

DOCKET NO. 98N-0056

**LIST OF APPROVED DRUGS FOR WHICH ADDITIONAL PEDIATRIC INFORMATION MAY
PRODUCE HEALTH BENEFITS IN THE
PEDIATRIC POPULATION**

BACKGROUND

On November 21, 1997, President Clinton signed into law the Food and Drug Administration Modernization Act of 1997 (Pub. L. 105-115) (Modernization Act). The Modernization Act (21 U.S.C. 355a(b)) requires the Food and Drug Administration (FDA), after consultation with experts in pediatric research, to develop, prioritize, and publish a list of approved drugs for which additional pediatric information may produce health benefits in the pediatric population (the list). FDA is publishing this list as required by statute and will update the list regularly.

For purposes of this list, "approved drug" is defined by FDA as a drug that is approved for use in adults for indications that occur in the pediatric population. This list is intended solely to satisfy the requirement of 21 U.S.C. 355a(b). The list does not constitute a written request under 21 U.S.C. 355a(c). Inclusion of a drug on the list does not necessarily mean that the drug is entitled to pediatric exclusivity. Some reasons a drug included on the list might not be entitled to pediatric exclusivity include: (1) ineligibility for any other exclusivity or patent protection to which pediatric exclusivity would be added, and (2) failure of submitted studies to satisfy a written request from FDA. Inclusion of a drug on the list does not mean that a sponsor is required to take any action.

PROCESS

FDA compiled an initial working list based on recommendations from the American Academy of Pediatrics (AAP), the Pharmaceutical Research and Manufacturers Association (PhRMA), the National Institutes of Health (NIH), the Pediatric Pharmacology Research Units Network (PPRU), the National Pharmaceutical Alliance (NPA), the Generic Pharmaceutical Industry Association (GPIA), the National Association of Pharmaceutical Manufacturers (NAPM), and the United States Pharmacopeia (USP). FDA also included on this initial working list drugs identified in the Orange Book as having remaining patent and/or exclusivity life.

After internal review of this working list based upon the criteria described in the Background to the draft list, a draft list was published on March 16, 1998, (63FR 12815) for comment from interested parties. A total of 89 comments were received on the draft list. Many comments suggested that specific drugs be added to or deleted from the list. A few comments described the list as too broad. A number of comments stated that the criteria used by FDA to compile the draft list were too narrow and that the list should include all drugs that are used in the treatment of diseases or conditions that occur in the pediatric population.

CONTENT OF THE LIST

After consideration of the comments, the Agency has concluded that information on any drug approved in adults for an indication that occurs in the pediatric population may have the potential for offering a health benefit to the pediatric population. Therefore, all drugs approved by the Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research that are approved for use in adults for indications that occur in the pediatric population are considered to be on the list¹.

¹Drugs approved under section 505 (including those products approved under former section 507) of the Food, Drug, and Cosmetic Act, are listed in the Orange Book.

The statute also requires FDA to prioritize the list. After reviewing the comments to the draft list, and considering alternative approaches to establishing priorities among the drugs on the initial list, FDA has concluded that the criteria used for the draft list (and described again below) best describe those drugs for which studies would provide a more significant benefit, and thus should be prioritized for study. Sponsors should note that inclusion of a drug on the priority list does not necessarily mean that an application containing such studies will be entitled to a priority review. Review classification of any application submitted with pediatric studies will be determined by established procedures².

FDA developed the list of priority drugs by reviewing the draft list and the comments submitted in response to the draft list. Comments requesting addition or deletion of specific drugs, along with any supporting information, were reviewed by the appropriate review division to determine whether the drug met the criteria. Based on the evaluations of the review divisions, changes were made to the draft list and the priority list was developed.

Attachments A and B represent the Agency's priority list of drugs. These are the drugs the Agency considers high priority for pediatric study. Due to resource constraints, the Agency will issue written requests for studies of drugs on the priority list first. Requests for studies of drugs on the broader list will be made as resources permit. If an interested party wishes to have a drug added to the priority list, it should petition the Agency in accordance with the requirements of 21 CFR 10.30. Petitioners should include in the header of their petition, "PEDIATRIC PRIORITY LIST."

CRITERIA FOR INCLUSION OF DRUGS ON THE PEDIATRIC PRIORITY LIST

After much discussion, consideration of the recommendations of the experts in pediatric research consulted by FDA, and review of the comments on the draft list, the Agency generally intends to include on the priority list those drugs that meet the following criteria:

- The drug product, if approved for use in the pediatric population, would be a significant improvement compared to marketed products labeled for use in the treatment, diagnosis, or prevention of a disease in the relevant pediatric population (i.e., a priority review drug); or,
- The drug is widely used in the pediatric population, as measured by at least 50,000 prescription mentions per year; or,
- The drug is in a class or for an indication for which additional therapeutic or diagnostic options for the pediatric population are needed.

Drugs that meet at least one of the above criteria have been included on the priority list. If a drug identified on the priority list no longer meets the criteria identified above, the drug may be removed from the priority list.

² Refer to the Center for Drug Evaluation and Research's *Manual of Policies and Procedures*, "Priority Review Policy" (MAPP 6020.3) and the Center for Biologics Evaluation and Research's *Manual of Standard Operating Procedures and Policies*, "Complete Review and Issuance of Action Letters," (SOP 8405) for the current policies and procedures for assigning a priority review designation to an application.

FORMAT OF THE PEDIATRIC PRIORITY LIST

Drugs are shown on the priority list by therapeutic class as defined by the FDA division where the drug was reviewed. Attachment A reflects those drugs regulated by the Center for Drug Evaluation and Research and Attachment B reflects those drugs regulated by the Center for Biologics Evaluation and Research. The drugs are listed in alphabetical order within each class. For ease of presentation, drugs are listed by active moiety with all approved indications for that moiety for which additional pediatric information may produce health benefits in the pediatric population. For purposes of 21 U.S.C. 355a(c), FDA's written requests will be specific to an approved drug product for its approved adult or limited pediatric indication. It is important to note that uses of the drugs in the pediatric population for indications not approved in adults are not included. Studies in support of an application for approval of a use that is currently not approved in adults may be eligible for exclusivity under 21 U.S.C. 355a(a).

The list indicates the pediatric age groups in which particular drug products need to be studied. The pediatric age groups for the purpose of this list are defined as neonate (birth to 1 month), infant (1 month to 2 years), child (2 to 12 years), and adolescent (12 years to <16 years). FDA understands that certain drugs are more appropriately studied in groups categorized by the maturity of certain biological processes (e.g., onset of puberty) and may make modifications to an identified pediatric age group if data is submitted to identify a drug that should be studied in pediatric groups identified by characteristics other than age.

REQUEST FOR UPDATES

If an interested party wishes to have a drug placed on or removed from the priority list, it should petition the Agency in accordance with the requirements of 21 CFR 10.30. Petitioners should include in the header of the petition, "PEDIATRIC PRIORITY LIST."

PUBLICATION OF THE LIST

FDA published the List of Approved Drugs for Which Additional Information May Produce Health Benefits in the Pediatric Population and announced the availability of the list in the Federal Register. The list is available for viewing at the web site <http://www.fda.gov/cder/pediatric> and at the Dockets Management Branch in Docket No. 98N-0056. A copy of the list is also available through faxon-demand (1-800-342-2722, Document number 0504).

