

**Approved Active Moieties to which FDA  
has issued a Written Request for Pediatric Studies under  
Section 505A of the Federal Food, Drug, and Cosmetic Act - May 2019**

NOTE: This list simply identifies approved active moieties to which FDA has issued a Written Request for pediatric studies since June 1998. If a product appears on this list, it does not imply that studies have been conducted or submitted to the Agency, nor does it mean that the studies described in the Written Request will be conducted. A sponsor is NOT required to perform pediatric studies in response to a Written Request. Conducting pediatric studies in response to a Written Request is voluntary. Upon occasion, information obtained by FDA subsequent to issuance of a Written Request causes FDA to rescind the Written Request. This list is not updated to indicate when a Written Request has been rescinded.

**Total Approved Active Moieties Issued a Written Request = 459**

Active Moiety	Sponsor
Abacavir	Glaxo Wellcome, Inc.
Abatacept	Bristol-Myers Squibb Company
Acamprosate	Forest Labs
Acetaminophen	Cadence Pharmaceuticals
Acetazolamide	Wyeth-Ayerst
Adefovir	Gilead Sciences
Aflibercept	Regeneron Pharmaceuticals, Incorporated
Afatinib	Boehringer Intelheim Pharmaceuticals, Inc.
Albuterol	Dey, L.P.
Albuterol	GlaxoSmithKline
Alendronate	Merck Research Laboratories
Alfuzosin	Sanofi-Aventis U.S. LLC
Aliskiren	Novartis Pharmaceuticals
Almotriptan	Pharmacia & Upjohn
Alogliptin	Takeda Pharmaceuticals U.S.A., Inc.
Alosetron	Glaxo Wellcome, Inc.

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Active Moiety	Sponsor
Alprazolam	Pharmacia & Upjohn
Amiodarone	Wyeth Ayerst
Amlexanox	Block Drug Company, Inc.
Amlodipine	Pfizer, Inc.
Amlodipine/Benazepril	Novartis Pharmaceuticals
Ammonium Lactate	Westwood Squibb
Amphetamine (mixed salts)	Shire Laboratories
Amprenavir	Glaxo Wellcome, Inc.
Anagrelide	Shire Laboratories
Anastrozole	AstraZeneca Pharmaceuticals LP
Apixaban	Bristol-Myers Squibb Company
Apremilast	Celgene Corporation
Aprepitant/Fosaprepitant	Merck & Company, Inc.
Argatroban	Encysive Pharmaceuticals
Aripiprazole	Otsuka Pharmaceutical Co., Ltd.
Asenapine	Organon USA, Inc.
Atazanavir	Bristol-Myers Squibb
Atezolizumab	Genentech, Inc.
Atomoxetine	Lilly Research Laboratories
Atorvastatin	Warner-Lambert Export, Ltd.
Atovaquone/Proguanil	Glaxo Wellcome, Inc.
Azelastine	ASTA Medica, Inc.
Azelastine	Meda Pharmaceuticals, Inc.
Azilsartan medoxomil	Takeda Pharmaceuticals U.S.A., Inc.
Azithromycin	Pfizer
Baclofen	Schwarz Pharma, Inc.
Balsalazide	Salix Pharmaceuticals
Beclomethasone	Schering Corporation
Beclomethasone	3M Pharmaceuticals

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Active Moiety	Sponsor
Benazepril	Novartis Pharmaceuticals
Bendamustine	Cephalon, Inc.
Besifloxacin	Bausch & Lomb, Inc.
Betamethasone	Schering Corporation
Betaxolol	Loxex Pharmaceuticals
Betaxolol	Alcon Laboratories
Bicalutamide	AstraZeneca Pharmaceuticals
Bictegravir/Emtricitabine/Tenofovir Alafenamide(B/F/TAF)	Gilead Sciences, Inc.
Bisoprolol	Wyeth-Ayerst Laboratories
Bivalirudin	The Medicines Company
Blinatumomab	Amgen, Inc.
Boceprevir	Schering-Plough
Bortezomib	Millenium Pharmaceuticals
Bosutinib	Wyeth Pharmaceuticals, Inc.
Brexanolone	Sage Therapeutics
Brimonidine	Allergan, Inc.
Brinzolamide	Alcon Laboratories
Budesonide	AstraZeneca Pharmaceuticals, L.P.
Budesonide/Formoterol	AstraZeneca Pharmaceuticals, L.P.
Buprenorphine	Purdue Pharma L.P.
Buprenorphine	Reckitt Benckiser Pharmaceuticals
Bupropion	Glaxo Wellcome, Inc
Buspirone	Bristol-Myers Squibb Company
Busulfan	Orphan Medical
C-Urea	Meretek Diagnostics, Inc.
Cabazitaxel	Sanofi-Aventis
Calcipotriene	Leo Pharmaceuticals
Calcitriol	Abbott Laboratories
Calcitriol	Galderma Laboratories

