



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration  
Rockville MD 20857

JUN 4 2003

Michele R. Flicker, MD, PhD, FACP  
Director, Regulatory Affairs  
Merck & Co., Inc.  
P.O. Box 2000  
Rahway, NJ 07065

Re: Docket Nos. 02P-0363/CP1 and 99P-2547/CP1

Dear Dr. Flicker:

This responds to your letter dated May 22, 2003, regarding Fosamax (alendronate sodium) tablets. In your letter, you request that FDA remove from docket numbers 02P-0363/CP1 and 99P-2547/CP1 the October 27, 2000, written request to Merck for studies of alendronate in pediatric patients with osteogenesis imperfecta and the March 8, 2002, amendment to the written request. You also state that Merck considers the contents of the written request and the amendment to be confidential and not subject to public disclosure under the Freedom of Information Act (FOIA) without the written permission of Merck.

The Agency generally considers written requests for pediatric studies to be confidential under the FOIA until the studies conducted pursuant to the written request are completed and the product is approved for a pediatric use based on the studies. The October 27, 2000, written request and March 8, 2002, amendment were originally placed in the public docket in response to your citizen petition dated August 12, 2002 (Docket No. 02P-0363/CP1, the Petition). In the Petition, you stated that you wanted the written request referenced in the public docket to reflect the Agency's position regarding the appropriateness and safety of the study of alendronate sodium in the pediatric population.

The Agency has removed the October 27, 2000, written request and the March 8, 2002, amendment from docket numbers 02P-0363/CP1 and 99P-2547/CP1. To clarify FDA's current position regarding the study of alendronate sodium in the pediatric population, we have replaced the written request and amendment with the publicly available list of *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*. Please let me know if you have any further concerns about this matter.

Sincerely yours,

Janet Woodcock, M.D.  
Director

Center for Drug Evaluation and Research

Enclosure

02P-0363

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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

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. For a list of approved products containing the active moiety by the sponsor please see "CDER New and Generic Drug Approvals" (<http://www.fda.gov/cder/approval/>).

Total Approved Active Moieties Issued a Written Request = 222

Active Moiety	Sponsor
Abacavir	Glaxo Wellcome, Inc.
Acetazolamide	Wyeth-Ayerst
Albuterol	Dey
Albuterol	GlaxoSmithKline
Alendronate	Merck
Almotriptan	Pharmacia & Upjohn
Alosetron	Glaxo Wellcome, Inc.
Amiodarone	Wyeth Ayerst
Amlexanox	Block Drug
Amlodipine	Pfizer, Inc.
Amlodipine/Benazepril	Novartis
Ammonium Lactate	Westwood Squibb
Amprenavir	Glaxo Wellcome, Inc.
Anagrelide HCL	Shire
Anastrozole	Astra Zeneca
Argatroban Injection	Texas Biotechnology
Aripiprazole	Otsuka
Atorvastatin	Warner-Lambert
Atovaquone/Proguanil	Glaxo Wellcome, Inc.
Azelastine	ASTA Medica
Balsalazide	Salix Pharm.

Beclomethasone	Schering
Benazepril	Novartis
Betamethasone	Schering
Betaxolol	Lorex Pharmaceuticals
Betaxolol	Alcon
Bicalutamide	AstraZeneca Pharm.
Bisoprolol	Wyeth-Ayerst
Brimonidine	Allergan, Inc.
Brinzolamide	Alcon
Budesonide	Astra Zeneca
Bupropion	Glaxo Wellcome, Inc
Buspirone	Bristol-Myers Squibb
Busulfan	Orphan Medical
Calcitriol	Abbott
Candesartan	Astra Pharmaceuticals
Carboplatin	Bristol-Myers Squibb
Carteolol	CIBA
Carvedilol	SmithKline Beecham
Caspofungin	Merck
Celecoxib	Searle
Cerivastatin	Bayer
Cetirizine	Pfizer
Cilostazol	Otsuka
Cimetidine	SmithKline Beecham
Ciprofloxacin	Bayer
Ciprofloxacin	Alcon
Cisatracurium	Glaxo Wellcome
Citalopram	Forest Laboratories, Inc.
Clopidogrel Bisulfate	Sanofi-Synthelabo
Colesevelam Hydrochloride	Sankyo Pharma
Cromolyn Sodium	Pharmacia & Upjohn
Cromolyn Sodium	Bausch & Lomb

