DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-848/S-021

Solvay Pharmaceuticals
Agent for Unimed Pharmaceuticals
Attn: Steven Wojtanowski
Manager, Regulatory Affairs
901 Sawyer Road
Marietta, GA 30062

Dear Mr. Wojtanowski:

Please refer to your supplemental new drug application dated February 24, 2004, received February 25, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for ANADROL®-50 (oxymetholone) Tablets, 50 mg.

We acknowledge receipt of your submission dated August 20, 2004, containing bottle and carton labels.

This "Changes Being Effected" supplemental new drug application provides for revisions to the PRECAUTIONS section (Drug Interactions, Information for Patients subsections) to state that pharmacokinetic and pharmacodynamic interactions have been reported in healthy volunteers taking anabolic steroids and warfarin, and suggesting careful monitoring of the INR or PT in patients taking them concomitantly. The supplement also provided for a revised storage statement.

We completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the attached agreed-upon labeling text for the package insert. The agreed-upon labeling text for the bottle and carton labels are acceptable as proposed, with the following minor editorial revision; delete the statement (b)(4)----------

The final printed labeling (FPL) must be identical, and include the minor editorial revisions indicated, to the enclosed labeling (text for the package insert) and labeling (container and carton labels). These revisions are terms of the approval of this application.

The electronic labeling rule published December 11, 2003, (68 FR 69009) requires submission of labeling content in electronic format effective June 8, 2004. For additional information, consult the following guidances for industry regarding electronic submissions: *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999) and *Providing Regulatory Submissions in Electronic Format – Content of Labeling* (February 2004). The guidances specify that labeling to be submitted in *pdf* format. To assist in our review, we request that labeling also be submitted in MS Word format. If formatted copies of all labeling pieces (i.e., package insert, patient package insert, container labels, and carton labels) are submitted electronically, labeling does not need to be submitted in paper. For administrative purposes, this submission should be designated "FPL for approved

supplement NDA 16-848/S-021." Approval of this submission by FDA is not required before the labeling is used.

We refer to your August 24, 2004 telephone conversation with Ms. Kati Johnson of this division. You were notified that it would be acceptable to exhaust the supply of your proposed labeling, already printed, and at the next printing, revise it to comply with the labeling approved with this supplement.

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

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 Monika Johnson, Regulatory Project Manager, at (301) 827-9087.

Sincerely,

{See appended electronic signature page}

David G. Orloff, MD
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/

David Orloff

8/25/04 10:00:15 PM