



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

AUG 10 2004

Edward John Allera
Donald E. Segal
Theodore M. Sullivan
Buchanan Ingersoll, P.C.
1776 K Street, N.W.
Suite 800
Washington, D.C. 20006-2365

Re: Docket No. 2004P-0074/CP1

Dear Messrs. Allera, Segal, and 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 February 17, 2004, submitted on behalf of Savient Pharmaceuticals, Inc. The petition requests that FDA establish specific bioequivalence requirements for oral products containing oxandrolone.

FDA has been unable to reach a decision on your petition because it raises 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 requests.

Sincerely,

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

2004P-0074

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