DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 16-092/S-039
NDA 16-093/S-043

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, 2003, 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 Intravenous Sodium Edecrin (ethacrynate sodium) Plug Form or Powder equivalent to 50 mg ethacrynic acid (NDA 16-093).

Your submissions dated October 1, 2003 constituted a complete response to our August 26, 2002 action letter.

These supplemental new drug applications provide for final printed labeling revised to add a *Geriatric Use* section at the end of the **PRECAUTIONS,** as follows:

Geriatric Use
Of the total number of subjects in clinical studies of EDECRIN/SODIUM EDECRIN, approximately 224 patients (21%) were 65 to 74 years of age, while approximately 100 patients (9%) were 75 years of age and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, and other reported clinical experience has not identified differences in responses between the elderly and younger patients, but greater sensitivity of some older individuals cannot be ruled out. (See WARNINGS.)

This drug is known to be substantially excreted by the kidney, and the risk of toxic reactions to this drug may be greater in patients with impaired renal function. Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection and it may be useful to monitor renal function. (See CONTRAINDICATIONS.)

In addition, the following minor editorial changes are noted:

- The address was changed **from** West Point, PA 19486, USA **to** Whitehouse Station, NJ 08889, USA.
- The word "subsection" was deleted from the statement "(see PRECAUTIONS, subsection Drug Interactions)" at the end of the WARNINGS section.
- The phrase "Dist. by:" was deleted from the sponsors name and address at the end of the package insert.
- The sponsor's code and issued dates were updated.

We have completed our review of these supplemental new drug applications, as amended, and they are approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on October 1, 2003.

If you issue a 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 the requirements for an approved NDA set forth under 21 CFR 314.80 and 314.81.

If you have any questions, please call:

Mr. Daryl Allis
Regulatory Project Manager
(301) 594-5309

Sincerely,

{See appended electronic signature page}

Douglas C. Throckmorton, M.D.
Director
Division of Cardio-Renal Drug Products
Center for Drug Evaluation and Research
Office for Drug Evaluation I

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

/s/

Doug Throckmorton

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