NDA 21-197

ASTA Medica, Inc.
Attention: Brian A. Green
Manager, Regulatory Affairs
890 East Street
Tewksbury, MA 01876-1496

Dear Mr. Green:

Please refer to your new drug application (NDA) dated October 28, 1999, received October 29, 1999, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cetrotide™ (cetrorelix acetate for injection) 0.25 mg and 3.0 mg.

We acknowledge receipt of your submissions dated November 15, December 3 and 23, 1999, February 29, March 3 and 29, May 19 and 22, June 1, 6, 7, 9, 16, 19 (2), 28 (3), 29 (2) and 30 (2), July 11, 14, 17, 18, 21, 25 and 26, August 8, 10 (2) and 11, 2000.

This new drug application provides for the use of Cetrotide™ (cetrorelix acetate for injection) 0.25 mg and 3.0 mg for the prevention of premature LH surges in women undergoing controlled ovarian stimulation.

We have completed the review of this application, as amended, 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 application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (package insert submitted August 11, 2000, immediate container and carton labels submitted July 17, 2000). Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please 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 ten of the copies on heavy-weight paper or similar material. Alternately, you may submit the FPL electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDAs* (January 1999). For administrative purposes, this submission should be designated "FPL for approved NDA 21-197." Approval of this submission by FDA is not required before the labeling is used.

Validation of the regulatory methods has not been completed. At the present time, it is the policy of the Center not to withhold approval because the methods are being validated. Nevertheless, we expect your continued

cooperation to resolve any problems that may be identified.

Be advised that, as of April 1, 1999, all applications for new active ingredients, new dosage forms, new indications, new routes of administration, and new dosing regimens are required to contain an assessment of the safety and effectiveness of the product in pediatric patients unless this requirement is waived or deferred (63 *FR* 66632). We are waiving the pediatric study requirement for this action on this application.

In addition, please submit three copies of the introductory promotional materials that you propose to use for this product. All proposed materials should be submitted in draft or mock-up form, not final print. Please send one copy to the Division of Reproductive and Urologic Drug Products and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, Maryland 20857

Please submit one market package of the drug product when it is available.

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,

Florence Houn, M.D., M.P.H., F.A.C.P.
Director
Office of Drug Evaluation III
Center for Drug Evaluation and Research