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Active Moiety	Sponsor
Canagliflozin	Janssen Pharmaceuticals, Inc.
Candesartan	Astra Pharmaceuticals
Capecitabine	Hoffmann-La Roche, Inc.
Carbamazepine	Shire Development, Inc.
Carboplatin	Bristol-Myers Squibb Company
Carfilzomib	Onyx Therapeutics, Inc.
Cariprazine	Forest Research Institute
Carteolol	CIBA Vision Corporation
Carvedilol	SmithKline Beecham Pharmaceuticals
Casposungin	Merck Research Laboratories
Celecoxib	G.D. Searle & Co.
Cemiplimab-RWLC	Regeneron Pharmaceuticals, Incorporated
Cerivastatin	Bayer Corporation Pharmaceutical
Cetirizine	Pfizer Pharmaceuticals
Cilostazol	Otsuka Pharmaceutical Co., Ltd.
Cimetidine	SmithKline Beecham
Cinacalcet	Amgen, Inc.
Ciprofloxacin	Bayer Corporation
Ciprofloxacin	Alcon Laboratories
Cisatracurium	Glaxo Wellcome
Citalopram	Forest Laboratories, Inc.
Clobazam	Lundbeck, LLC
Clofarabine	ILEX Products, Inc.
Clopidogrel	Sanofi-Synthelabo, Inc.
Cobicistat	Gilead Sciences, Inc.
Cobimetinib	Genentech, Inc.
Colchicine, USP	AR Holding Co., Inc.
Colesevelam	Sankyo Pharma Development
Conivaptan	Astellas Pharma US, Inc.

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Active Moiety	Sponsor
Copanlisib	Bayer HealthCare Pharmaceuticals, Inc.
Crizotinib	Pfizer
Cromolyn	Pharmacia & Upjohn
Cromolyn	Bausch & Lomb Pharmaceuticals, Inc.
Cysteamine	Raptor Therapeutics, Inc.
Cytarabine	SkyePharma Inc.
Dabrafenib	Novartis Pharmaceuticals Corporation
Dactinomycin	Merck & Company, Inc.
Dapagliflozin	AstraZeneca
Daptomycin	Cubist Pharmaceuticals, Inc.
Darbepoetin	Amgen, Inc.
Darifenacin	Novartis Pharmaceuticals Corporation
Darunavir	Tibotec, Inc.
Dasatinib	Bristol-Myers Squibb Company
Daunorubicin	Hisun Pharm Hangzhou
Decitabine	Eisai Medical Research, Inc.
Deferasirox	Novartis Pharmaceuticals Corporation
Deflazacort	PTC Therapeutics, Inc.
Denosumab	Amgen, Inc.
Desflurane	Baxter Healthcare Corporation
Desloratadine	Schering Corporation
Desvenlafaxine	Wyeth Pharmaceuticals, Inc.
Dexmedetomidine	Hospira, Inc.
Dexmethylphenidate	Novartis Pharmaceuticals
Dexrazoxane	Pfizer Pharmaceuticals
Dichlorphenamide	Merck Research Laboratories
Diclofenac	Novartis Consumer Health, Inc.
Diclofenac	Xanodyne Pharmaceuticals, Inc.
Didanosine	Bristol-Myers Squibb Company

