOHYDRATE	N019389
BERACTANT	N020032
CALFACTANT	N020521
CARMUSTINE	N020637
CHLORPHENIRAMINE MALEATE; PSEUDOEPHEDRINE SULFATE	N018397
CIPROFLOXACIN HYDROCHLORIDE; HYDROCORTISONE	N020805
CLOFAZIMINE	N019500
COLISTIN SULFATE; HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; THONZONIUM BROMIDE	N050356
COPPER	N018680
CORTICORELIN OVINE TRIFLUTATE*	N020162
DESIRUDIN RECOMBINANT*	N021271
DOCOSANOL	N020941
DOXYCYCLINE CALCIUM	N050480
ESTRADIOL HEMIHYDRATE	N021371
ESTRADIOL; LEVONORGESTREL	N021258
ESTROGENS, CONJUGATED	N020216
ESTROGENS, CONJUGATED; MEDROXYPROGESTERONE ACETATE	N020527
ETHOTOIN	N010841
FERRIC HEXACYANOFERRATE(II)	N021626
FLUOROMETHOLONE ACETATE	N019079
GADOBENATE DIMEGLUMINE	N021357; N021358
GADODIAMIDE	N020123; N022066
GADOPENTETATE DIMEGLUMINE	N019596; N021037
GADOTERIDOL	N020131; N021489
GADOVERSETAMIDE	N020937; N020975; N020976
GALLIUM CITRATE GA-67	N017478; N018058
GENTAMICIN SULFATE; PREDNISOLONE ACETATE	N050586; N050612
GLUCAGON HYDROCHLORIDE	N201849
GLUCAGON HYDROCHLORIDE RECOMBINANT	N020918
GLUCAGON RECOMBINANT	N020928
GONADOTROPIN, CHORIONIC*	N017016; N017067; N017692

GUANIDINE HYDROCHLORIDE	N001546
HEXACHLOROPHENE	N017433
HYALURONIDASE	N021640; N021665
HYDROCORTISONE ACETATE; NEOMYCIN SULFATE; POLYMYXIN B SULFATE	N050218
HYDROCORTISONE PROBUTATE	N020453
HYDROXYPROPYL CELLULOSE	N018771
IMIGLUCERASE*	N020367
INDIUM IN-111 CHLORIDE	N019841; N019862
INDIUM IN-111 OXYQUINOLINE	N019044
INDIUM IN-111 PENTETATE DISODIUM	N017707
IOBENGUANE SULFATE I-123	N022290
IODINE POVACRYLEX; ISOPROPYL ALCOHOL	N021586
IODIPAMIDE MEGLUMINE	N009321
IODIXANOL	N020351; N020808
IOFLUPANE I-123	N022454
IOHEXOL	N018956; N020608; N205383
IOPROMIDE	N020220; N021425
IOTHALAMATE MEGLUMINE	N013295; N016983; N017057
IOTHALAMATE SODIUM I-125	N017279
IOVERSOL	N019710; N020923
IRON DEXTRAN	N017441; N017807; N040024
IRON SUCROSE	N021135
ISOCARBOXAZID	N011961
ISONIAZID; PYRAZINAMIDE; RIFAMPIN	N050705
LEUPROLIDE ACETATE; NORETHINDRONE ACETATE	N203696
LIOTRIX (T4;T3)	N016807
LOTEPREDNOL ETABONATE	N020803; N200738; N202872
MEPENZOLATE BROMIDE	N010679
METHSUXIMIDE	N010596
METYRAPONE	N012911
METYROSINE	N017871
NAFARELIN ACETATE	N019886
NATAMYCIN	N050514
NESIRITIDE RECOMBINANT	N020920
NONOXYNOL-9	N018683
PEGADEMASE BOVINE*	N019818
PEGAPTANIB SODIUM	N021756
PEGVISOMANT*	N021106
PORACTANT ALFA	N020744
PORFIMER SODIUM	N020451
POVIDONE-IODINE	N019240; N019476
PSEUDOEPHEDRINE SULFATE	N018191
RIFAPENTINE	N021024
RUBIDIUM CHLORIDE RB-82	N019414; N202153
SALMETEROL XINAFOATE	N020692
SAMARIUM SM-153 LEXIDRONAM PENTASODIUM	N020570
SECRETIN SYNTHETIC HUMAN	N021256
SERTACONAZOLE NITRATE	N021385
SILVER SULFADIAZINE	N017381; N018578; N018810
SODIUM FLUORIDE; TRICLOSAN	N020231

