DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-591/S-004 **SUPPLEMENT APPROVAL**

Ranbaxy Inc.
Attention: Mike Yefimenko
U.S. Agent for Ranbaxy Ltd.
600 College Road East
Princeton, NJ 08540

Dear Mr. Yefimenko:

Please refer to your supplemental new drug application dated April 29, 2008, received April 30, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Riomet (metformin HCl oral solution), 500 mg/5 mL.

This supplemental new drug application provides for labeling changes to the package insert as requested in our correspondence dated November 19, 2007.

We have completed our review of this application. This application is approved, effective on the date of this letter, for use as recommended in the agreed-upon labeling text, and minor editorial changes that will be implemented as per the conversation with Mr. Juan Grijalva, from your establishment, and Ms. Jena Weber, from FDA on October 20, 2008.

As soon as possible, but no later than 14 days from the date of this letter, please submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format as described at http://www.fda.gov/oc/datacouncil/spl.html that is identical to the attached labeling (text for the package insert submitted April 29, 2008). Upon receipt, we will transmit that version to the National Library of Medicine for public dissemination. For administrative purposes, please designate this submission, "SPL for approved NDA 21-591/S-004."

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
Food and Drug Administration
5515 Security Lane
HFD-001, Suite 5100
Rockville, MD 20852

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 301-796-1306.

Sincerely,

{See appended electronic signature page}

Mary H. Parks, M.D.
Director
Division of Metabolism & Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure (PI)

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

/s/

Mary Parks

10/20/2008 06:55:07 PM