Attachment A

**Pediatric Priority List of Drugs Regulated by the
 Center for Drug Evaluation and Research**

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
<i>Cardio-Renal Drug Products</i>					
Acebutolol	Hypertension	Yes	Yes	Yes	Yes
Adenosine	Conversion to sinus rhythm of paroxysmal supraventricular tachycardia, including that associated with accessory bypass tracts	Yes	Yes	Yes	Yes
Amiloride	Hypertension	Yes	Yes	Yes	Yes
Amiloride/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Amiodarone	Treatment and prophylaxis of frequently recurring ventricular fibrillation and hemodynamically destabilizing ventricular tachycardia	Yes	Yes	Yes	Yes
Amlodipine	Hypertension	Yes	Yes	Yes	Yes
Amlodipine/Benazepril	Hypertension	Yes	Yes	Yes	Yes
Atenolol	Hypertension	Yes	Yes	Yes	Yes
Atenolol/Chlorthalidone	Hypertension	Yes	Yes	Yes	Yes
Benazepril	Hypertension	Yes	Yes	Yes	Yes
Benazepril/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Bendroflumethiazide	Hypertension	Yes	Yes	Yes	Yes
Betaxolol	Hypertension	Yes	Yes	Yes	Yes
Bisoprolol	Hypertension	Yes	Yes	Yes	Yes
Bisoprolol/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Bumetanide	Treatment of edema (CHF, liver or kidney disease)	Yes	Yes	Yes	Yes
Captopril	1) Hypertension 2) Treatment of heart failure	Yes	Yes	Yes	Yes
Captopril/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Carteolol	Hypertension	Yes	Yes	Yes	Yes
Carvedilol	Treatment of heart failure	Yes	Yes	Yes	Yes
Chlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Chlorthalidone	Hypertension	Yes	Yes	Yes	Yes
Clonidine	Hypertension	Yes	Yes	Yes	Yes
Clonidine/Chlorthalidone	Hypertension	Yes	Yes	Yes	Yes
Diazoxide	Emergency use in hypertensive emergencies; insulin antagonism	Yes	Yes	Yes	Yes
Digoxin	For rapid control of ventricular rate in the face of supraventricular tachycardia; CHF in specific cardiovascular disorders and malformations	Yes	Yes	Yes	Yes
Diltiazem	Hypertension	Yes	Yes	Yes	Yes
Disopyramide	Arrhythmias	Yes	Yes	Yes	Yes
Dobutamine	Treatment of heart failure	Yes	Yes	Yes	Yes
Dopamine	Treatment of heart failure	Yes	Yes	Yes	Yes
Doxazosin	Hypertension	Yes	Yes	Yes	Yes
Enalapril	1) Hypertension 2) Treatment of heart failure	Yes	Yes	Yes	Yes
Enalapril/Diltiazem	Hypertension	Yes	Yes	Yes	Yes

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Enalapril/Felodipine	Hypertension	Yes	Yes	Yes	Yes
Enalapril/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Enalaprilat	For emergency use in hypertensive emergencies	Yes	Yes	Yes	Yes
Eprosartan	Hypertension	Yes	Yes	Yes	Yes
Esmolol	For rapid control of ventricular rate in the face of supraventricular tachycardia	Yes	Yes	Yes	Yes
Ethacrynic acid	Hypertension	Yes	Yes	Yes	Yes
Felodipine	Hypertension	Yes	Yes	Yes	Yes
Fenoldopam	For emergency use in hypertensive emergencies	Yes	Yes	Yes	Yes
Flecainide	1) Prolonging the time to recurrence of supraventricular tachycardia 2) Treatment of life threatening ventricular arrhythmias	Yes	Yes	Yes	Yes
Fosinopril	Hypertension	Yes	Yes	Yes	Yes
Fosinopril/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Furosemide	Treatment of edema (CHF, liver or kidney disease); treatment of BPD and other forms of chronic lung disease	Yes	Yes	Yes	Yes
Guanabenz	Hypertension	Yes	Yes	Yes	Yes
Guanfacine	Hypertension	Yes	Yes	Yes	Yes
Hydralazine	Hypertension	Yes	Yes	Yes	Yes
Hydralazine/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Hydrochlorothiazide	1) Hypertension 2) Treatment of edema 3) Sparing Calcium excretion	Yes	Yes	Yes	Yes
Hydrochlorothiazide/Triamterene	Hypertension	Yes	Yes	Yes	Yes
Hydroflumethiazide	Hypertension	Yes	Yes	Yes	Yes
Ibutilide	Conversion of atrial fibrillation and flutter to normal sinus rhythm	Yes	Yes	Yes	Yes
Indapamide	Treatment of edema (CHF, liver or kidney disease)	Yes	Yes	Yes	Yes
Irbesartan	Hypertension	Yes	Yes	Yes	Yes
Irbesartan/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Isradipine	Hypertension	Yes	Yes	Yes	Yes
Labetalol	For use in hypertensive emergencies	Yes	Yes	Yes	Yes
Lisinopril	Hypertension	Yes	Yes	Yes	Yes
Lisinopril/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Losartan	Hypertension	Yes	Yes	Yes	Yes
Losartan/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Magnesium sulfate	Hypertension	Yes	Yes	Yes	Yes
Mannitol	Diuresis	Yes	Yes	Yes	Yes
Methylclothiazide	Hypertension	Yes	Yes	Yes	Yes
Methyldopa	Hypertension	Yes	Yes	Yes	Yes
Methyldopate	Hypertension	Yes	Yes	Yes	Yes
Metolazone	Treatment of refractory edema	Yes	Yes	Yes	Yes
Metoprolol	Hypertension	Yes	Yes	Yes	Yes
Metoprolol/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Mexiletine	Arrhythmias	Yes	Yes	Yes	Yes
Mibefradil	Hypertension	Yes	Yes	Yes	Yes

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Milrinone	Treatment of heart failure	Yes	Yes	Yes	Yes
Minoxidil	Hypertension	Yes	Yes	Yes	Yes
Moexipril	Hypertension	Yes	Yes	Yes	Yes
Moexipril/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Nadolol	Hypertension	Yes	Yes	Yes	Yes
Nadolol/Bendroflumethiazide	Hypertension	Yes	Yes	Yes	Yes
Nicardipine	Hypertension	Yes	Yes	Yes	Yes
Nifedipine	Hypertension	Yes	Yes	Yes	Yes
Nisoldipine	Hypertension	Yes	Yes	Yes	Yes
Nitroglycerin	Hypertension	Yes	Yes	Yes	Yes
Nitroprusside	1) Treatment of heart failure 2) For emergency use in hypertensive emergencies	Yes	Yes	Yes	Yes
Penbutolol	Hypertension	Yes	Yes	Yes	Yes
Perindopril	Hypertension	Yes	Yes	Yes	Yes
Phentolamine	Hypertension	Yes	Yes	Yes	Yes
Pindolol	Hypertension	Yes	Yes	Yes	Yes
Pindolol/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Polythiazide	Hypertension	Yes	Yes	Yes	Yes
Prazosin	Hypertension	Yes	Yes	Yes	Yes
Prazosin/Polythiazide	Hypertension	Yes	Yes	Yes	Yes
Procainamide	Arrhythmias	Yes	Yes	Yes	Yes
Propafenone	1) Prolonging the time to recurrence of supraventricular tachycardia 2) Treatment of life threatening ventricular arrhythmias	Yes	Yes	Yes	Yes
Propranolol	Hypertension	Yes	Yes	Yes	Yes
Propranolol/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Quinapril	1) Treatment of heart failure 2) Hypertension	Yes	Yes	Yes	Yes
Quinethazone	Hypertension	Yes	Yes	Yes	Yes
Quinidine	1) Conversion of atrial fibrillation and flutter to normal sinus rhythm 2) Prolonging the time to recurrence of supraventricular tachycardia 3) Treatment of life threatening ventricular arrhythmias	Yes	Yes	Yes	Yes
Ramipril	Hypertension	Yes	Yes	Yes	Yes
Reserpine	Hypertension	Yes	Yes	Yes	Yes
Reserpine/Chlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Reserpine/Chlorthalidone	Hypertension	Yes	Yes	Yes	Yes
Reserpine/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Reserpine/Hydroflumethiazide	Hypertension	Yes	Yes	Yes	Yes
Reserpine/Methyclothiazide	Hypertension	Yes	Yes	Yes	Yes
Reserpine/Polythiazide	Hypertension	Yes	Yes	Yes	Yes
Reserpine/Trichlormethiazide	Hypertension	Yes	Yes	Yes	Yes
Reserpine/Hydralazine/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Spirapril	Hypertension	Yes	Yes	Yes	Yes
Spironolactone	Hypertension	Yes	Yes	Yes	Yes