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Active Moiety	Sponsor
Difluprednate	Sirion Therapeutics, Inc.
Divalproex	Abbott Laboratories
Divalproex(valproate)	Abbott Laboratories
Docetaxel	Sanofi-Aventis, U.S., Inc.
Dolutegravir	ViiV Healthcare
Dorzolamide	Merck Research Laboratories
Dulaglutide	Eli Lilly and Company
Duloxetine	Eli Lilly & Co.
Efavirenz	DuPont Pharmaceuticals Company
Efinaconazole	Dow Pharmaceutical Sciences
Eletriptan	Pfizer, Inc.
Eltrombopag	GlaxoSmithKline
Elvitegravir	Gilead Sciences, Inc.
Emtricitabine	Triangle Pharmaceuticals, Inc.
Enalapril	Merck Research Laboratories
Enfuvirtide	Hoffman-La Roche, Inc.
Enoxaparin	Aventis Pharmaceuticals, Inc.
Entecavir	Bristol-Myers Squibb Company
Eribulin	Eisai, Inc.
Epirubicin	Pharmacia & Upjohn
Eplerenone	G.D. Searle and Company
Erlotinib	OSI Pharmaceuticals, Inc.
Ertapenem	Merck & Co., Inc.
Esketamine	Janssen Pharms
Eslicarbazepine	Sunovion Pharmaceutical, Inc.
Esmolol	Baxter Pharmaceuticals Products, Inc.
Esomeprazole	AstraZeneca Pharmaceuticals, LP
Eszopiclone	Sepracor, Inc.
Etodolac	Wyeth-Ayerst Research

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Active Moiety	Sponsor
Etravirine	Tibotec, Inc.
Everolimus	Novartis Pharmaceuticals Corporation
Exenatide	Amylin Pharmaceuticals, Inc.
Ezetimibe	MSP Singapore Co., LLC
Famciclovir	Novartis Pharmaceuticals Corporation
Famotidine	Merck & Company, Inc.
Felodipine	Astra Pharmaceuticals, L.P.
Fenoldopam	Elan Pharmaceuticals
Fentanyl	Anesta Corporation
Fentanyl	Janssen Pharmaceuticals
Ferric Citrate	Keryx Biopharmaceuticals, Inc.
Fesoterodine	Pfizer, Inc.
Fexofenadine	Aventis Pharmaceuticals
Fidaxomicin	Merck Sharp & Dohme Corp./Cubist Pharmaceuticals, LLC
Fingolimod	Novartis Pharmaceutical Corporation
Fluconazole	Pfizer Pharmaceuticals Group
Fludarabine	Berlex Laboratories
Fluocinolone	Bausch & Lomb Pharmaceuticals, Inc.
Fluoxetine	Eli Lilly and Company
Fluticasone	Glaxo Wellcome, Inc.
Fluvastatin	Novartis Pharmaceuticals Corporation
Fluvoxamine	Solvay Pharmaceuticals
Formoterol	Novartis Pharmaceuticals Corporation
Fosamprenavir	GlaxoSmithKline
Fosaprepitant	Merck
Fosinopril	Bristol-Myers Squibb Company
Fosphenytoin	Pfizer, Inc.
Fospropofol	Eisai, Inc.
Fulvestrant	AstraZeneca Pharmaceuticals, LP

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Gabapentin	Parke-Davis Pharmaceutical Research
Gadopentetate	Bayer HealthCare Pharmaceuticals, Inc.
Gatifloxacin	Bristol-Myers Squibb Company
Gatifloxacin	Allergan, Inc.
Gefitinib	AstraZeneca, Pharmaceuticals, LP
Gemcitabine	Lilly Research Laboratories
Gemtuzumab	Wyeth-Ayerst Research Laboratories
Gentamicin	Schering Corporation
Glatiramer	TEVA Pharmaceuticals USA
Glecaprevir/Pibrentasvir	AbbVie, Inc.
Glimepiride	Aventis Pharmaceuticals
Glipizide/Metformin	Bristol-Myers Squibb Company
Glyburide/Metformin	Bristol-Myers Squibb Company
Granisetron	Hoffman La-Roche, Inc.
Griseofulvin	Pedinol Pharmacial, Inc.
Guanfacine	Shire Development, Inc.
Halobetasol Propionate	Sun Pharmaceutical Industries, Inc.
Hydrocortisone	Atlanta, Inc.
Hydrocortisone	Bristol-Myers Squibb Company
Hydromorphone	Mallinckrodt, Inc.
Hydroxyurea	Bristol-Myers Squibb Company
Ibrutinib	Pharmacyclics, LLC
Ibuprofen	McNeil Consumer Products Company
Ibuprofen	Whitehall-Robbins
Ibuprofen/pseudoephedrine	McNeil Consumer Products Company
Ibuprofen/pseudoephedrine	Whitehall-Robbins Healthcare
Iloperidone	Novartis Pharmaceuticals Corporation
Imatinib	Novartis Pharmaceuticals Corporation
Imiquimod	3M Pharmaceuticals

