NDA 18-554/S-022

Schering Corporation 30 MAR 2001
Attention: Mary Jane Nehring
Senior Director, Marketed Products
Support and Training, Worldwide Regulatory Affairs
2000 Galloping Hill Road
Kenilworth, NJ 07033

Dear Ms. Nehring:

Please refer to your supplemental new drug application dated March 5, 2001, received March6, 2001, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Eulexin® (flutamide) Capsules, USP.

This "Changes Being Effected" supplemental new drug application provides for the following revisions to the Patient Information Sheet in the **Who should not take the Eulexin product?** section (to make consistent with the package insert revisions submitted on March 5, 2001), and the **Where can I get further support?** section:

Who should not take EULEXIN product?

> "You should not take EULEXIN Capsules if you have liver problems or if you are allergic to it. EULEXIN Capsules are for use **only** in men, therefore ~~W~~women should not take EULEXIN Capsules."

Where can I get further support?

> "Patients taking EULEXIN Capsules have access to Schering's Commitment To Care℠, which can help you find financial reimbursement assistance for your EULEXIN therapy. The following services are available (1-800-521-~~7517~~7157)
>
> - research into reimbursement options
> - advice on how to obtain reimbursement assistance
> - support through Schering's Indigent Patient program
> - access to flexible payment programs
> - ~~counseling from registered pharmacists~~
>
> Please ask your doctor about any questions concerning prostate cancer or EULEXIN Therapy, or you can also ask for a more detailed leaflet that is written for healthcare professionals. ~~Also, visit Schering's prostate cancer web site at www.prostate-cancer.com for more information.~~"

We have completed the review of this supplemental application and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, the supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (Patient Information Sheet submitted March 6, 2001).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 18-554/S-022." Approval of this submission by FDA is not required before the labeling is used.

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
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, call Jeanine Best, M.S.N., R.N., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

Susan Allen, M.D., M.P.H.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research