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Spironolactone/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Terazosin	Hypertension	Yes	Yes	Yes	Yes
Timolol	Hypertension	Yes	Yes	Yes	Yes
Timolol/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Torsemide	1) Hypertension 2) Treatment of edema (CHF, liver or kidney disease)	Yes	Yes	Yes	Yes
Trandolapril	Hypertension	Yes	Yes	Yes	Yes
Triamterene	Hypertension	Yes	Yes	Yes	Yes
Triamterene/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Trichlormethiazide	Hypertension	Yes	Yes	Yes	Yes
Valsartan	Hypertension	Yes	Yes	Yes	Yes
Valsartan/Hydrochlorothiazide	Hypertension	Yes	Yes	Yes	Yes
Verapamil	For rapid control of ventricular arrhythmia in the face of supraventricular tachycardia	Yes	Yes	Yes	Yes
Verapamil/Trandolapril	Hypertension	Yes	Yes	Yes	Yes
Neuropharmacological Drug Products					
Alprazolam	Anxiety, panic	No	No	Yes	Yes
Amphetamine/Dextroamphetamine	ADHD	No	No	Yes	Yes
Baclofen	Treatment of spasticity resulting from spinal cord injury or multiple sclerosis in patients who's oral baclofen therapy has failed	No	No	Yes	Yes
Bupropion	Treatment of depression	No	No	Yes	Yes
Buspirone	Anxiety	No	No	Yes	Yes
Clomipramine	Obsessive compulsive disorders	No	No	Yes	Yes
Clonazepam	Lennox-Gastaut syndrome, akinetic & myoclonic seizures; Pananti convulsion; treatment of (convulsions) akinetic myoclonic and absent seizure	Yes	Yes	Yes	Yes
	Panic disorder	No	No	No	Yes
Clozapine	Psychotic disorders	No	No	Yes	Yes
Diazepam	1) Management of selected, refractory, patients with epilepsy, on stable regimes of AEDs, who require intermittent use of diazepam to control bouts of increased seizure activity	Yes	Yes	No	No
	2) Anxiety disorders	No	No	Yes	Yes
Dihydroergotamine	Symptomatic treatment of common or classic migraine headaches in adults	No	No	Yes	Yes
Divalproex	1) Therapy in simple (petit mal) & complex absence seizures & multiple seizure types.	Yes	Yes	Yes	Yes
	2) Mania	Pediatric information needed in > 9 years of age.			
Ethosuximide	Control of absence epilepsy (petit mal)	Pediatric information needed in < 3 years of age.			

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Felbamate	Treatment of Lennox-Gastaut	Yes	Yes	No	No
	Monotherapy or adjunctive therapy for the treatment of partial seizures with and without generalization in patients with epilepsy	Pediatric information needed in < 14 years of age.			
Fluoxetine	1) Treatment of depression	No	No	Yes	Yes
	2) Obsessive compulsive disorder	No	No	Yes	Yes
Fluvoxamine	For the treatment of obsessions and compulsions in patients with obsessive compulsive disorder	No	No	Yes	Yes
Fosphenytoin	Treatment of epilepsy	Yes	Yes	Yes	Yes
Gabapentin	Treatment of epilepsy	Yes	Yes	Yes	Yes
Glatiramer	Slowing progression of disability and reducing frequency of relapses in patients with multiple sclerosis.	No	No	No	Yes
Lamotrigine	Indicated as add-on therapy in the control of partial seizures with or without secondarily generalized tonic-clonic seizures	Yes	Yes	Yes	Yes
Lithium	Manic phase of bipolar disorder	Pediatric information needed in > 9 years of age.			
Lorazepam	1) Status epilepticus	Yes	Yes	Yes	Yes
	2) Anxiety	No	No	Yes	Yes
Methylphenidate	ADHD	Pediatric information on ADHD needed between 3 to 6 years of age. Information on effects on growth needed between 3-16 years			
Naratriptan	Acute treatment of migraine (with or without aura)	No	No	Yes	Yes
Nefazodone	Treatment for depression	No	No	Yes	Yes
Olanzapine	Management of the manifestations of psychotic disorders	No	No	Yes	Yes
Oxazepam	Anxiety	No	No	Yes	Yes
Paroxetine	1) Treatment of all types of depression	No	No	Yes	Yes
	2) OCD	No	No	No	Yes
	3) Panic disorder				
Pemoline	ADHD	Pediatric information on ADHD needed in 3 to 6 years of age. Information on growth effects needed in 3 to 16 years of age.			
Pimozide	Tourettes	No	No	Yes	No
Pralidoxime	Component of antinerve gas	Yes	Yes	Yes	Yes
Quetiapine	Management of the manifestations of psychotic disorders	No	No	Yes	Yes
Risperidone	Manifestations of psychotic disorders,	No	No	Yes	Yes
Scopolamine	Motion sickness	No	No	Yes	Yes
Sertraline	1) Depression	No	No	Yes	Yes
	2) Obsessive compulsive disorder	No	No	Yes	Yes
	3) Panic disorder	No	No	No	Yes
Sumatriptan	Acute treatment of migraine (with or without aura)	No	No	Yes	Yes
Temazepam	Short term treatment insomnia	No	No	Yes	Yes

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Tiagabine	Adjunctive therapy for partial seizures with and without secondary generalization	Yes	Yes	Yes	Yes
Tizanidine	Management of spasticity	No	Yes	Yes	Yes
Topiramate	Adjunctive therapy in patients with partial onset seizures with or without secondarily generalized seizures	Yes	Yes	Yes	Yes
Trazodone	Depression	No	No	Yes	Yes
Valproate	1) Therapy in simple (petit mal) & complex absence seizures & multiple seizure types. 2) Mania	Yes	Yes	Yes	Yes
		Pediatric information needed > 9 years of age			
Venlafaxine	Treatment of depression	No	No	Yes	Yes
Zolmitriptan	An oral agent for the acute treatment of migraine attacks with or without aura	No	No	Yes	Yes
Zolpidem	Treatment of insomnia	No	No	Yes	Yes
Oncology Drug Products					
Amifostine	Chemoprotective agent that selectively protects against the serious toxicities associated with intensive regimens of platinum and alkylating agent chemotherapy	Yes	Yes	Yes	Yes
Busulfan	Chronic myelogenous leukemia	No	Yes	Yes	Yes
Carmustine	Central nervous system malignancies, lymphoma	No	Yes	Yes	Yes
Dacarbazine	Hodgkin's Disease	No	Yes	Yes	Yes
Dexrazoxane	For the prevention of cardiomyopathy associated with doxorubicin administration	Yes	Yes	Yes	Yes
Hydroxyurea	Chronic myelocytic leukemia	Yes	Yes	Yes	Yes
Mesna	Detoxicant (ifosfamide-induced hemorrhagic cystitis prophylaxis)	Yes	Yes	Yes	Yes
Talc	Treatment of malignant pleural effusion	Yes	Yes	Yes	Yes
Medical Imaging And Radiopharmaceutical Drug Products					
Ferric Ammonium Citrate	Delineate the gastrointestinal tract in magnetic resonance imaging of the upper abdomen	Yes	Yes	Yes	Yes
Ferumoxides	Intended for the detection of lesions of the liver and spleen manifested by an alteration in RES distribution as an adjunct to MRI	Yes	Yes	Yes	Yes
Ferumoxsil	Used with magnetic resonance imaging/to enhance delineation of the bowel in order to distinguish it from adjacent organs and areas of suspected pathology	Yes	Yes	Yes	Yes
Gadodiamide	IV administration with magnetic resonance imaging in adult patients to provide contrast enhancement & facilitate visualization of central nervous system, as well as intrathoracic intra-abdominal, pelvic and retroperitoneal regions of the body	Repeat dosing information needed for all ages. Other pediatric information needed for above 2 years old.			
Gadopentetate	Magnetic resonance imaging contrast medium for adult intracranial tumors(primary or metastatic)	Yes	Yes	No	No