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Active Moiety	Sponsor
Indinavir	Merck Research Laboratories
Insulin aspart [rDNA origin]	Novo Nordisk Pharmaceuticals, Inc.
Insulin glargine	Aventis Pharmaceutical, Inc.
Ipilimumab	Bristol-Myers Squibb Company
Irbesartan	Bristol-Myers Squibb Company
Irinotecan	Pharmacia & Upjohn
Isavuconazonium	Astellas Pharma US, Inc.
Isotretinoin	Hoffman-LaRoche, Inc.
Itraconazole	Janssen Pharmaceutica Research
Ivabradine	Corlanor
Ivacaftor	Vertex Pharmaceutical
Ixabepilone	Bristol-Myers Squibb Company
Ketoconazole	Janssen Pharmaceutica Research
Ketorolac	Allergan, Inc.
Labetalol	Schering Corporation
Lamivudine	Glaxo Wellcome, Inc.
Lamotrigine	Glaxo Wellcome, Inc.
Lansoprazole	TAP Holdings, Inc.
<b>Lasmiditan</b>	<b>Eli Lilly and Company</b>
Ledipasvir	Gilead Sciences, Inc.
Leflunomide	Hoechst Marion Roussel, Inc.
Lenalidomide	Celgene Corporation
Levalbuterol	Sepracor, Inc.
Levetiracetam	UCB Pharma, Inc.
Levobetaxolol	Alcon Laboratories, Inc.
Levobunolol	Allergan, Inc.
Levocetirizine	UCB, Inc.
Levofloxacin	R.W. Johnson
Levofloxacin	Santen, Inc.

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Active Moiety	Sponsor
Levomilnacipran	Forest Laboratories, Inc.
Levonorgestrel/ethinyl estradiol	Duramed Research, Inc.
Linaclotide	Forest Laboratories, LLC
Linezolid	Pharmacia & UpJohn
Liraglutide	Novo Nordisk, Inc.
Lisdexamfetamine	Shire
Lisinopril	Zeneca Pharmaceuticals
Lisinopril	Merck & Co., Inc.
Lithium	Roxane
Lomitapide	Aegerion
Lopinavir/Ritonavir	Abbott Laboratories
Loratadine	Schering Corporation
Lorazepam	Wyeth-Ayerst Research
Lorcaserin	Eisai, Inc.
Losartan	Merck Research Laboratories
Loteprednol	Bausch & Lomb, Inc.
Lovastatin	Merck & Co., Inc.
Lurasidone	Sunovion Pharmaceuticals, Inc.
Macitentan	Actelion Clinical Res., Inc.
Malathion	Taro Pharm, USA, Inc.
Maraviroc	Pfizer, Inc.
Meloxicam	Boehringer Ingelheim Pharmaceuticals
Memantine	Forest Research Institute
Meropenem	AstraZeneca
Mesalamine	Procter & Gamble Pharmaceuticals, Inc.
Mesalamine	Shire
Metformin	Bristol-Myers Squibb Company
Methazolamide	Wyeth-Ayerst Laboratories
Methotrexate	Mayne Pharma (USA) Inc.

