



NDA 19-726/S-037
NDA 20-578/S-016

AstraZeneca Pharmaceuticals LP
Attention: Lisa V. DeLuca, Ph.D.
Director, Urology Regulatory Affairs
P.O. Box 8355
Wilmington, DE 19803-8355

Dear Dr. DeLuca:

Please refer to your supplemental new drug applications dated February 12, 2002, received February 14, 2002, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NDA Number	Supplement Number	Drug Name
19-726	S-037	Zoladex® (goserelin acetate implant) 3.6 mg
20-578	S-016	Zoladex® (goserelin acetate implant) 10.8 mg

These supplemental new drug applications provide for the deletion the following statement from step # 5 in the **Administration Technique** section under the **DOSAGE AND ADMINISTRATION** section of the package insert.

DOSAGE AND ADMINISTRATION
Administration Technique

5. Change the direction of the needle so it parallels the abdominal wall. Push the needle in until the barrel hub touches the patient's skin. ~~Withdraw the needle one centimeter to create a space to discharge ZOLADEX.~~ Fully depress the plunger to discharge ZOLADEX.

We have completed the review of these supplemental applications 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 agreed upon enclosed labeling text. Accordingly, these supplemental applications are approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the draft labeling (text for the package insert) submitted February 12, 2002.

Please submit the copies of final printed labeling (FPL) electronically to each application 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, these submissions should be designated "FPL for approved supplement NDA 19-726/S-037, 20-578/S-016." Approval of these submissions by FDA is not required before the labeling is used.

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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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