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Gallium Citrate Ga-67	Useful to demonstrate the following malignancies: Hodgkins disease, lymphomas and bronchogenic carcinoma	Yes	Yes	Yes	Yes
Human Albumin Microspheres	Used to opacify the left ventricle and to improve the delineation of the left ventricular endocardial borders	Yes	Yes	Yes	Yes
Indium In-111 Pentate Disodium	Radionuclide cisternography	Yes	Yes	Yes	Yes
Indium In-111 Oxyquinoline	Radiolabeled autologous leukocytes for the detection of inflammatory process	Yes	Yes	Yes	Yes
Iodixanol	Radiographic contrast medium for purposes of angiography and arteriography	Pediatric information needed in <1 year of age.			
Iofetamine I-123	Radioactive diagnostic-nonlacunar stroke	Yes	Yes	Yes	Yes
Iopromide	Aortography and visceral angiography coronary arteriography/left ventriculography	Yes	Yes	No	No
Iotrolan	For contrast enhancement for lumbar, thoracic, cervical and total columnar myelography of spinal and subarachnoid spaces	Yes	Yes	Yes	Yes
Ioversol	Radiopaque diagnostic (cerebral angiography and venography, cardiovascular angiography, contrast enhanced computed tomographic imaging of the head and body and excretory urography)	Yes	No	No	No
Ioxilan	Computer enhanced computed tomographic imaging of head and body aortofemoral arteriography, cerebral arteriography, ventriculography	Yes	Yes	Yes	Yes
Mangafodipir	Indicated for the detection/classification/and diagnostic characterization of hepatic disease during magnetic resonance imaging (MRI) in adults	Yes	Yes	Yes	No
Manganese	Contrast agent for MRI of the abdomen and pelvis for delineation of the gastrointestinal tract	Yes	Yes	Yes	Yes
Rubidium Rb-82 Chloride	To assess regional myocardial perfusion in the diagnosis and localization of myocardial infarction	Yes	Yes	Yes	Yes
Samarium Sm-153 Lexidronam	Relief of bone pain in patients with painful osteoblastic skeletal metastases	No	Yes	Yes	Yes
Sodium Iodide I-123	Indicated for the use in the evaluation of thyroid function and/or morphology	No	No	Yes	Yes
Sodium Iodide I-131	Therapeutic for the treatment of hyperthyroidism and selected cases of carcinoma of the thyroid	No	No	Yes	Yes
Strontium Sr-89 Chloride	Palliation of pain from bone metastases	No	Yes	Yes	Yes
Technetium Tc-99m Albumin Aggregated	Scintigraphic imaging of the lungs as an adjunct to other diagnostic procedures whenever information about pulmonary circulation is needed	Yes	Yes	Yes	Yes
Technetium Tc-99m Bicisate	Used as an adjunct to conventional CT or MRI imaging in the localization of stroke in patients in whom stroke has already been diagnosed	Yes	Yes	Yes	Yes
Technetium Tc-99m Disofenin	Hepatobiliary imaging agent	Yes	Yes	Yes	Yes
Technetium Tc-99m Exametazime	Radioactive diagnostic (altered regional cerebral perfusion in stroke)	Yes	Yes	Yes	Yes
Technetium Tc-99m Lidofenin	Hepatobiliary imaging agent	Yes	Yes	Yes	Yes

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Technetium Tc-99m Mebrofenin	Radioactive diagnostic for hepatobiliary imaging	Yes	Yes	Yes	Yes
Technetium Tc-99m Medronate	Bone imaging agent to delineate areas of altered osteogenesis	Yes	Yes	Yes	Yes
Technetium Tc-99m Pentetate	Used to perform kidney imaging, brain imaging, to assess renal perfusion and to estimate glomerular filtration rate	Yes	Yes	Yes	Yes
Technetium Tc-99m Red Blood Cell	Blood pool imaging including cardiac first pass and gated equilibrium imaging and for the detection of sites of gastrointestinal bleeding	Yes	Yes	Yes	Yes
Technetium Tc-99m Sestamibi	Myocardial perfusion imaging agent that is indicated for detecting coronary artery disease	No	Yes	Yes	Yes
Technetium Tc-99m Sodium Gluceptate	Used to image kidney and brain, and to assess renal and brain perfusion	Yes	Yes	Yes	Yes
Technetium Tc-99m Succimer	Evaluation of renal parenchymal disorders	Yes	Yes	Yes	Yes
Technetium Tc-99m Teboroxime	Measurement of coronary blood flow at rest and stress	Yes	Yes	Yes	Yes
Technetium Tc-99m Tetrofosmin	Useful for the scintigraphic imaging of the myocardium following separate administrations under exercise and resting conditions for the delineation of regions of reversible myocardial ischemia in the presence or absence of infarcted myocardium	Yes	Yes	Yes	Yes
Xenon Xe-133	Evaluation of pulmonary function and for imaging of the lungs and the assessment of cerebral blood flow	No	Yes	Yes	Yes
Anesthetic, Critical Care And Addiction Drug Products					
Alfentanil	Anesthesia maintenance, induction of anesthesia, monitored anesthesia care	Yes	Yes	Yes	Yes
Atracurium	Neuromuscular blocking agent	Yes	Yes	No	No
Atropine/Edrophonium	Reversal agent or antagonist of nondepolarizing muscle relaxants	Yes	Yes	Yes	Yes
Bupivacaine	Production of local or regional anesthesia or analgesia	Yes	Yes	Yes	No
Bupropion	Aid to smoking cessation treatment	Pediatric information needed in > 10 years of age.			
Cisatracurium	Intermediate neuromuscular blocking agent	Yes	Yes	No	No
Clonidine	For the continuous epidural administration as adjunctive therapy with intraspinal opiates for the treatment of pain in cancer patients	No	No	Yes	Yes
Dezocine	Pain management when use of opioid analgesic indicated	Yes	Yes	Yes	Yes
Doxacurium	Indicated as an adjunct to general anesthesia, to provide skeletal muscle relaxation during surgery	Yes	Yes	No	No
Droperidol	Tranquilization, decrease nausea and vomiting, premedication, induction, adjunct in maintenance of general and regional anesthesia, neuroleptanalgesia	Yes	Yes	No	No
Epinephrine	Intraosseous and endotracheal for resuscitation	Yes	Yes	Yes	Yes
Etomidate	Anesthesia/hypnosis	Yes	Yes	Yes	No

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Fentanyl	Analgesia, induction and maintenance of anesthesia, administration with neuroleptic agent	Yes	Yes	No	No
Flumazenil	Complete or partial reversal of the sedative effects of benzodiazepines	Yes	Yes	Yes	Yes
Hydromorphone	1) For the relief of moderate to severe pain	No	Yes	Yes	Yes
	2) For the control of persistent, exhausting cough or dry, nonproductive cough	No	Yes	Yes	Yes
Isoflurane	Anesthesia	Yes	Yes	Yes	Yes
Ketamine	Anesthesia	Yes	Yes	Yes	Yes
Ketorolac	Analgesia, pain control	Yes	Yes	Yes	Yes
Lorazepam	Sedation, analgesia	Yes	Yes	Yes	Yes
Midazolam	Anesthesia, sedation	Yes	Yes	Yes	Yes
Mivacurium	Adjunct to general anesthesia, neuromuscular blocking agent	Yes	Yes	No	No
Morphine	Management of pain where treatment with an opioid analgesic is indicated for extended periods	Yes	Yes	Yes	Yes
Nalbuphine	Analgesia, anesthesia supplement	Yes	Yes	Yes	Yes
Naltrexone	For treatment of opiate dependence	Yes	Yes	Yes	Yes
Nicotine	Temporary nicotine replacement for facilitating smoking cessation with or without a behavioral and/or psychological modification program	Pediatric information needed in > 10 years of age.			
Oxycodone	Management of pain	Yes	Yes	Yes	Yes
Pancuronium	Neuromuscular blocking agent	Yes	Yes	Yes	Yes
Propofol	Induction and maintenance of anesthesia, ICU and MAC sedation	Yes	Yes	Yes	No
Remifentanyl	Analgesic agent for use during induction and maintenance of general anesthesia, analgesia in the immediate post operative period	Yes	Yes	Yes	Yes
Rocuronium	Non depolarizing neuromuscular blocking agent	Yes	Yes	No	No
Ropivacaine	Production of local or regional anesthesia	Yes	Yes	Yes	No
Sevoflurane	Induction and maintenance of anesthesia	Yes	Yes	Yes	Yes
Vecuronium	Neuromuscular blockade	Yes	Yes	Yes	Yes
<i>Gastro-Intestinal And Coagulation Drug Products</i>					
Aminocaproic Acid	Hemostasis enhancement after fibrinolysis	Yes	Yes	Yes	Yes
Anagrelide	Essential thrombocythemia	No	No	Yes	Yes
Cholestyramine	For relief of pruritus associated with partial biliary obstruction	No	Yes	Yes	Yes
Cimetidine	Treatment of active duodenal ulcer, maintenance of duodenal ulcer healing, treatment of active benign gastric ulcer, treatment of erosive gastroesophageal reflux disease, treatment of pathological hypersecretory syndromes, such as Zollinger-Ellison Syndrome, prevention of upper gastrointestinal bleeding in critically ill patients	Yes	Yes	Yes	Yes
Deferoxamine	Treatment of acute iron intoxication and chronic iron overload due to transfusion-dependent anemias	Pediatric information needed in 1 to 3 years of age.			
Diclofenac/Misoprostol	Treatment of the signs and symptoms of rheumatoid arthritis	No	No	Yes	Yes

