CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-015/S-010

APPROVAL 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 August 15, 20, September 4 and 9, 2003.

Your submission of August 15, 2003 constituted a complete response to our August 8, 2003, approvable letter for this supplement.

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, as amended. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text and with the minor editorial revisions listed below.

> The instructions to prime need to change from 4 pumps to 3 pumps as follows:
> "*Before using the pump for the first time, you must prime the AndroGel® pump by fully depressing the pump mechanism (actuation)* ***3 times*** *and discarding the gel.*" (page 2, lines 47-48, Patient Information and Instructions for Using, 1E Rev 8/2003)

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 21-015/S-010." 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

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

If you have any questions, call Mr. John Kim, R.Ph., J.D., Regulatory Project Manager, at (301) 827-3003.

Sincerely,

{See appended electronic signature page}

Moo-Jhong Rhee, 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

Enclosure

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/s/

Moo-Jhong Rhee
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