



NDA 13-718/S-023

Savient Pharmaceuticals, Inc.
Attention: Briti Kundu
One Tower Center, 14th Floor
East Brunswick, NJ 08816

Dear Ms. Kundu:

Please refer to your supplemental new drug application dated August 23, 2002, received August 26, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Oxandrin (oxandrolone tablets, USP)

We acknowledge receipt of your submissions dated May 20, 2005 (2), which constituted a complete response to our May 11, 2005, action letter.

This supplemental new drug application provides for the addition of a Geriatric Use subsection to the PRECAUTIONS section of the package insert, to comply with 21 CFR 201.57(f)(10).

We completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert) submitted May 20, 2005.

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this submission "**FPL for approved supplement NDA 13-718/S-023.**" Approval of this submission by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, call Kati Johnson, Supervisor, Project Management Staff, at (301) 827-6380.

Sincerely,

{See appended electronic signature page}

David Orloff, M.D.
Director
Division of Metabolic & Endocrine Drug Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Mary Parks
6/20/05 03:14:06 PM
for Dr. Orloff