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Active Moiety	Sponsor
Methylphenidate	McNeil Consumer & Specialty Pharm.
Metipranolol	Bausch & Lomb
Metoclopramide	Schwarz Pharma, Inc.
Metoprolol	AstraZeneca, Pharmaceuticals, LP
Micafungin	Astellas Pharma US, Inc.
Miconazole	BioAlliance Pharma
Midazolam	Hoffmann-La Roche, Inc.
Milnacipran	Cypress Bioscience, Inc.
Milrinone	Sanofi Synthelabo, Inc.
Minoxidil	Pharmacia & Upjohn Company
Mirabegron	Astellas Pharma Global Development, Inc.
Mirtazapine	Organon, Inc.
Modafinil	Cephalon, Inc.
Moexipril	Schwarz Pharmaceuticals
Mometasone	Schering Corporation
Mometasone/Formoterol	Merck Sharp & Dohme Corp.
Montelukast	Merck & Co., Inc.
Morphine	Elan Drug Delivery
Morphine	Faulding Pharmaceuticals
Motexafin	Pharmacyclics
Moxifloxacin	Alcon Universal, Ltd.
NAB-paclitaxel	Celgene Corporation
Nabumetone	SmithKline Beecham
Nateglinide	Novartis Pharmaceuticals
Nefazodone	Bristol-Myers Squibb Company
Nelfinavir	Agouron Pharmaceuticals, Inc.
Nevirapine	Boehringer Ingelheim Pharmaceuticals
Nicardipine	PDL BioPharma, Inc.
Nicotine	SmithKline Beecham

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Active Moiety	Sponsor
Nilotinib	Novartis Pharmaceuticals
Nitric Oxide	INO Therapeutics
Nivolumab	Bristol-Myers Squibb Company
Nizatidine	Reliant Pharmaceuticals
Norfloxacin	Merck & Co., Inc.
Norgestimate/ethinyl estradiol	R.W. Johnson Pharmaceutical Research
Octreotide	Novartis Pharmaceuticals Corporation
Ofloxacin	Allergan, Inc.
Olanzapine	Lilly Research Laboratories
Olmesartan	Sankyo Pharma, Inc.
Olopatadine	Alcon Research, Ltd.
Omeprazole	AstraZeneca Pharmaceuticals, LP
Ondansetron	Glaxo Wellcome, Inc.
Orlistat	Hoffman-La Roche, Inc.
Oseltamivir	Hoffman-La Roche, Inc.
Oxaliplatin	Sanofi-Synthelabo, Inc.
Oxaprozin	Searle
Oxcarbazepine	Novartis Pharmaceuticals Corporation
Oxybutynin	Alza Corporation
Oxybutynin	Watson Laboratories, Inc.
Oxycodone	Purdue Pharma L.P.
Oxymorphone	Endo Pharmaceuticals
Palbociclib	Pfizer, Inc.
Paliperidone	J&J Pharmaceuticals
Palonosetron	Helsinn Healthcare SA
Pantoprazole	Wyeth-Ayerst Laboratories
Paricalcitol	Abbott Laboratories
Paroxetine	SmithKline Beecham Pharmaceuticals
Peginesatide	Affymax, Inc.

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Pegvisomant	Pharmacia & Upjohn Co.
Pemetrexed	Eli Lilly & Company
Pemirolast	Santen, Inc.
Perampanel	Eisai, Inc.
Pimavanserin	Acadia Pharms, Inc.
Pimecrolimus	Novartis Pharmaceutical Corporation
Pioglitazone	Takeda Pharmaceuticals, Inc.
Pitavastatin	Kowa Research Institute, Inc.
Plerixafor	Genzyme
Polyethylene Glycol 3350	Braintree Laboratories, Inc.
Pomalidomide	Celgene Corporation
Posaconazole	Schering Corporation
Pramipexole	Boehringer-Ingelheim
Prasugrel	Eli Lilly & Co.
Pravastatin	Bristol-Myers Squibb
Pregabalin	Pfizer Global
Propofol	Zeneca Pharmaceuticals
Quetiapine	AstraZeneca Pharmaceuticals, LP
Quinapril	Parke-Davis Pharmaceutical Research
Rabeprazole	Eisai, Inc.
Raltegravir	Merck & Co., Inc.
Ramelteon	Takeda Global Research
Ramipril	King Pharmaceuticals
Ramucirumab	Eli Lilly and Company
Ranitidine	GlaxoWellcome, Inc.
Remifentanyl	Glaxo Wellcome, Inc.
Repaglinide	Novo Nordisk
Ribavirin/Interferon alfa-2B, recombinant	Schering-Plough Research Institute
Rifampin	Aventis Pharmaceuticals, Inc.

