



NDA 19-297/S-029

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

Dear Dr. Lammers:

Please refer to your supplemental new drug application dated October 10, 2006, received October 11, 2006, submitted under section 505(b)/pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Novantrone® (mitoxantrone for injection concentrate).

This "Changes Being Effected in 30 days" supplemental new drug application provides for an additional drug product manufacturing facility for Novantrone®, 2mg/mL.

We acknowledge receipt of your submission dated March 8, 2007.

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 labeling submitted October 10, 2006.

We have recently updated the references that will be included in the REFERENCES Section of the package insert. Therefore, we request that you update the REFERENCES Section with the following new references at the next printing:

1. NIOSH Alert: Preventing occupational exposures to antineoplastic and other hazardous drugs in healthcare settings. 2004. U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control and Prevention, National Institute for Occupational Safety and Health, DHHS (NIOSH) Publication No. 2004-165.
2. OSHA Technical Manual, TED 1-0.15A, Section VI: Chapter 2. Controlling Occupational Exposure to Hazardous Drugs. OSHA, 1999.
http://www.osha.gov/dts/osta/otm/otm_vi/otm_vi_2.html
3. NIH [2002]. 1999 recommendations for the safe handling of cytotoxic drugs. U.S. Department of Health and Human Services, Public Health Service, National Institutes of Health, NIH Publication No. 92-2621.

4. American Society of Health-System Pharmacists. (2006) ASHP Guidelines on Handling Hazardous Drugs.
5. Polovich, M., White, J. M., & Kelleher, L.O. (eds.) 2005. Chemotherapy and biotherapy guidelines and recommendations for practice (2nd. ed.) Pittsburgh, PA: Oncology Nursing Society.

The final printed labeling (FPL) must be identical to the submitted labeling (text for the package insert, immediate container and carton labels).

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 19-297/S-029.**" Approval of this submission by FDA is not required before the labeling is used.

Submit content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/oc/datacouncil/spl.html>, that is identical in content to the enclosed labeling text. Upon receipt and verification, we will transmit that version to the National Library of medicine for posting on the DailyMed website.

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 Patricia Garvey, Senior Regulatory Project Manager, at (301) 796-1356.

Sincerely,

{See appended electronic signature page}

Hasmukh B. Patel, Ph.D.
Branch Chief
Branch VIII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

**This is a representation of an electronic record that was signed electronically and
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/s/

Hasmukh Patel

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