DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 19-297/S-028

Serono, Inc.
Attention: Pamela Williamson Joyce, RAC
One Technology Place
Rockland, MA 02370

Dear Ms. Williamson Joyce:

Please refer to your supplemental new drug application dated March 15, 2005 submitted under section 505(b of the Federal Food, Drug, and Cosmetic Act for Novantrone (mitoxantrone for injection concentrate).

We acknowledge receipt of your submissions dated:
March 23, 2005 March 30, 2005

This supplemental new drug application provides for labeling changes regarding cardiac toxicity and leukemia.

We 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 agreed-upon labeling text.

The final printed labeling (FPL) must be identical to the agreed upon labeling submitted March 23, 2005, the attached Patient Package Information, submitted March 23, 2005, and revised April 25, 2005, and the attached Dear Healthcare Provider Letter submitted March 30, 2005.

The Patient Package Information (text for the patient package insert) should contain the one additional revision agreed upon on April 25, 2005. Specifically, you agreed to remove the last sentence of the section titled, "**What are the possible side effects of NOVANTRONE**?"

> *"These problems generally happen in people who get a total lifetime dose of more than 12 doses (usually more than 140 mg/m2) of NOVANTRONE."*

These revisions are terms of the approval of this application.

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 NDA19-297/S-028**." Approval of this submission by FDA is not required before the labeling is used.

In addition, submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print. Send one copy to the Division of Oncology Drug Products and two copies of both the promotional materials and the package insert(s) directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

When you issue the 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, 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, call CDR Teresa Wheelous, Sr. Regulatory Management Officer, at (301) 594-2850.

Sincerely Yours

Russell Katz, M.D.
Director
Division of Neuropharmacological Drug Products
Office of Drug Evaluation I
Center for Drug Evaluation and Research

Enclosures

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

/s/

Russell Katz
4/27/05 12:42:49 PM