



NDA 21-015/S-012

PRIOR APPROVAL SUPPLEMENT

Solvay Pharmaceuticals, Inc
Attention: Steven Wojtanowski, R.Ph.
Manager, Regulatory Affairs
901 Sawyer Road
Marietta, GA 30062

Dear Mr. Wojtanowski:

Please refer to your supplemental new drug application dated May 20, 2004, received May 21, 2004, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for AndroGel[®] (testosterone gel) 1%.

This supplemental application proposes change to your approved product labeling based on the results of a phototoxicity clinical study (UMD-98-039) that was submitted to the original NDA.

We completed our review of this application, and it 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 enclosed labeling (text for the package insert, text for the patient package insert).

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-012." Approval of this submission by FDA is not required before the labeling is used.

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 John C. Kim, R.Ph., J.D., Regulatory Health Project Manager, at (301) 827-3003.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug
Products, HFD-580
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure: Agreed-upon PI & PPI

**This is a representation of an electronic record that was signed electronically and
this page is the manifestation of the electronic signature.**

/s/

Margaret Kober
11/19/04 03:28:09 PM
signed for Daniel Shames