



NDA 20-169/S-003

Aventis Pharmaceuticals, Inc.
Attention: Jay Kraker
Associate Specialist, Regulatory Affairs
200 Crossing Boulevard, P.O. Box 6890
Bridgewater, N.J. 08807-0890

Dear Mr. Kraker:

Please refer to your supplemental new drug application dated April 25, 2003 received April 28, 2003, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Nilandron[®] (nilutamide) Tablets.

We acknowledge receipt of your submission dated May 19, 2004. Your submission constituted a complete response to our February 2, 2004, action letter.

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.

The final printed labeling (FPL) must be identical, and include the revisions indicated in your May 19, 2004, submission, to the package insert submitted on April 25, 2003. These revisions are terms of the approval of this application.

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 20-169/S-003." 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, please call Nenita Crisostomo, R.N., 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, HFD-580
Office of Drug Evaluation III
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Daniel A. Shames
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