



Food and Drug Administration
Rockville, MD 20857

December 5, 2006

FILE COPY

Edward John Allera
Theodore Sullivan
William A. Garvin
Buchanan Ingersoll P. C.
1700 K Street, N.W.
Suite 300
Washington, DC 20006-3807

Dear Mr. Allera, Mr. Sullivan, and Mr. Garvin

Your petition, submitted on behalf of Savient Pharmaceuticals, Inc., requesting the Food and Drug Administration reconsider its decision on the docket to verify the scope of Savient's three year exclusivity for geriatric dosing information and geriatric studies data for its Oxandrin drug product, was received by this office on 12/05/2006. It was assigned docket number 2005P-0383/PRC 1 and it was filed on 12/05/2006. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Jennie C. Butler
Division of Dockets Management
Office of Management Programs
Office of Management

2005P-0383

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