DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 20-715/S-003
NDA 20-715/S-004

Pharmacia & Upjohn Company
Attention: Carl M. DeJuliis, R.Ph.
Regulatory Manager, Global Regulatory Affairs
7000 Portage Road
Kalamazoo, MI 49001

Dear Mr. DeJuliis:

Please refer to your supplemental new drug applications dated September 6, 2001 (S-003), and November 28, 2001 (S-004), received September 10, 2001 (S-003), and November 30, 2001 (S-004), submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Trelstar™ Depot (triptorelin pamoate for injectable suspension).

These "Changes Being Effected" supplemental new drug applications provide for an updated storage statement with a specified temperature range: "Store at 20-25°C (68-77°F)", in all labeling (outer cartons, immediate container, Debioclip blister pack, prefilled syringe and package insert), and updated directions for use of the Debioclip system (to harmonize with the Trelstar™ LA label) in the **DOSAGE AND ADMINISTRATION** section of the package insert:

For the **TRELSTAR™ DEPOT** Debioclip™ single-dose delivery system:
1. Remove the Tyvek® cover from the blister pack.
2. Remove the vial from its case. Remove the flip-off vial cover and place the vial in the vertical position.
3. Hold the lower part of the **TRELSTAR™ DEPOT** Debioclip™ and press it firmly onto the top of the vial (See Figure).
4. Hold firmly the syringe barrel. Push the finger grip in the direction of the vial as far as it will do (until you hear a click).
5. Take the plunger rod and screw it into the upper joint of the syringe.
6. Press the plunger rod to release the contents of the syringe into the vial.
7. Mix and withdraw the contents of the vial into the syringe.
8. Remove the syringe from the **TRELSTAR™ DEPOT** Debioclip™.
9. Inject the patient in either buttock with the contents of the syringe.

We have completed the review of these supplemental applications, as amended, and have concluded that adequate information has been presented to demonstrate that the drug products are safe and effective for use as recommended in the submitted final printed labeling (package insert submitted November 28, 2001, immediate container and carton labels submitted September 6 and November 28, 2001). Accordingly, these supplemental applications are 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
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., Senior Regulatory Associate, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

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