

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

50-807

APPROVAL LETTER



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 50-807

Mayne Pharma (USA) Inc.
Attention: Steve Richardson
Director, Regulatory and Medical Affairs
Mack-Cali Centre II, Second Floor
650 From Road
Paramus, NJ 07652

Dear Mr. Richardson:

Please refer to your new drug application (NDA) dated July 15, 2005, received July 19, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Epirubicin Hydrochloride for Injection lyophilized, 50mg/vial, 200 mg/vial. We also refer to your amendment dated August 21, 2006.

The August 21, 2006 submission constitutes a complete response to our August 17, 2006 action letter.

This new drug application provides for the use of for Epirubicin Hydrochloride for Injection lyophilized, 50mg/vial, 200 mg/vial, as a component of adjuvant therapy in patients with evidence of axillary node tumor involvement following resection of primary breast cancer.

We completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the agreed upon labeling (refer to the enclosed text for the package insert, immediate container and carton labels).

The final printed labeling (FPL) must be identical to the enclosed labeling. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

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 NDA 50-807.**" Approval of this submission by FDA is not required before the labeling is used.

If you choose to use a proprietary name for this product, the name and its use in the labels must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit any proprietary name to the Agency for our review prior to its implementation.

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 this division and two copies of both the promotional materials and the package inserts directly to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Drug Marketing, Advertising, and Communications
5901-B Ammendale Road
Beltsville, MD 20705-1266

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 Paul Zimmerman, Regulatory Project Manager, at (301) 796-1489.

Sincerely,

{See appended electronic signature page}

Ann Farrell, M.D.
Acting Deputy Division Director
Division of Drug Oncology Products
Office of Oncology Drug Products
Center for Drug Evaluation and Research

Enclosure

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

/s/

Ann Farrell

9/15/2006 09:10:01 AM