

**LACHMAN CONSULTANT SERVICES, INC.**  
CONSULTANTS TO THE PHARMACEUTICAL AND ALLIED INDUSTRIES

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October 23, 2000

**OVERNIGHT DOCUMENT 10/23/00**

Dockets Management Branch  
Food and Drug Administration (HFA-305)  
5630 Fishers Lane  
Room 1061  
Rockville, MD 20852

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**Citizen Petition**

Dear Sir or Madam:

The undersigned submits this petition on behalf of a client, in quadruplicate, pursuant to 21 CFR 10.30 and in accordance with the regulations at 21 CFR 314.161, requesting the Commissioner of the Food and Drug Administration to provide a determination whether a listed drug has been withdrawn for safety or effectiveness reasons as outlined below.

**A. Action Requested**

The petitioner requests that the Commissioner of the Food and Drug Administration determine whether Fosamax (Alendronate Sodium) Tablets 35 mg and 70 mg (NDA 20-560, S-021 and S-022), manufactured by Merck & Co., Inc., have been voluntarily withdrawn or withheld from sale for safety or efficacy reasons.

**B. Statement of Grounds**

The Food and Drug Administration maintains a list of drug products which are eligible for submission as abbreviated new drug applications (ANDAs). The List, referred to as the Orange Book, contains all FDA-approved drug products. Fosamax Tablets 35 mg and 70 mg were recently approved by the FDA on October 20, 2000 and are, upon approval, considered to be "listed drug products" in the Orange Book. The approval of the above referenced drug products was announced on the FDA's homepage on October 23, 2000 (see attached page from the FDA approval list), but do not yet appear in the electronic version of the FDA's Orange Book presumably because it has not yet been updated to reflect the listing. As of the date of submission of this petition, our client has not been able to obtain either the Fosamax 35 mg or the 70 mg product upon which to perform the required testing for the submission of an ANDA, therefore testing

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has been conducted against the marketed Fosamax Tablet 10 mg. The FDA has previously determined "for purposes of 21 CFR 314.161 and 314.162 that never marketing an approved product is equivalent to withdrawing the drug from sale". (65 FR 38561)

Under FDA regulations, drugs are withdrawn from the list if the Agency withdraws or suspends approval of the drug product's application for reasons of safety or effectiveness, or if the FDA determines that the listed drug was withdrawn or withheld from sale for reasons of safety or effectiveness (21 CFR 314.162). The regulations also provide that the Agency must make a determination as to whether a listed drug is withdrawn from sale for reasons of safety or effectiveness before an ANDA that refers to that listed drug may be approved (21 CFR 314.161(a)(1)).

As stated above, at the time of submission of this petition, there is no evidence that the innovator has commenced marketing of its Fosamax Tablet, 35 mg and 70 mg products. Therefore, because there has been no commercial distribution of these drug products, it is requested that the FDA determine whether Merck's decision not to market Fosamax Tablets 35 mg and 75 mg was for reasons of safety or effectiveness.

Should Merck commence marketing Fosamax Tablets 35 mg and/or 70 mg after the submission of this petition and prior to FDA response, and we have evidence that the product is available in the marketplace, we will consider that portion of the petition referring to the marketed strength(s) moot. We will at that time take appropriate action to request withdrawal of the petition. In the case where only one of the strengths is brought to market, we will consider the relevant part of the petition (referring to the marketed strength), withdrawn.

### **C. Environmental Impact**

A claim for categorical exclusion of the requirement for submission of an environmental assessment is made pursuant to 21 CFR 25.31.

### **D. Economic Impact**

Pursuant to 21 CFR 10.30(b), economic impact information is to be submitted only when requested by the Commissioner. This information will promptly be submitted if so requested.

### **E. Certification**

The undersigned certifies, that to the best of its knowledge and belief, this petition includes all information and views on which the petitioner relies, and that includes

representative data and information known to the petitioner, which are unfavorable to the petition.

Respectfully submitted,



Robert W. Pollock  
Vice President

RP/pk

Attachment: Excerpt from FDA's 10/20/00 Home Page

cc: L. Lachman

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→ <b>Fosamax (alendronate sodium) Tablets, 35 &amp; 70mg, Rx</b>	Merck Research Laboratories	NDA 20-560/S-021 & S-22	10/20/00			
	<b>Fosamax Indication:</b> for the prevention (S-021) and treatment (S-022) of postmenopausal osteoporosis, respectively.					
<b>Fosamax (alendronate sodium) Tablets, 10mg, Rx</b>	Merck Research Laboratories	NDA 20-560/S-023	9/29/00	10/10/00		
	<b>Fosamax Indication:</b> Treatment to increase bone mass in men with osteoporosis.					
<b>Fragmin (dalteparin sodium injection), Rx</b>	Pharmacia and Upjohn	NDA 20-287/S-008	3/30/99	3/31/99	3/31/99	5/18/00
	<b>Fragmin Indication:</b> Prophylaxis of deep vein thrombosis (DVT), which may lead to pulmonary embolism, in patient undergoing hip replacement surgery.					
<b>Fragmin (dalteparin sodium injection), Rx</b>	Pharmacia and Upjohn	NDA 20-287/S-018	8/3/00	8/4/00	8/4/00	
<b>Fragmin (dalteparin sodium injection), Rx</b>	Pharmacia and Upjohn	NDA 20-287/S-010	5/25/99			6/19/00
	<b>Fragmin Indication:</b> Treatment of unstable angina and non-Q-wave myocardial infarction for the prevention of ischemic complications in patients on concurrent aspirin therapy.					
<b>Furosemide Injection USP, 10 mg/mL, packaged in Ansyr Syringes [4 mL (40mg) &amp; 10 mL (100mg)]</b>	Abbott Laboratories	ANDA 75-241	5/28/99	6/1/99		
<b>Gemfibrozil Tablets USP, 600mg</b>	Apotex	ANDA 75-034	7/20	7/20		
<b>Gemzar (gemcitabine HCl) for Injection, Rx</b>	Eli Lilly	NDA 20-509 SE1-005	8/26	8/28	8/28	
	<b>Gemzar Indications:</b> For use in combination with cisplatin for the first-line treatment of patients with inoperable, locally advanced (Stage IIIA or IIIB) or metastatic (Stage IV) non-small cell lung cancer.					
<b>Genotropin (somatropin [rDNA origin] ) Injection, Rx</b>	Pharmacia & Upjohn Co.	NDA 20-280/S-023	6/20/00	7/24/00		

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Dockets Management Branch Food & Drug Admin. (HFA-305)

Company 5630 Fishers Lane

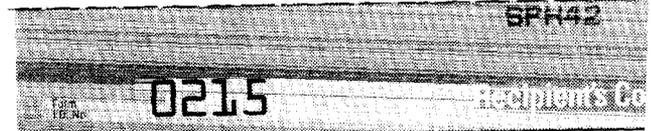
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