DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-197/S-003
21-197/S-004
21-197/S-005

Serono, Inc.
Attention: Pamela Williamson Joyce
Vice President, US Regulatory Affairs
One Technology Place
Rockland, MA 02370

Dear Ms. Williamson Joyce:

Please refer to your supplemental new drug applications dated August 23, 2002, December 4, 2002, and January 31, 2003, received August 26, 2002, December 6, 2002 and February 3, 2003 respectively, submitted under section 505 (b) of the Federal Food, Drug, and Cosmetic Act for Cetrotide (cetrorelix acetate for injection).

These "Changes Being Effected" supplemental new drug applications provide for editorial changes to the labeling, add and strengthen safety information to the **CONTRAINDICATIONS, PRECAUTIONS,** and **ADVERSE REACTIONS** sections, and update the **Instructions for Use** section for the Serono's Fertility Auto-Injector.

We completed our review of these applications and they are approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text.

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, these submissions should be designated "FPL for approved supplement NDA 21-197/S-003, S-004, S-005." Approval of these submissions by FDA is not required before the labeling is used.

If you issue a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter), we request that you submit a copy of the letter to this NDA and a copy to the following address:

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MEDWATCH, HFD-410
FDA
5600 Fishers Lane
Rockville, MD 20857

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}

Donna Griebel, M.D.
Division Deputy Director
Division of Reproductive and Urologic Drug Products
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/

Donna Griebel

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