DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-197/S-010

EMD Serono, Inc.
Attention: Robert M. Kirsch, R.A.C.
Director, Global Regulatory Affairs – Endocrinology & Reproductive Health
One Technology Place
Rockland, MA 02370

Dear Mr. Kirsch:

Please refer to your supplemental new drug application dated October 5, 2007, received October 5, 2007, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Cetrotide® (cetrorelix acetate for injection).

We also acknowledge receipt of your submission dated March 25, 2008.

This supplemental new drug application provides for revision of the Package Insert, under **PRECAUTIONS,** subsection **General**, to include post-marketing information regarding hypersensitivity reactions related to the use of Cetrotide®.

We have completed our review of this application, as amended. This application is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling text.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(1)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling. Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-197/S-010." The final printed labeling (FPL) must be identical to the enclosed labeling (text for the package insert).

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:

MEDWATCH
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 Health Project Manager, at (301) 796-0875.

Sincerely,

{See appended electronic signature page}

Scott Monroe, M.D.
Director
Division of Reproductive and Urologic Products
Office of Drug Evaluation III
Center for Drug Evaluation and Research

Enclosure

This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

Scott Monroe

4/4/2008 06:06:09 PM