DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration
Rockville, MD 20857

NDA 16-848/S-020

Solvey Pharmaceuticals, Inc.
Attention: Stephen Tamsett
Manager Regulatory Affairs
901 Sawyer Rd.
Marietta, GA 30062

Dear Mr. Tamsett:

Please refer to your supplemental new drug application dated March 7, 2003, received March 10, 2003, 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 September 26, and October 10, and 20, 2003.

This supplemental new drug application provides for the following revisions:

1. Under the PRECAUTIONS section of the package insert:
    - the addition of geriatric use statement to comply with 21CFR 201.57(f)(10).

2. Updating the Carcinogenesis, Mutagenesis, Impairment of Fertility subsection to include information from studies conducted by the National Toxicology Program.

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 submitted labeling (package insert submitted March 7, 2003), revised to include the text contained in the submission dated October 20, 2003. In addition, the header “Storage Conditions”, should be deleted as it does not comply with 21CFR 201.57(k).

Please submit the FPL electronically according to the guidance for industry titled Providing Regulatory Submissions in Electronic Format – NDA. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 16-848/S-020.” Approval of this submission by FDA is not required before the labeling is used.

We remind you that you must submit patent information on form FDA 3542, *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, within 30 days of the date of this letter as required by 21 CFR 314.53(c)(2)(ii) and 314.53(d)(2) at the address provided by 21 CFR

314.53(d)(4). The form may be obtained at http://www.fda.gov/opacom/morechoices/fdaforms/cder.html. To expedite review of this patent declaration form, we request you submit an additional copy of the form to this application and to the Center for Drug Evaluation and Research "Orange Book" staff at

Food and Drug Administration
Office of Generic Drugs, HFD-610
Orange Book Staff
7500 Standish Place
Metro Park North II
Rockville, MD 20855-2773

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 Valerie Jimenez, Regulatory Project Manager, at (301) 827-9090.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolic and Endocrine Drug Products
Office of Drug Evaluation II
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/

David Orloff

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