Cytarabine	SkyePharma Inc.
Desflurane	Baxter Healthcare
Dichlorphenamide	Merck
Didanosine	Bristol-Myers Squibb
Dorzolamide	Merck
Efavirenz	DuPont Pharmaceuticals
Enalapril Maleate	Merck
Enfuvirtide	Hoffman-La Roche
Enoxaparin	Aventis
Epirubicin	Pharmacia & Upjohn
Ertapenem	Merck
Esmolol	Baxter Pharmaceutical
Esomeprazole	AstraZeneca
Etodolac	Wyeth-Ayerst
Famciclovir	Novartis
Famotidine	Merck
Felodipine	Astra Pharmaceuticals
Fenoldopam	Elan Pharmaceuticals
Fentanyl	Janssen Pharmaceutica
Fexofenadine	Aventis
Fluconazole	Pfizer
Fludarabine	Berlex
Fluoxetine	Lilly
Fluticasone	Glaxo Wellcome, Inc.
Fluvastatin	Novartis
Fluvoxamine	Solvay Pharmaceuticals
Formoterol fumarate	Novartis
Fosinopril	Bristol-Myers Squibb
Fosphenytoin	Pfizer
Fulvestrant	AstraZeneca Pharmaceut
Gabapentin	Parke-Davis
Gatifloxacin	Bristol-Myers Squibb

Gemcitabine	Lilly
Gemtuzumab	Wyeth-Ayerst
Gentamicin	Schering
Glatiramer Acetate	Teva
Glimepiride	Aventis Pharm.
Glyburide and Metformin	Bristol-Myers Squibb
Granisetron HCL	Hoffman La-Roche
Hydroxyurea	Bristol-Myers Squibb
Ibuprofen	McNeil Consumer Prod
Ibuprofen	Whitehall-Robbins
Ibuprofen/pseudoephedrine	McNeil Consumer Prod
Ibuprofen/pseudoephedrine	Whitehall-Robbins
Imiquimod	3M Pharmaceuticals
Indinavir	Merck
Insulin aspart [rDNA origin]	Novo Nordisk
Insulin glargine	Aventis
Irbesartan	Bristol-Myers Squibb
Irinotecan	Pharmacia & Upjohn
Isotretinoin	Hoffman-LaRoche, Inc
Itraconazole	Janssen Pharmaceutica
Ketoconazole	Janssen Pharmaceutica
Ketorolac	Allergan
Labetalol	Schering
Lamivudine	Glaxo Wellcome, Inc.
Lamotrigine	Glaxo Wellcome, Inc.
Lansoprazole	TAP Holdings, Inc.
Leflunomide	Hoechst Marion Roussel
Levalbuterol	Sepracor
Levetiracetam	UCB Pharma
Levobetaxolol	Alcon
Levobunolol	Allergan
Levofloxacin	R. W. Johnson

