DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
Rockville MD 20857

NDA 5-619/S-016

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

Dear Mr. Kramer:

Please refer to your supplemental new drug application dated November 29, 2000, received December 1, 2000, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Aminohippurate Sodium Injection "PAH".

We acknowledge receipt of your submission dated February 13, 2001.

This supplemental new drug application provides for (1) a new container for the drug product, which is a new EP Type 1 glass vial that has been treated with aluminum sulfate; (2) a reduction in the expiration dating period from 60 to 36 months; and (3) a revised storage statement in the immediate container label, carton, and the package insert to reflect the new expiration dating period.

We have completed the review of this supplemental application, as amended, and have concluded that adequate information has been presented to demonstrate that the drug product is safe and effective for use as recommended in the agreed upon labeling text. Accordingly, this supplemental application is approved effective on the date of this letter.

The final printed labeling (FPL) must be identical to the submitted draft labeling (text for the package insert, immediate container, and carton labels submitted November 29, 2000).

Please submit the copies of final printed labeling (FPL) electronically to the application according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA* (January 1999). 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. Please individually mount ten of the copies on heavy-weight paper or similar material. For administrative purposes, this submission should be designated "FPL for approved supplement NDA 5-619/S-016." Approval of this submission by FDA is not required before the labeling is used.

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, call Steve McCort, Regulatory Project Manager, at (301) 827-6415.

Sincerely,

{See appended electronic signature page}

Duu-Gong Wu, Ph.D.
Chemistry Team Leader II, DNDC II for the
Division of Metabolic and
Endocrine Drug Products, (HFD-510)
Office of New Drug Chemistry
Center for Drug Evaluation and Research

/s/

Duu-gong Wu
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