CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-015/S-010

APPROVABLE LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-015/S-010

Unimed Pharmaceuticals
Attention: Suzanne LoGalbo, J.D., R.Ph.
Vice President, Regulatory Affairs
Solvay Pharmaceuticals, Inc.
901 Sawyer Road
Marietta, GA 30062

Dear Ms. LoGalbo:

Please refer to your supplemental new drug application dated April 9, 2003, received April 10, 2003, submitted under section 505(b)of the Federal Food, Drug, and Cosmetic Act for AndroGel® (testosterone gel) 1%.

We acknowledge receipt of your submissions dated April 9, June 6 and July 23, 2003.

This supplemental new drug application provides for an alternate container/closure system consisting of a multi-use pump and canister delivery system in 44 g and 88 g sizes.

We completed our review of this application, and it is approvable. Before the application may be approved, however, you must submit additional information to address the following deficiency:

The proposal to [redacted] is not acceptable. You must provide a better justification that the [redacted] Analytical data should be provided to show that [redacted] The data should include a summary that [redacted]

In addition, we have also made a preliminary review of your proposed labeling changes submitted and we are requesting a labeling revision as follows:

The sentence, "Allow gel to dry completely before smoking or going near an open flame," (Patient Information, page 2, line 78 (page 28 of supplement)) should be incorporated after the phrase containing the sentence, "Let AndroGel® dry for a few minutes before you

dress."(Patient Information, page 3, line 71-73 (page 29 of supplement)). This may help stress the importance of washing one's hands immediately after application.

Please resubmit a draft copy of the revisions to the Patient Information to facilitate another review of the proposed labeling changes.

Within 10 days after the date of this letter, you are required to amend the application, notify us of your intent to file an amendment, or follow one of your other options under 21 CFR 314.110. If you do not follow one of these options, we will consider your lack of response a request to withdraw the application under 21 CFR 314.65. Any amendment should respond to all the deficiencies listed. We will not process a partial reply as a major amendment nor will the review clock be reactivated until all deficiencies have been addressed.

This product may be considered to be misbranded under the Federal Food, Drug, and Cosmetic Act if it is marketed with these changes before approval of this supplemental application.

If you have any questions, call Mr. John Kim, R.Ph., J.D., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

David T. Lin, Ph.D.
Chemistry Team Leader, for the
Division of Reproductive and Urologic Drug
Products, HFD-580
DNDC II, Office of New Drug Chemistry
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 T. Lin
8/8/03 12:14:48 PM
I concur.