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Pharmacia & Upjohn

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April 3, 2003

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

RE: Docket No. 98N-1109

Mercury Compounds in Drugs and Foods -- List

Information for Docket

Dear Sir or Madam,

FDA published a Notice in the February 3, 2003 edition of the *Federal Register* directing manufacturers of drugs and biologics containing mercury compounds to examine FDA's list of such products and provide updates as necessary. Pharmacia & Upjohn noted that FDA's current list includes **ATGAM® Sterile Solution** (lymphocyte immune globulin, anti-thymocyte globulin (equine)), a licensed biological product with Biologics License No. **BLA 103676**. We are hereby notifying FDA's Docket Management Branch that our ATGAM® product was converted to a thimerosal-free formulation in 1995. This reformulation was submitted as Prior Approval Supplement 95-0464 to our ATGAM® license on March 28, 1995, and approved on September 27, 1995. A copy of the approval letter for this supplement has been included in **Attachment 1**. In **Attachment 2** we have included copies of all current labeling for ATGAM® as directed in the *Federal Register* Notice.

Please direct any questions regarding ATGAM® to the undersigned by telephone at (269) 833-5315, by facsimile at (269) 833-8237 or by mail at Mail Stop 0638-298-136 at the address provided in our letterhead above.

Sincerely,

PHARMACIA & UPJOHN COMPANY

James Balun
Associate Director, Regulatory Affairs

desk copy: Mr. Gerald M. Rachanow – FDA / CDER / OND / DOTCDE (HFD-560)

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