



NDA 17-646/S-049

Serono, Inc.
Attention: Pamela Williamson Joyce
Vice President, U.S. Regulatory Affairs
100 Longwater Circle
Norwell, MA 02061

Dear Ms. Joyce:

Please refer to your supplemental new drug application dated August 8, 2000, received August 9, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Pergonal® (menotropins for injection, USP).

We acknowledge receipt of your submission dated September 14, 2001.

This supplemental new drug application provides for the addition of a "Geriatric Use" subsection under PRECAUTIONS section of the labeling in compliance with 21 CFR 201.57(f)(10)(ii)(A).

We have completed the review of this supplemental application, as amended, and it 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 September 14, 2001).

Please submit the copies of final printed labeling (FPL) electronically according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 17-646/S-049." Approval of this submission by FDA is not required before the labeling is used.

If a letter communicating important information about this drug product (i.e., a "Dear Health Care Professional" letter) is issued to physicians and others responsible for patient care, we request that you submit a copy of the letter to this NDA and a copy to the following address:

MEDWATCH, HF-2
FDA
5600 Fishers Lane
Rockville, MD 20857

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 Kassandra Sherrod, R.Ph., Regulatory Project Manager, at (301) 827-4260.

Sincerely,

{See appended electronic signature page}

Daniel Shames, M.D.
Director
Division of Reproductive and Urologic Drug Products
Office of Drug Evaluation III
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/

Daniel A. Shames
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