



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

MAR 16 2006

Edward John Allera
Theodore Sullivan
Counsel to Savient Pharmaceuticals, Inc.
Buchanan Ingersoll P.C.
1776 K Street, NW
Suite 800
Washington, DC 20006

Re: Docket No. Docket 2005P-0383/CP1 & SUP1

Dear Mr. Allera and Mr. Sullivan:

I am writing to inform you that the Food and Drug Administration (FDA) has not yet resolved the issues raised in your citizen petition dated September 19, 2005, on behalf of Savient Pharmaceuticals, Inc (Savient). Your petition requests that the FDA verify the scope of Savient's three year exclusivity for geriatric dosing information and geriatric studies for Oxandrin (oxandrolone). As part of this request, you ask FDA to refuse to approve any Abbreviated New Drug Application for a generic oral product containing oxandrolone until the expiration of Savient's exclusivity period on June 20, 2008.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring extensive review and analysis by Agency officials. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Jane A. Axelrad
Associate Director for Policy
Center for Drug Evaluation and Research

2005P-0383

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