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Rifapentine	Hoechst Marion Roussel, Inc.
Rifaximin	Salix Pharmaceuticals, Inc.
Rilpivirine	Janssen Prods
Risedronate	Procter & Gamble Pharmaceuticals
Risperidone	Janssen Research Foundation
Ritonavir	Abbott Laboratories
Rivaroxaban	Janssen Research & Development, LLC
Rizatriptan	Merck Research Laboratories
Rocuronium	Organon, Inc.
Rofecoxib	Merck & Co., Inc.
Ropivacaine	AstraZeneca Pharmaceuticals, LP
Rosiglitazone	SmithKline Beecham Pharmaceuticals
Rosiglitazone	S.B. Pharmco Puerto Rico, Inc.
Rosuvastatin	AstraZeneca Pharmaceuticals, LP
Rufinamide	Eisai, Inc.
Ruxolitinib	Jakafinda
Sacubitril/Valsartan	Novartis Pharmaceuticals Corp.
Salmeterol	Glaxo Wellcome, Inc.
Sapropterin	BioMarin Pharmaceutical, Inc.
Saquinavir	Hoffman-La Roche Inc.
Sertraline	Pfizer Pharmaceuticals
Sevelamer	GelTex Pharmaceuticals, Inc.
Sevoflurane	Abbott Laboratories
Sibutramine	Knoll Pharmaceuticals
Sildenafil	Pfizer, Inc.
Simvastatin	Merck & Co., Inc.
Sirolimus	Wyeth-Ayerst Research
Sitagliptin	Merck Sharp & Dohme Corp.
Sodium ferric gluconate complex	Watson Laboratories, Inc.

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<b>Active Moiety</b>	<b>Sponsor</b>
Sodium Nitroprusside	Abbott Laboratories
Sodium oxybate	Jazz Pharmaceuticals
Sofosbuvir	Gilead Sciences, Inc.
Solifenacin	Astellas Pharma Global
Somatropin [rDNA origin]	Serono Laboratories
Sotalol	Berlex Laboratories, Inc.
Stavudine	Bristol-Myers Squibb
Sugammadex	Organon USA, Inc.
Sumatriptan	Glaxo Wellcome, Inc.
Sumatriptan/naproxen	Pozen, Inc.
Sunitinib	C.P. Pharmaceuticals Intl c/o Pfizer, Inc.
Tacrolimus	R-Tech Ueno (USA), Inc.
Tadalafil	Eli Lilly and Company
Tamoxifen	AstraZeneca Pharmaceuticals
Tamsulosin	Boehringer Ingelheim Pharmaceuticals
Tapentadol	Janssen Research & Development, LLC
Tavaborole	Anacor Pharmaceuticals, Inc.
Tbo-filgrastin	Teva Branded Pharmaceutical Products R&D, Inc.
Technetium Tc99m Sestamibi	Bristol-Myers Squibb Medical Imaging
Teduglutide	NPS Pharmaceuticals, Inc.
Telaprevir	Vertex Pharmaceuticals, Inc.
Telbivudine	Idenix Pharmaceuticals Inc.
Temozolomide	Schering Corporation
Temsirolimus	Wyeth-Ayerst Research Laboratories
Tenofovir	Gilead Sciences, Inc.
Terbinafine	Novartis Pharmaceuticals Corporation
Teriflunamide	Sanofi-Aventis U.S., Inc.
Testosterone	Unimed Pharmaceuticals, Inc.
Tetrabenazine	Biovail Technologies, Ltd.

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Active Moiety	Sponsor
Ticagrelor	AstraZeneca Pharm
Timolol	Merck Research Laboratories
Timolol	Falcon Pharmaceuticals
Timolol	Santen Incorporated
Tiotropium Bromide	Boehringer Ingelheim
Tipranavir	Boehringer Ingelheim Pharmaceuticals
Tizanidine	Acorda Therapeutics, Inc.
Tobramycin	Alcon Laboratories
Tobramycin	Falcon Pharmaceuticals
Tocilizumab	Hoffmann-LaRoche, Inc.
Tofacitinib	P.F. Prism CV
Tolterodine	Pharmacia & Upjohn Company
Tolvaptan	Otsuka Pharmaceutical Company, Ltd.
Topiramate	The R.W. Johnson
Topotecan	SmithKline Beecham
Tramadol	R.W. Johnson
Trametinib	Novartis Pharmaceuticals Corporation
Valacyclovir	GlaxoSmithKline
Valganciclovir	Roche Pharmaceuticals
Valsartan	Novartis Pharmaceuticals
Varenicline	Pfizer, Inc.
Velpatasvir(VEL)	Gilead Sciences, Inc.
Venetoclax	AbbVie, Inc.
Venlafaxine	Wyeth-Ayerst Laboratories
Verapamil	Elan Pharmaceutical Research Corp.
Vigabatrin	Lundbeck, Inc.
Vilazodone	Forest Labs
Vinorelbine	Glaxo Wellcome, Inc.
Voriconazole	Pfizer Global Research & Development

