DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-149/S-013 **CBE-0 SUPPLEMENT**

EMD Serono, Inc.
Attention: Paul Lammers, M.D., M.Sc.
Acting Head, Regulatory Affairs and Quality Assurance, US
One Technology Place
Rockland, MA 02370

Dear Dr. Lammers:

Please refer to your supplemental new drug application dated August 16, 2006, received August 17, 2006, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Ovidrel® (choriogonadotropin alfa for injection).

This "Changes Being Effected" supplemental new drug application provides for an addition of a Post-marketing Reports subsection to the ADVERSE EVENTS section, changes to the HOW SUPPLIED section, and other editorial changes.

We have completed our review of this application and it is approved, effective on the date of this letter, for use as recommended in the 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(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the enclosed labeling for the package insert. 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 21-149/S-013."

Please submit an electronic version of the FPL 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 but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "**FPL for approved supplement NDA 21-149/S-013**." Approval of this submission by FDA is not required before the labeling is used.

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, call John C. Kim, R.Ph., J.D., Regulatory Project Manager, at (301) 796-0932.

Sincerely,

{See appended electronic signature page}

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

Enclosure: Agreed-upon package insert

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

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