DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-092/S-042
NDA 16-093/S-044

Merck & Co., Inc.
Attention: Mr. Kenneth A. Kramer
Sumneytown Pike, P.O. Box 4
BLA-20
West Point, PA 19486

Dear Mr. Kramer:

Please refer to your electronic supplemental new drug applications dated October 1, 2004, received October 4, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Edecrin (ethacrynic acid) 25 & 50 mg Tablets (NDA 16-092) and Sodium Edecrin (ethacrynate sodium) equivalent to 50 mg of ethacrynic acid in a plug form or powder for Intravenous Injection.

These supplemental new drug applications provide for draft labeling revised to delete reference to the 50-mg tablet, as follows:

1. Under DESCRIPTION, 3rd paragraph, the reference for the 50 mg tablet was deleted to read: Edecrin is supplied as 25 mg tablets for oral use. The tablets contain the following inactive ingredients: colloidal silicon dioxide, lactose, magnesium stearate, starch and talc.

2. Under DOSAGE AND ADMINISTRATION,
    a. Oral Use, the reference to the 50 mg tablets was deleted.
    b. Dosage: To Initiate Diuresis, Day-1, the phrase “single dose” was changed to “once daily.”

3. Under HOW SUPPLIED, the reference to the 50 mg tablet was deleted.

In addition, the following minor editorial changes are noted:

1. Under DESCRIPTION, Ethacrynate sodium, the text “Inactive ingredients” was change to “Inactive ingredient.”

2. Under PRECAUTIONS, General, 1st paragraph, 2nd sentence, a comma was added following the first word “Rarely,.”

3. Under DOSAGE AND ADMINISTRATION, *In Pediatric Patients*:, the colon at the end of the subsection was changed to italicized font.

4. Under HOW SUPPLIED, *Storage:*, the italics colon were deleted from the subheading to read "Storage."

5. The "Issued" date would be updated in the final printed labeling.

We have completed our review of these applications, as amended, and they are 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 enclosed labeling text for the package insert submitted October 1, 2004.

Please submit the FPL electronically 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, in no case more than 30 days after it is printed. Please individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, these submissions should be designated "FPL for approved supplement NDA 16-092/S-042 and NDA 16-093/S-044." Approval of these submissions 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, please call:

Mr. Daryl Allis
Regulatory Project Manager
(301) 594-5332

Sincerely,

{See appended electronic signature page}

Norman Stockbridge, M.D., Ph.D.
Acting Director
Division of Cardio-Renal Drug Products
Office of Drug Evaluation I
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/

Norman Stockbridge

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