



NDA 05-619/S-020

Merck and Co., Inc.
Attention: Kenneth Kramer
Manager, Regulatory Affairs
Sumnytown Pike, PO Box 4
West Point, PA 19486

Dear Mr. Kramer:

Please refer to your supplemental new drug application dated February 8, 2005, received February 9, 2005, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for PAH (aminohippurate sodium) Injection.

This "Changes Being Effectuated" supplemental new drug application provides revised language to include the term "anaphylaxis" under ADVERSE REACTIONS and to make the associated editorial revisions in the package insert.

We completed our review of this supplemental new drug application, and it is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on February 8, 2005.

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

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.

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 Holly Wieland, Regulatory Project Manager, at (301)827-6410.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.

Director

Division of Metabolic and Endocrine Drug Products HFD-510

Office of Drug Evaluation II

Center for Drug Evaluation and Research

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

David Orloff

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