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Dimercaprol	Antidote for heavy metal poisoning	Yes	Yes	Yes	Yes
Dolasetron	The prevention of nausea and vomiting associated with emetogenic cancer chemotherapy including initial and repeat courses	No	Yes	Yes	Yes
Enoxaparin	DVT and pulmonary emboli	Yes	Yes	Yes	No
Epoprostenol	Indicated for the long-term intravenous treatment of NYHA class III and class IV patients with primary pulmonary hypertension	No	No	No	Yes
Famotidine	Treatment of active duodenal ulcer, treatment of active benign gastric ulcer, maintenance of duodenal ulcer healing, treatment of gastroesophageal reflux disease and erosive esophagitis, treatment of pathological hypersecretory syndromes, such as Zollinger-Ellison syndrome	Yes	Yes	Yes	Yes
Granisetron	Prevention of nausea and vomiting associated with initial and repeat courses of emetogenic cancer therapy	No	Yes	Yes	Yes
Heparin	Anticoagulant, prevention of extension of thrombosis	Yes	Yes	Yes	Yes
Lansoprazole	Treatment of active duodenal ulcer, in triple therapy combination with clarithromycin and amoxicillin for treatment of patients with <i>Helicobacter pylori</i> infection and duodenal ulcer disease to eradicate <i>H. pylori</i> , in dual therapy combination with amoxicillin for treatment of patients with <i>H. pylori</i> infection and duodenal ulcer disease who are either allergic or intolerant to clarithromycin or in whom resistance to clarithromycin is known or suspected, maintenance of healing of duodenal ulcer, treatment of active benign gastric ulcer/treatment of gastroesophageal reflux disease and erosive esophagitis, maintenance of healing of erosive esophagitis, treatment of pathological hypersecretory syndromes, such as Zollinger-Ellison syndrome, reflux esophagitis	Yes	Yes	Yes	Yes
Mesalamine	Treatment and maintenance of ulcerative colitis	No	No	Yes	Yes
Metoclopramide	Symptomatic gastroesophageal reflux, diabetic gastroparesis (diabetic gastric stasis), prevention of nausea and vomiting associated with emetogenic cancer chemotherapy, prevention of post-operative nausea and vomiting	Yes	Yes	Yes	Yes
Misoprostol	Prevention of NSAID induced gastric ulcers in high risk patients	No	No	Yes	Yes
Nizatidine	Treatment of active duodenal ulcer, treatment of active benign gastric ulcer, maintenance of duodenal ulcer healing, treatment of gastroesophageal reflux disease and erosive esophagitis	Yes	Yes	Yes	Yes

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Olsalazine	Maintenance of ulcerative colitis (second line therapy)	No	No	Yes	Yes
Omeprazole	Treatment of active duodenal ulcer, in combination with clarithromycin for treatment of patients with <i>Helicobacter pylori</i> infection and active duodenal ulcer disease to eradicate <i>H. pylori</i> , treatment of active benign gastric ulcer, treatment of gastroesophageal reflux disease and erosive esophagitis, maintenance of healing of erosive esophagitis, treatment of pathological hypersecretory syndromes, such as Zollinger-Ellison syndrome	Yes	Yes	Yes	Yes
Ondansetron	Prevention of nausea and vomiting associated with cancer chemotherapy and for the prevention of postoperative nausea and vomiting	Pediatric information needed in <3 years of age.			
Polyethylene glycol-containing electrolyte solutions	Bowel cleansing prior to colonoscopy and/or barium enema x-ray examination	No	Yes	Yes	Yes
Pancrelipase	Indicated in conditions where exocrine pancreatic deficiency is present	Yes	Yes	Yes	Yes
Ranitidine	Treatment of active duodenal ulcer, treatment of active benign gastric ulcer, maintenance of duodenal ulcer healing, maintenance of gastric ulcer healing, treatment of gastroesophageal reflux disease and erosive esophagitis, maintenance of healing of erosive esophagitis, treatment of pathological hypersecretory syndromes, such as Zollinger-Ellison syndrome.	Yes	Yes	Yes	Yes
Sulfasalazine	Ulcerative colitis (treatment and maintenance)	No	No	Yes	Yes
Zinc	Maintenance treatment of patients with Wilson's disease	No	Yes	Yes	Yes
Metabolic And Endocrine Drug Products					
Acarbose	Type II Diabetes	No	No	Yes	Yes
Atorvastatin	Heterozygous and homozygous familial hypercholesterolemia	No	No	Yes	Yes
Calcitriol	Renal osteodystrophy, end stage renal disease	Yes	Yes	Yes	Yes
Calcium acetate	For treatment of hyperphosphatemia in end stage renal failure patients	Yes	Yes	Yes	Yes
Cerivastatin	Heterozygous familial hypercholesterolemia	No	No	Yes	Yes
Corticotropin Ovine	Diagnostic aid for adrenal cortical function and Cushing's syndrome	No	Yes	Yes	Yes
Desmopressin	1) Central diabetes insipidus 2) Treatment of hemophilia A and mild to moderate von Willebrand disease	Yes	Yes	Yes	Yes
Fenofibrate	Cholesterol lowering and acute pancreatitis	No	No	Yes	Yes
Fluvastatin	Heterozygous familial hypercholesterolemia	No	No	Yes	Yes
Gallium nitrate	For the treatment of cancer-related hypercalcemia	No	No	Yes	Yes
Insulin lispro	Type 1 Diabetes	Yes	Yes	Yes	Yes
Levocarnitine	Treatment of primary/secondary carnitine deficiency	Yes	Yes	Yes	Yes
Lovastatin	Heterozygous familial hypercholesterolemia	No	No	Yes	Yes

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Metformin	Diabetes secondary to cystic fibrosis, NIDDM	No	No	Yes	Yes
Niacin	Hyperlipidemia	No	No	Yes	Yes
Octreotide	Antisecretory, gastric (symptomatic control in metastatic carcinoid and vasoactive intestinal peptide secreting tumors) acromegaly	Yes	Yes	Yes	Yes
Pamidronate	Hypercalcemia of malignancy	No	No	Yes	Yes
Pravastatin	Heterozygous familial hypercholesterolemia	No	No	Yes	Yes
Repaglinide	Type II Diabetes	No	No	Yes	Yes
Simvastatin	Heterozygous familial hypercholesterolemia	No	No	Yes	Yes
Sulfonylurea agents	Type II Diabetes	No	No	Yes	Yes
Anti-Infective Drug Products					
Ampicillin	Respiratory tract infections, bacterial meningitis, septicemia, endocarditis, UTI, and gastrointestinal infections	Yes	No	No	No
Ampicillin/sulbactam	1) Skin/skin structure infections	Pediatric information needed in < 1 year of age			
	2) Intraabdominal infections	Yes	Yes	Yes	No
Azithromycin	Pneumonia (community acquired)	Pediatric information needed in <6 months of age.			
Aztreonam	UTI, lower respiratory tract infections, septicemia, skin infections, intra-abdominal infections	Pediatric information needed in <9 months of age.			
Cefepime	UTI, skin infections, pneumonia, intra-abdominal, febrile neutropenia	Yes	Yes	Yes	No
Cefdinir	1) Community-acquired pneumonia	Yes	Yes	Yes	No
	2) Acute bacterial otitis media	Pediatric information needed in <6 months of age.			
	3) Uncomplicated skin and skin structure infections				
Cefixime	Uncomplicated gonorrhea	Yes	Yes	Yes	No
Cefprozil	1) Uncomplicated skin and skin structure infections	Yes	Yes	No	No
	2) Otitis media	Pediatric information needed in <6 months of age.			
Ceftizoxime	Lower respiratory tract infections, urinary tract infections, intra-abdominal infections, skin and skin structure infections, and bone and joint infections.	Pediatric information needed in < 6 months of age.			
Cephalexin	1) Skin and skin structure infections	Pediatric information needed in < 1 year of age.			
	2) Bone and joint infections	Yes	Yes	Yes	Yes
Loracarbef	1) Otitis media, skin and skin structure infections	Pediatric information needed in <6 months of age.			
	2) Pneumonia, sinusitis, UTI	Pediatric information needed in <12 years of age.			
Meropenem	Meningitis and intra-abdominal infections	Pediatric information needed in <3 months of age.			
Mupirocin	Eradication of methicillin resistant S. aureus during institutional outbreaks	Yes	Yes	Yes	No

