



NDA 21-591/S-003

Ranbaxy Inc.
Attention: Abha Pant, U.S. Agent
Regulatory Affairs
600 College Road East
Princeton, NJ 08540

Dear Ms. Pant:

Please refer to your supplemental new drug application dated July 27, 2005, received July 29, 2005, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Riomet™ (metformin HCl oral solution), 500 mg/5 mL.

This "Changes Being Effected in 30 days" supplemental new drug application provides for revisions to the **CONTRAINDICATIONS** section of the package insert as specified in our supplement request letter dated June 24, 2005.

We completed our review of this supplemental new drug application. It is approved, effective on the date of this letter, for use as recommended in the final printed labeling (FPL) submitted on July 27, 2005.

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 Ms. Jena Weber, Regulatory Health Project Manager at 301-827-6422.

Sincerely,

{See appended electronic signature page}

David G. Orloff, M.D.
Director
Division of Metabolism and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: (package insert)

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/s/

David Orloff
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