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Vortioxetine	Takeda Pharms, USA
Zafirlukast	Zeneca Pharmaceuticals
Zanamivir	Glaxo Wellcome, Inc
Ziprasidone	Pfizer, Inc.
Zoledronic acid	Novartis Pharmaceuticals Corporation
Zolmitriptan	Zeneca Pharmaceuticals
Zolpidem	Sanofi-Synthelabo Research
Zonisamide	Elan Pharmaceuticals, Inc.

New\*

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<b>Date Issued</b>
8/20/1998
9/13/2013
11/9/2005
8/24/2007
10/15/1999
4/12/2002
6/4/2019
4/7/2017
10/30/2001
12/31/2001
10/27/2000
2/21/2006
5/13/2008
10/5/2001
10/1/2013
4/7/2000

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Date Issued
5/21/2003
11/5/1999
3/23/2000
2/4/1999
12/19/2001
2/22/1999
5/6/2003
4/7/1999
3/27/2003
5/9/2001
3/24/2017
5/29/2015
2/2/2009
4/2/2003
2/11/2003
9/22/2009
8/2/2001
8/10/2016
10/10/2001
2/16/1999
1/16/2001
4/16/1999
9/6/2013
12/6/2012
7/31/2003
4/30/2004
12/17/2001
6/24/1999
12/31/2001

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Date Issued
5/27/1999
1/19/2010
1/13/2011
7/16/1999
2/11/1999
3/5/2004
4/17/2003
5/26/2017
12/23/1998
5/7/2007
11/12/2014
10/14/2011
4/27/2010
7/30/2015
3/20/2018
6/25/1999
10/15/1999
12/14/1998
1/28/2011
9/20/2011
4/12/2006
7/21/2000
10/9/1998
3/27/2000
6/10/2004
3/20/2012
2/20/2007
9/17/1999
10/13/2010

Approved Active Moieties to which FDA  
has issued a Written Request for Pediatric Studies under  
Section 505A of the Federal Food, Drug, and Cosmetic Act - May 2019

Date Issued
3/8/2014
3/15/1999
3/16/2005
9/7/2005
4/11/2001
3/17/2005
2/3/2017
10/15/1999
12/23/1998
1/26/2001
4/24/2000
12/3/2018
2/29/2000
9/3/1999
12/17/2001
10/13/2000
5/5/2010
5/12/1999
10/22/1999
3/17/1999
4/28/1999
9/23/2013
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10/15/2001
3/27/2014
5/27/2017
3/30/2010
8/31/2004
6/14/2011

Approved Active Moieties to which FDA  
has issued a Written Request for Pediatric Studies under  
Section 505A of the Federal Food, Drug, and Cosmetic Act - May 2019

Date Issued
11/16/2016
11/28/2011
11/24/1998
6/25/1999
8/19/2013
2/4/2000
3/1/2016
8/3/2004
3/26/2019
5/24/2013
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9/18/2017
11/30/2012
12/31/2001
6/6/2000
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6/17/2004
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4/30/2009
2/22/2011
8/5/1999

Approved Active Moieties to which FDA  
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Section 505A of the Federal Food, Drug, and Cosmetic Act - May 2019

Date Issued
2/18/2009
1/31/2006
8/9/2002
6/11/2007
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8/17/2000
11/27/2000
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Approved Active Moieties to which FDA  
has issued a Written Request for Pediatric Studies under  
Section 505A of the Federal Food, Drug, and Cosmetic Act - May 2019

Date Issued
4/3/2008
4/25/2000
3/29/2006
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4/14/1999
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12/4/2001
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Date Issued
10/9/1998
1/26/2009
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6/25/1999
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9/5/2014
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