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Nafcillin	Severe infections due to penicillinase producing staphylococci	Yes	Yes	No	No
Oxacillin	Infections due to penicillinase producing staphylococci	Yes	No	No	No
Piperacillin	Severe infections, including intra-abdominal, UTI, respiratory, skin, bone and joint, and gonococcal infections	Yes	Yes	Yes	No
Piperacillin/Tazobactam	Appendicitis (complicated by rupture/abscess), peritonitis, community-acquired pneumonia, hospital acquired pneumonia, skin and skin structure infections	Yes	Yes	Yes	Yes
Silver Sulfadiazine	Treatment of burns	Yes	Yes	Yes	Yes
Ticarcillin/Clavulanate	Septicemia, skin and skin structure infections, lower respiratory, UTI, and intra-abdominal infections	Pediatric information needed in <3 months of age.			
Trimethoprim	Urinary tract infection	Yes	Yes	Yes	No
Anti-Viral Drug Products					
Acyclovir	Systemic herpes infections	Yes	No	No	No
Amantadine	Prophylaxis and treatment of illness caused by influenza virus.	Pediatric information needed in < 1 year of age.			
Cidofovir	Treatment of CMV retinitis in patients with AIDS	Yes	Yes	Yes	Yes
Delavirdine	Treatment of HIV infection	Yes	Yes	Yes	Yes
Didanosine	Adult patients and children over 6 months of age with symptomatic HIV disease	Yes	No	No	No
Famciclovir	Herpes zoster and recurrent genital herpes	Yes	Yes	Yes	Yes
Foscarnet	Treatment of CMV retinitis in AIDS patients	Yes	Yes	Yes	Yes
Ganciclovir	1) Life or sight threatening cytomegalovirus infection in immunocompromised patients 2) CMV prophylaxis in adults	Yes	Yes	Yes	Yes
Indinavir	Treatment of HIV infection	Yes	Yes	Yes	Yes
Lamivudine	Treatment of HIV infection	Pediatric information needed in <5 months of age.			
Nelfinavir	Treatment of HIV infection	Yes	Yes	No	No
Nevirapine	Treatment of HIV infection	Yes	Yes	Yes	Yes
Penciclovir	Recurrent herpes labialis	Yes	Yes	Yes	Yes
Rimantadine	Prophylaxis and treatment of illness caused by influenza virus.	Pediatric information needed in < 1 year age.			
Ritonavir	Treatment of HIV infection	Yes	Yes	No	No
Saquinavir	Treatment of HIV infection	Yes	Yes	Yes	Yes
Stavudine	Treatment of HIV infection	Yes	No	No	No
Valcyclovir	Treatment of initial and recurrent episode genital herpes and herpes zoster	Yes	Yes	Yes	Yes
Zalcitabine	Treatment of HIV infection	Yes	Yes	Yes	Yes
Zidovudine	Treatment of HIV infection	Pediatric information needed between 6 weeks and 3 months of age.			
Dermatologic And Dental Drug Products					
Acitretin	Treatment of severe psoriasis including erythrodermic and pustular types	No	No	No	Yes
Amlexanox	Treatment of oral aphthous ulcers	No	No	Yes	Yes

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Ammonium Lactate	Ichthyosis vulgaris/xerosis and relief associated with pruritus	No	No	Yes	Yes
Betamethasone	Corticosteroid responsive dermatoses.	No	No	Yes	Yes
Calcipotriene	Treatment of plaque psoriasis	No	No	No	Yes
Clobetasol	Topical treatment of inflammatory and pruritic manifestations of moderate to severe corticosteroid-responsive dermatoses	No	No	No	Yes
Clotrimazole/Betamethasone	Treatment of tinea pedis, tinea cruris, and tinea corporis	No	No	No	Yes
Doxepin	Treatment of cutaneous histamine-mediated pruritus accompanying eczematous dermatitis	No	No	Yes	Yes
Etretinate	Treatment of severe recalcitrant psoriasis including erythrodermic and generalized pustular types	No	No	No	Yes
Fluocinolone	Relief of inflammatory and pruritic manifestations of corticosteroid responsive dermatoses	No	No	Yes	Yes
Fluticasone	Topical treatment of corticosteroid responsive dermatoses	No	No	Yes	Yes
Isotretinoin	Treatment of severe recalcitrant nodular acne	No	No	No	Yes
Ketoconazole	1) Topical cutaneous candidiasis	No	Yes	Yes	Yes
	2) Treatment of dermatophytosis				
	3) Treatment for seborrheic dermatitis	No	No	No	Yes
	4) Treatment for tinea versicolor				
Mometasone	Corticosteroid responsive dermatoses.	No	No	Yes	Yes
Oxiconazole	Topical antifungal for treatment of superficial cutaneous fungal infections	No	Yes	Yes	Yes
Pilocarpine	For treatment of xerostomia induced by radiation therapy for head and neck cancers	No	No	Yes	Yes
Tazarotene	Once daily treatment of stable plaque psoriasis of up to 20% of body surface area and once daily treatment of facial acne vulgaris of mild to moderate severity	No	No	No	Yes
Terbinafine	Topical treatment of tinea pedis, tinea cruris, and tinea corporis caused by <i>Trichophyton rubrum</i> , <i>Epidermophyton floccisum</i> , or <i>Trichophyton entagrophytes</i>	No	No	Yes	Yes
Tretinoin	Topical treatment of acne vulgaris	No	No	No	Yes
Anti-Inflammatory, Analgesic, And Ophthalmologic Drug Products					
Apraclonidine	1) Control of acute IOP elevation after anterior-segment laser surgery	No	No	Yes	Yes
	2) Adjunctive therapy in glaucoma patients				
Azathioprine	Rheumatoid arthritis	No	No	Yes	Yes
Betaxolol	Control of IOP for glaucoma and ocular hypertensive patients.	Yes	Yes	Yes	Yes
Betaxolol /Pilocarpine	Lowering of intraocular pressure in patients with primary open angle glaucoma or ocular hypertension	No	No	Yes	Yes
Bromfenac	For management of acute pain for 10 days or less	No	No	Yes	Yes

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Brimonidine	Lowering intraocular pressure in patients with chronic open angle glaucoma or ocular hypertension	No	No	Yes	Yes
Carteolol	Treatment of chronic open-angle glaucoma or ocular hypertension	Yes	Yes	Yes	Yes
Ciprofloxacin	Corneal ulcers and conjunctivitis	Pediatric information needed in <1 year of age.			
Cyclosporine	Rheumatoid arthritis	No	No	Yes	Yes
D-penicillamine	Rheumatoid arthritis	No	No	Yes	Yes
Dapiprazole	Use in the practice of ophthalmology to reverse mydriasis.	No	Yes	Yes	Yes
Diclofenac	Treatment of rheumatoid arthritis	No	No	Yes	Yes
Dorzolamide	Treatment of elevated intraocular pressure in patients with ocular hypertension or open angle glaucoma	Yes	Yes	Yes	Yes
Emedastine	Relief of the signs and symptoms of allergic conjunctivitis	Yes	Yes	No	No
Etodolac	Rheumatoid arthritis	No	No	Yes	Yes
Foscarnet	CMV Retinitis	Yes	Yes	Yes	Yes
Ganciclovir	Treatment of cytomegalovirus retinitis	No	No	Yes	Yes
Gold	Rheumatoid arthritis	No	No	Yes	Yes
Hydroxychloroquine	Rheumatoid arthritis	No	No	Yes	Yes
Ibuprofen	Rheumatoid arthritis	No	No	Yes	Yes
Ketoprofen	Pain management	Yes	Yes	Yes	Yes
Latanoprost	Indicated for the reduction of elevated intraocular pressure in patients with open-angle glaucoma and ocular hypertension who are insufficiently responsive to other medications	No	No	No	Yes
Levocabastine	For the temporary relief of the signs and symptoms of allergic conjunctivitis	No	No	Yes	No
Methotrexate	Rheumatoid arthritis	No	No	Yes	Yes
Nabumetone	Rheumatoid arthritis	No	No	Yes	Yes
Naproxen	Analgesia, antipyresis, rheumatoid arthritis	Yes	Yes	No	No
Norfloxacin	Superficial infections of the eye caused by strains susceptible to norfloxacin.	Pediatric information needed in <1 year of age.			
Ofloxacin	Treatment of ocular infections	Pediatric information needed in <1 year of age.			
Olopatidine	Temporary treatment of itching in allergic conjunctivitis	Pediatric information needed in <3 years age of age.			
Oxaprozin	Rheumatoid arthritis	No	No	Yes	Yes
Prednisolone	Steroid responsive disease	Yes	Yes	Yes	Yes
Rimexolone	Uveitis	No	No	Yes	Yes
Timolol	Lowering intraocular pressure in patients with chronic open-angle glaucoma, aphakic glaucoma, secondary glaucoma, other patients with elevated intraocular pressure	Yes	Yes	Yes	Yes
Tolmetin	Rheumatoid arthritis	No	No	Yes	Yes
Tramadol	Management of acute and chronic pain	No	No	Yes	Yes

