CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

21-015/S-008

APPROVAL LETTER

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-015/S-008

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

Dear Ms. LoGalbo:

Please refer to your supplemental new drug application dated December 4, 2002, received December 5, 2002 submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AndroGel® (testosterone gel).

This "Changes Being Effected" supplemental new drug application provides for changes in the Physician and Patient Package Insert regarding the potential hazard in gel products containing alcohol. The sponsor also provided a justification for the change in alcohol content.

We completed our review of this supplemental new drug application and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on December 4, 2002.

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 requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call Eufrecina DeGuia, Regulatory Health Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluate 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/

Daniel A. Shames
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