DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville, MD 20857

ANDA 76-761

Upsher-Smith Laboratories, Inc.
Attention: Kimberly C. Oakins
Regulatory Affairs Specialist
6701 Evenstad Drive
Maple Grove, MN 55369

Dear Madam:

This is in reference to your abbreviated new drug application (ANDA) dated June 12, 2003, submitted pursuant to section 505(j) of the Federal Food, Drug, and Cosmetic Act (the Act), for Oxandrolone Tablets USP, 2.5 mg.

Reference is also made to your amendments dated August 3, 2004; March 29, May 21, and June 6, 2005; and September 14, October 10, and November 8, 16, and 29, 2006. We also refer to your correspondences dated January 14, and December 20, 2005, addressing patent issues listed below.

We have completed the review of this ANDA and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly the ANDA is approved. The Division of Bioequivalence has determined your Oxandrolone Tablets, 2.5 mg, to be bioequivalent and, therefore, therapeutically equivalent to the reference listed drug, Oxandrin Tablets, 2.5 mg, of Savient Pharmaceuticals Inc. Your dissolution testing should be incorporated into the stability and quality control program using the same method proposed in your ANDA.

The reference listed drug (RLD) upon which you have based your ANDA, Oxandrin Tablets, 2.5 mg, of Savient Pharmaceuticals Inc., is subject to periods of patent protection. The following patents and expiration dates are currently listed in the Agency's publication titled Approved Drug Products with Therapeutic Equivalence Evaluations (the "Orange Book"):

U.S. Patent No.	Expiration Date
5,872,147 (the '147 patent)	December 5, 2017
6,090,799 (the ‘799 patent)	July 18, 2017
6,576,659 (the '659 patent)	December 5, 2017
6,670,351 (the ‘351 patent)	October 20, 2012
6,828,313 (the ‘313 patent)	December 5, 2017

FDA has determined that information on the '147, ‘799, ‘659, and ‘351 patents was submitted to FDA by the NDA holder after the date of the submission of your ANDA. FDA has also determined that information on the '147, ‘799, ‘659, and ‘351 patents was submitted by the NDA holder more than 30 days after the patent was issued by the U.S. Patent and Trademark Office (PTO). Therefore, under 21 CFR 314.94(a)(12)(vi), no person with an appropriate patent certification at the time of the submission of the patents was required to submit an amended patent certification to address the ‘147, ‘799, ‘659, and ‘351 patents. You elected not to submit an amended patent certification with respect to these patents.

With respect to the ‘313 patent, which was submitted to the agency within 30 days of issuance by the PTO, your ANDA contains a statement under section 505(j)(2)(A)(viii) of the Act indicating that the ‘313 patent is a method of use patent that does not claim any of the indications for which you are seeking approval.

Under section 506A of the Act, certain changes in the conditions described in this ANDA require an approved supplemental application before the change may be made.

Postmarketing reporting requirements for this ANDA are set forth in 21 CFR 314.80-81 and 314.98. The Office of Generic Drugs should be advised of any change in the marketing status of this drug.

Promotional materials may be submitted to FDA for comment prior to publication or dissemination. Please note that these submissions are voluntary. If you desire comments on proposed launch promotional materials with respect to compliance with applicable regulatory requirements, we recommend you submit, in draft or mock-up form, two copies of both the promotional materials and package insert(s) directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705

We call your attention to 21 CFR 314.81(b)(3) which requires that all promotional materials be submitted to the Division of Drug Marketing, Advertising, and Communications with a completed Form FDA 2253 at the time of their initial use.

Sincerely yours,

{See appended electronic signature page}

Gary Buehler
Director
Office of Generic Drugs
Center for Drug Evaluation and Research

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

/s/

Robert L. West
12/1/2006 01:43:15 PM
for Gary Buehler