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
<i>Over-The-Counter Drug Products³</i>					
Acetaminophen	Minor aches and pains associated with the common cold, headache, toothache, muscular aches, backache, minor pain of arthritis, reduction of fever	No	Yes	No	No
Brompheniramine /Pseudoephedrine	Cold and allergy relief.	No	Yes	Yes	No
Butoconazole	Treatment of vulvovaginal candidiasis	No	No	No	Yes
Chlorpheniramine	Allergy and cold relief	No	Yes	Yes	No
Cimetidine	Relief and prevention of heartburn, acid indigestion, sour stomach	No	No	Yes	No
Clemastine /Phenylpropanolamine	Cold and allergy relief; relief of nasal congestion associated with sinusitis	No	Yes	Yes	No
Clotrimazole	Treatment of vaginal yeast infection, relief of external itching and irritation	No	No	No	Yes
Cromolyn	To prevent and relieve nasal symptoms of hay fever and other nasal allergies	No	No	Yes	No
Famotidine	Relief and prevention of heartburn associated with acid indigestion and sour stomach	No	No	Yes	No
Ibuprofen	Temporarily reduces fever, temporarily relieves minor aches and pains due to colds, flu, sore throat, headaches, and toothaches	No	Yes	No	No
Ibuprofen/Pseudoephedrine	Symptoms associated with sinusitis, common cold or flu including nasal congestion, headaches, body aches, pains, and fever	No	Yes	Yes	No
Ketoconazole	Dandruff	No	Yes	Yes	No
Ketoprofen	Temporary relief of minor aches and pains associated with the common cold, headache, toothache, muscular aches, backache, minor pain of arthritis, menstrual cramps; temporary reduction of fever	No	No	Yes	Yes
Loperamide	Controls the symptoms of diarrhea, including travelers diarrhea	No	No	Yes	No
Loperamide/Simethicone	Controls the symptoms of diarrhea and associated gas symptoms	No	No	Yes	No
Miconazole	Treatment of vaginal yeast infections and the relief of external vulvar itching and irritation	No	No	No	Yes
Nicotine	To reduce withdrawal symptoms, including nicotine craving, associated with quitting smoking	Pediatric information needed in > 10 years of age.			
Nizatidine	Prevention of heartburn, acid indigestion, sour stomach	No	No	Yes	No
Permethrin	Treatment of pediculus humanus capitis (head lice) infestation	Yes	Yes	Yes	Yes
Pseudoephedrine	Nasal decongestant, colds, sinus and allergy congestion	No	Yes	No	No
Quaternium-18	Protects against poison ivy, poison oak, and poison sumac rash when applied before exposure	No	Yes	No	No

³ Inclusion of a drug in this section simply states the location of the application. Information derived from pediatric studies provided to the Agency may be reflected in prescription and/or over-the-counter labeling.

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Ranitidine	Treatment of episodic heartburn	No	No	Yes	No
Tioconazole	Treatment of vaginal yeast infection	No	No	No	Yes
<i>Pulmonary Drug Products</i>					
Albuterol	Treatment and prevention of bronchospasm in patients with reversible obstructive airway disease	Yes	Yes	No	No
Azelastine	Allergic rhinitis	No	Yes	Yes	No
Beclomethasone	1) For patients who require chronic treatment with corticosteroids for control of the symptoms of bronchial asthma	Pediatric information needed in <6 years of age.			
	2) Relief of symptoms of allergic and non-allergic (vasomotor) rhinitis	Pediatric information needed between 1 month and 6 years of age.			
Bitolterol	Prophylaxis and treatment of asthma or bronchospasm	Yes	Yes	Yes	No
Budesonide	1) Prevention and relief of symptoms of seasonal or perennial allergic and nonallergic (vasomotor) rhinitis	Pediatric information needed between 1 month and 6 years of age.			
	2) Treatment of bronchial asthma	Pediatric information needed in <6 years of age.			
Cetirizine	Seasonal allergic rhinitis perennial allergic rhinitis; and chronic idiopathic urticaria	Pediatric information needed between 1 month and 6 years of age.			
Clemastine	1) Allergic rhinitis	Pediatric information needed between 1 month and 6 years of age.			
	2) Urticaria & common cold	Pediatric information needed between 1 month and 12 years of age			
Cromolyn	1) Treatment of systemic mastocytosis 2) Prophylaxis treatment of asthma	Yes	Yes	No	No
Fexofenadine	Treatment of seasonal allergic rhinitis	No	Yes	Yes	No
Fexofenadine/Pseudoephedrine	Treatment of seasonal allergic rhinitis	No	Yes	Yes	No
Flunisolide	Management of symptoms of seasonal or perennial rhinitis	Pediatric information needed between 1 month and 6 years of age.			
Fluticasone	1) Relief of the symptoms of seasonal or perennial rhinitis	Pediatric information needed between 1 month and 12 years of age.			
	2) Maintenance treatment of bronchial asthma	Pediatric information needed < 4 years of age.			
Ipratropium	Symptomatic relief of rhinorrhea associated with perennial rhinitis & common cold	No	Yes	Yes	No
Loratadine	Relief of nasal and non nasal symptoms of seasonal allergic rhinitis and management of idiopathic chronic urticaria	Pediatric information needed between 1 month and 6 years of age.			
Loratadine/Pseudoephedrine	Seasonal allergic rhinitis and nasal congestion	Pediatric information needed between 1 month and 12 years of age.			
Metaproterenol	For treatment of asthma attacks and reversible bronchospasm	Pediatric information needed in <6 years of age.			
Mometasone	Prophylaxis and treatment of seasonal allergic rhinitis and treatment of symptoms of perennial rhinitis	No	Yes	Yes	No
Montelukast	Prophylaxis and chronic treatment of asthma	Pediatric information needed in <6 years of age.			

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Nedocromil	Maintenance therapy in the management of patients with mild to moderate asthma	Pediatric information needed in <6 years of age.			
Pirbuterol	Prevention and reversal of bronchospasm	Yes	Yes	Yes	No
Salmeterol	For long term daily use in the maintenance and treatment of asthma and prevention of bronchospasm	Yes	Yes	Yes	No
Terbutaline	Prevention and reversal of bronchospasm	Yes	Yes	Yes	No
Triamcinolone	1) For the treatment of seasonal and perennial rhinitis symptoms	Pediatric information needed between 1 month and 12 years of age.			
	2) For patients who require chronic treatment with corticosteroids for control of the symptoms of bronchial asthma	Pediatric information needed in <6 years of age.			
Zafirlukast	Prophylaxis and chronic treatment of asthma	Yes	Yes	Yes	No
Zileuton	Prophylaxis and chronic treatment of asthma	Yes	Yes	Yes	No
Special Pathogen And Immunologic Drug Products					
Albendazole	Treatment of hydatid disease and neurocysticercosis	Pediatric information between 1 month and 6 years of age.			
Amphotericin B	Treat potentially life-threatening fungal infections	Yes	Yes	Yes	No
Atovaquone	Treatment and prophylaxis of PCP infection in patients with HIV	Yes	Yes	Yes	Yes
Azithromycin	Prevention of MAI infection	Yes	Yes	Yes	Yes
Chloroquine	1) Suppressive treatment and acute attacks of malaria due to <i>P. vivax</i> , <i>P. malariae</i> , <i>P. ovale</i> , and susceptible strains of <i>P. falciparum</i> 2) Treatment of amebiasis	No	Yes	Yes	Yes
Ciprofloxacin	Urinary tract infections, lower respiratory tract infections, nosocomial pneumonia, skin and skin structure infections, bone and joint infections, complicated intra-abdominal infections, acute sinusitis, infectious diarrhea, typhoid fever	Yes	Yes	Yes	Yes
Clarithromycin	Treatment of MAI infection	Yes	Yes	Yes	Yes
Eflornithine	Treatment of trypanosoma brucei gambiense sleeping sickness	No	Yes	Yes	Yes
Enoxacin	Uncomplicated urethral or cervical gonorrhea, uncomplicated and complicated urinary tract infections urinary tract infections (cystitis).	Yes	Yes	Yes	Yes
Ethambutol	Pulmonary tuberculosis	Yes	Yes	Yes	No
Ethionamide	Active tuberculosis (after failing primary drugs)	Yes	Yes	Yes	Yes
Fluconazole	Treatment of 1) vaginal candidiasis, 2) oropharyngeal candidiasis, 3) cryptococcal meningitis. Prophylaxis against candidiasis in patients undergoing bone marrow transplantation, or who have received cytotoxic chemotherapy and/or radiation therapy	Pediatric information needed in < 6 years of age.			
Flucytosine	Serious infections caused by Candida (septicemia, endocarditis and urinary infections) and/or Cryptococcus (meningitis and pulmonary infections)	Yes	Yes	Yes	Yes