Linezolid	Pharmacia & UpJohn
Lisinopril	Zeneca Pharmaceuticals
Lisinopril	Merck
Lopinavir/Ritonavir	Abbott
Loratadine	Schering
Losartan	Merck
Lovastatin	Merck
Mesalamine	Procter & Gamble
Metformin	Bristol-Myers Squibb
Methazolamide	Wyeth-Ayerst
Metipranolol	Bausch & Lomb
Metoprolol	Astra Zeneca
Midazolam	Hoffmann-La Roche
Milrinone	Sanofi Synthelabo, Inc.
Minoxidil	Pharmacia & UpJohn
Mirtazapine	Organon Inc.
Moexipril	Schwarz Pharma
Mometasone	Schering
Montelukast	Merck & Co., Inc.
Morphine	Elan Drug Delivery
Morphine	Faulding
Nabumetone	SmithKline Beecham
Nateglinide	Novartis
Nefazodone	Bristol-Myers Squibb
Nelfinavir	Agouron Pharmaceutical
Nevirapine	Boehringer Ingelheim
Nicotine	SmithKline Beecham
Nizatidine	Reliant
Norfloxacin	Merck
Norgestimate/ethinyl estradiol	R. W. Johnson
Ofloxacin	Allergan
Olanzapine	Lilly

Omeprazole	Astra Zeneca
Ondansetron	Glaxo Wellcome
Orlistat	Hoffman-LaRoche
Oseltamivir	Roche
Oxaprozin	Searle
Oxcarbazepine	Novartis
Oxybutynin	Alza
Oxycodone	Purdue Pharma L.P.
Pantoprazole	Wyeth-Ayerst
Paricalcitol	Abbott
Paroxetine	SmithKline Beecham
Pemirolast	Santen
Pimecrolimus	Novartis
Pioglitazone	Takeda
Polyethelene Glycol	Braintree Labs
Pravastatin	Bristol-Myers Squibb
Propofol	Zeneca Pharmaceuticals
Quetiapine Fumerate	AstraZeneca
Quinapril	Parke-Davis
Rabeprazole	Eisai, Inc.
Ramipril	King Pharm.
Ranitidine	GlaxoWellcome, Inc.
Remifentanil	Glaxo Wellcome, Inc.
Repaglinide	Novo Nordisk
Ribavirin in combination with Interferon alfa-2B, recombinant	Schering
Rifapentine	Hoechst-Marion Roussel
Risedronate	Procter & Gamble
Risperidone	Janssen Research
Ritonavir	Abbott Laboratories
Rocuronium	Organon
Rofecoxib	Merck

Ropivacaine	Astra Zeneca
Rosiglitazone	SmithKline Beecham
Salmeterol	Glaxo Wellcome, Inc.
Saquinavir	Hoffman-La Roche Inc.
Sertraline	Pfizer Pharmaceuticals
Sevelamer	GelTex
Sevoflurane	Abbott
Sibutramine	Knoll Pharmaceutical
Sildenafil	Pfizer
Simvastatin	Merck
Sirolimus	Wyeth-Ayerst
Sodium ferric gluconate complex	Watson Laboratories
Somatropin [rDNA origin]	Serono Laboratories
Sotolol	Berlex Laboratories, Inc.
Stavudine	Bristol-Myers Squibb
Sumatriptan	Glaxo Wellcome, Inc.
Tamoxifen	Astra Zeneca
Temozolomide	Schering
Tenofovir	Gilead Sciences
Terbinafine	Novartis
Testosterone	Unimed Pharmaceuticals
Timolol	Merck
Timolol	Falcon Pharmaceuticals
Timolol	Santen
Tobramycin	Falcon Pharmaceuticals
Tolterodine	Pharmacia & Upjohn
Topotecan	SmithKline Beecham
Tramadol	R. W. Johnson
Valacyclovir	GlaxoSmithKline
Valganciclovir	Roche
Valproate	Abbott Laboratories
Valsartan	Novartis Pharmaceuticals



Venlafaxine	Wyeth-Ayerst
Verapamil	Elan Pharmaceuticals
Vinorelbine	Glaxo Wellcome
Voriconazole	Pfizer
Zafirlukast	Zeneca Pharmaceuticals
Zanamivir	Glaxo Wellcome, Inc
Ziprasidone	Pfizer
Zoledronic acid	Novartis Pharmaceuticals
Zolmitriptan	Zeneca Pharmaceuticals
Zonisamide	Elan Pharmaceuticals

[Back to Pediatric Page](#)

Last Updated: May 8, 2003