NDA 021197/S-032

SUPPLEMENT APPROVAL

EMD Serono, Inc.
Attention: Ruchi Khanna
Regulatory Lead, Neurology & Immunology (N&I) and Fertility Products, US
200 Pier 4 Blvd., Suite 300
Boston, MA 02110

Dear Ruchi Khanna:

Please refer to your supplemental new drug application (sNDA) dated and received July 22, 2024, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Cetrotide (cetrorelix acetate for injection).

This Prior Approval sNDA provides for incorporating (b) (4) study report entitled, "Cetrorelix extractable volume study for commercial Cetrorelix kits", into the existing Electronic Common Technical Document (eCTD) dossier in Module 3.2.P.2.

APPROVAL

We have completed our review of this supplemental new drug application. This supplement is approved.

If you have any questions, call Samantha Bell, Regulatory Project Manager, at (301) 796-9687.

Sincerely,

{See appended electronic signature page}

Ramesh Raghavachari, Ph.D.
Supervisor
Division of Product Quality Assessment IV
Office of Product Quality Assessment I
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

RAMESH RAGHAVACHARI
11/18/2024 12:57:35 PM