SODIUM IODIDE I-131	N016515; N016517; N021305
SOYBEAN OIL	N017643; N018449; N019531; N019942; N020248
SUCCIMER	N019998
SULCONAZOLE NITRATE	N018737; N018738
TALC	N020587; N021388; N205555
TECHNETIUM TC-99M ALBUMIN AGGREGATED KIT	N017776; N017881
TECHNETIUM TC-99M BICISATE KIT	N020256
TECHNETIUM TC-99M DISOFENIN KIT	N018467
TECHNETIUM TC-99M EXAMETAZIME KIT	N019829
TECHNETIUM TC-99M MEDRONATE	N018035
TECHNETIUM TC-99M MEDRONATE KIT	N018107; N018124
TECHNETIUM TC-99M MERTIATIDE KIT	N019882
TECHNETIUM TC-99M OXIDRONATE KIT	N018321
TECHNETIUM TC-99M PENTETATE KIT	N017714; N018511
TECHNETIUM TC-99M PYROPHOSPHATE KIT	N017538; N019039
TECHNETIUM TC-99M RED BLOOD CELL KIT	N019981
TECHNETIUM TC-99M SODIUM PERTECHNETATE GENERATOR	N017243; N017693; N017771
TECHNETIUM TC-99M TETROFOSMIN KIT	N020372
TERBINAFINE	N021958
THYROTROPIN ALFA*	N020898
TIOPRONIN	N019569
TRIMETHADIONE	N005856
UREA, C-14	N020617
VALRUBICIN	N020892
XENON XE-133	N017284; N018327
ZANAMIVIR	N021036
ZINC ACETATE	N020458
ZINC CHLORIDE	N018959
ZIPRASIDONE MESYLATE	N020919

Methodology

1. The list is based on the [Orange Book Data Files](#), accessed May 30, 2017.
2. The list considers products by their Orange Book-listed active ingredient. The list does not differentiate between different strengths or dosage forms of products with the same listed active ingredient. However, the Agency has identified the corresponding NDA numbers for these products to assist applicants with identification of the correct reference listed drug (RLD).
3. A given ingredient (or combination of ingredients in the case of multi-ingredient products) is included on the list if:
 - a. There is at least one active and approved NDA for the ingredient,^{1,2} and
 - b. There are no approved ANDAs for the ingredient³, and
 - c. There are no patents or exclusivities listed for the NDAs.⁴
4. Each ingredient and corresponding NDA numbers are 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.
 - b. Part II identifies drug products involving potential legal, regulatory, or scientific issues which should be addressed with the Agency prior to submission of an ANDA.

¹ "Active and approved" means that the product is listed in the Orange Book (i.e. the product is approved) and that it is not listed as a "discontinued" product. If all approved applications (NDAs and ANDAs) for a given ingredient are flagged as "discontinued" in the Orange Book, that ingredient is not included on the list.

² Ingredients with only approved and Orange Book-listed ANDAs but no Orange Book-listed NDAs are not included on the list.

³ Ingredients with an approved but discontinued ANDA are not included on the list.

⁴ Ingredients that have at least one Orange Book-listed patent or exclusivity are not included on the list. This includes cases where one product lacks any patents or exclusivities, but another product of the same ingredient does have at least one listed patent or exclusivity.