DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-591/S-001

Ranbaxy USA Inc.
Attention: Abha Pant
Executive Director Regulatory Affairs
600 College Road East
Princeton, NJ 08540

Dear Ms. Pant:

Please refer to your supplemental new drug application dated May 17, 2004, received May 18, 2004, 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" supplemental new drug application provides for revisions to the **CLINICAL PHARMACOLOGY** section, **Special Populations, Pediatrics** subsection, **OVERDOSAGE** and **WARNINGS** sections of the package insert labeling.

We completed our review of this application. It is approved, effective on the date of this letter, for use as recommended in the final labeling (FPL) submitted on May 17, 2004.

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 reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

If you have any questions, please call Ms. Jena Weber, Regulatory Project Manager, at 301-827-6422.

Sincerely,

{See appended electronic signature page}

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

Enclosure (FPL/S-001)

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

/s/

David Orloff

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