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Furazolidine	Specific and symptomatic treatment of bacterial or protozoal diarrhea and enteritis caused by susceptible organisms	Yes	Yes	Yes	Yes
Grepafloxacin	Acute bacterial exacerbation of chronic bronchitis, community-acquired pneumonia, uncomplicated gonorrhea (urethral in males, endocervical and rectal in females), nongonococcal urethritis and cervicitis.	Yes	Yes	Yes	Yes
Halofantrine	Treatment of mild to moderate acute malaria caused by <i>Plasmodium falciparum</i> or <i>Plasmodium vivax</i>	Yes	Yes	Yes	Yes
Itraconazole	1) Treatment of histoplasmosis and blastomycosis 2) Antifungal for the treatment of oropharyngeal candidiasis	Yes	Yes	Yes	Yes
Levofloxacin	Acute maxillary sinusitis, acute exacerbation of chronic bronchitis, community-acquired pneumonia, complicated urinary tract infections, acute pyelonephritis, uncomplicated skin and skin structure infections	Yes	Yes	Yes	Yes
Lomefloxacin	Acute bacterial exacerbation of chronic bronchitis, complicated and uncomplicated urinary tract infections. Prevention of infection in the following situations: Transrectal prostate biopsy – to reduce the incidence of urinary tract infection, in the early and late postoperative periods (3-5 days and 3-4 weeks postsurgery); Transurethral surgical procedures -- to reduce the incidence of urinary tract infection in the early postoperative periods (3-5 days postsurgery).	Yes	Yes	Yes	Yes
Mefloquine	Treatment of mild to moderate acute malaria caused by <i>Plasmodium falciparum</i> or <i>Plasmodium vivax</i>	Yes	Yes	Yes	Yes
Mebendazole	Intestinal worm infestation	Yes	Yes for <1 year	No	No
Metronidazole	Anaerobic infections (intra-abdominal, skin and skin structure, gynecologic, bacterial septicemia, bone and joint, lower respiratory tract, and endocarditis) and treatment of bacterial vaginosis	Yes	Yes	Yes	Yes
Miconazole	Fungal infections	Yes	Yes	Yes	Yes
Norfloxacin	Uncomplicated and complicated urinary tract infections, uncomplicated urethral and cervical gonorrhea, prostatitis	Yes	Yes	Yes	Yes
Ofloxacin	Acute bacterial exacerbations of chronic bronchitis, community-acquired pneumonia, uncomplicated skin and skin structure infections, nongonococcal urethritis and cervicitis, mixed infections of the urethra and cervix, complicated and uncomplicated cystitis, prostatitis	Yes	Yes	Yes	Yes
Pentamidine	Prevention of <i>Pneumocystis carinii</i> infection	Yes	Yes	Yes	Yes

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
Praziquantel	Infections due to all species of Schistosoma and infections due to the liver flukes, Clonorchis sinensis, Opisthorchis viverrini	No	Yes	Yes	Yes
Pyrazinamide	Treatment of tuberculosis	No	Yes	Yes	Yes
Ranitidine bismuth citrate	Healing and prevention of duodenal ulcer relapse due <i>H pylori</i> infection when use in conjunction with clarithromycin	Yes	Yes	Yes	Yes
Rifampin	1) Tuberculosis 2) Meningococcal carrier state	Yes	Yes	Yes	Yes
Rifampin/Isoniazid/Pyrazinamide	Pulmonary tuberculosis	No	No	No	Yes
Sparfloxacin	Community-acquired pneumonia, acute bacterial exacerbation of chronic bronchitis.	Yes	Yes	Yes	Yes
Thiabendazole	Treatment of Strongyloidiasis (threadworm), cutaneous larva migrans (creeping eruption);, Trichinosis; second line agent in Uncinariasis (hookworm: Necator americanus and Ancylostoma duodenale), Trichuriasis (whipworm), and Ascariasis (large roundworm)	No	Yes	Yes	Yes
Trovafloxacin	Nosocomial pneumonia, community acquired pneumonia, acute exacerbation of chronic bronchitis, acute sinusitis, complicated intra-abdominal infections (including post-surgical infections), gynecologic and pelvic infections; surgical prophylaxis in colorectal surgery, vaginal and abdominal hysterectomy, uncomplicated and complicated skin and skin structure infections, uncomplicated urinary tract infections, bacterial prostatitis, uncomplicated gonorrhea, pelvic inflammatory disease.	Yes	Yes	Yes	Yes

Attachment B

**Pediatric Priority List of Drugs Regulated by the
 Center for Biologics Evaluation and Research**

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		birth to 1 mos	1 mos to 2 yrs	2 to 12 years	12 to 16 years
<i>Office of Therapeutics Research and Review</i>					
Alteplase	DVT and pulmonary emboli	No	No	No	Yes
Antithrombin III	Hereditary antithrombin III deficiency	Yes	Yes	Yes	Yes
Autologous chondrocytes	Femoral condyle repair	No	No	No	Yes
Dacluzimab	Renal allograft rejection	No	Yes	Yes	Yes
Epoetin alpha	1) Anemia associated with cancer chemotherapy	Yes	Yes	Yes	Yes
	2) Anemia associated with zidovudine therapy	Yes	Yes	Yes	Yes
	3) Perisurgical use to minimize need for transfusion	No	No	Yes	Yes
G-CSF, Filgrastim	1) Acute myelogenous leukemia	Yes	No	No	No
	2) Neutropenia associated with cancer chemotherapy	Yes	Yes	Yes	No
	3) PBPC mobilization	No	No	Yes	Yes
	4) Reduce duration of neutropenia after allo and autologous bone marrow transplant	No	Yes	Yes	Yes
	5) Severe chronic neutropenia	Yes	Yes	Yes	Yes
GM-CSF, Sargramostim	1) PBPC mobilization	No	No	Yes	Yes
	2) Reduce duration of neutropenia after allo and autologous bone marrow transplant	No	Yes	Yes	Yes
Interferon alfacon	Hepatitis C	No	No	Yes	Yes
Interferon- α 1a	1) Chronic myelogenous leukemia	No	Yes	Yes	Yes
	2) Hepatitis C	No	No	Yes	Yes
Interferon- α 1b	1) Adjuvant treatment of melanoma	No	No	No	Yes
	2) Condyloma acuminata	No	No	No	Yes
	3) Hepatitis C	No	No	Yes	Yes
	4) Hepatitis B	No	Yes	No	No
Interferon- α n3	Condyloma acuminata	No	No	No	Yes
Interferon- β 1a	Relapsing-remitting multiple sclerosis	No	No	No	Yes
Interferon- β 1b	Relapsing-remitting multiple sclerosis	No	No	No	Yes
Interferon- γ 1b	Chronic granulomatous disease	Yes	Yes	No	No
Interleukin-11, Oprevelkin	Thrombocytopenia associated with cancer chemotherapy	No	Yes	Yes	Yes
Interleukin-2, Aldesleukin	Metastatic melanoma	No	No	No	Yes
OKT3	1) Acute renal allograft rejection	No	Yes	Yes	Yes
	2) Steroid resistant cardiac allograft rejection				
	3) Steroid resistant liver allograft rejection				
Streptokinase	4) Arterial thromboembolism;	Yes	Yes	Yes	Yes
	5) Arteriovenous cannula occlusion				
Urokinase	3) DVT and pulmonary emboli	No	No	No	Yes
	1) Catheter clearance	Yes	Yes	Yes	Yes
	2) DVT and pulmonary emboli	No	No	No	Yes

Drug Name	Potential pediatric use limited to approved indications	Age Group In Which More Information Needed			
		<i>birth to 1 mos</i>	<i>1 mos to 2 yrs</i>	<i>2 to 12 years</i>	<i>12 to 16 years</i>
<i>Office of Blood Research and Review</i>					
Cytomegalovirus Immune Globulin Intravenous	Prevention of CMV disease in AIDS	No	Yes	Yes	Yes
Lymphocyte Immune Globulin, Anti-thymocyte Globulin	Prevention of allo-transplant Rejection	No	Yes	Yes	Yes
<i>Office of Vaccine Research and Review</i>					
Anthrax Vaccine	Prevention of anthrax	No	Yes	Yes	Yes
Botulinum Toxin Type A	Strabismus and blepharospasm	No	Yes	Yes	No
Hepatitis A Vaccine	Prevention of Hepatitis A	No	Yes	No	No