



NDA 21-015/S-004

Unimed Pharmaceuticals, Inc.
Attention: Judy Athy
Manager, Regulatory Affairs
Four Parkway North, Suite 200
Deerfield, IL 60015-2544

Dear Ms. Athy:

Please refer to your supplemental new drug application dated November 30, 2000, received December 1, 2000, and to your submission dated March 26, 2002, received March 27, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AndroGel® (testosterone gel).

Please also refer to the approvable letter dated December 12, 2001, issued by the Division of Reproductive and Urologic Drug Products requesting additional revisions to the **Clinical Studies** section of the physician package insert and the What is **AndroGel®?** section of the patient package insert. The previous proposals submitted by the sponsor to the physician package insert contained in the submission dated November 30, 2000, received December 1, 2000, were acceptable. The following additional changes were requested by the Agency:

1. Physician Insert
Clinical Studies

“The degree of penile erection as subjectively estimated by the patients, increased with AndroGel® treatment, as did the subjective score for “satisfactory duration of erection”.

rather than

(b)-----

2. Patient Package Insert
What is AndroGel®?

Deletion of this sentence:

(b)-----

We have completed the review of this supplemental application, and have concluded that the final printed labeling Patient Package Insert and Physician Insert received on March 27, 2002, incorporating the changes requested by the Agency are acceptable. Accordingly, this supplemental application is approved effective on the date of this letter.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
Food and Drug Administration
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, call Kassandra Sherrod, R.Ph., Regulatory 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 Evaluation and Research

Enclosure

**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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