



NDA 021591/S-005

SUPPLEMENT APPROVAL

Ranbaxy Laboratories Limited, India
Attention: Scott D. Tomsky
US Agent for Ranbaxy Ltd.
600 College Road East
Princeton, NJ 08540

Dear Mr. Tomsky:

Please refer to your Supplemental New Drug Application (sNDA) dated June 9, 2010, received June 9, 2010, submitted under 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Riomet (metformin HCl oral solution), 500 mg/5 mL.

This “Changes Being Effected” supplemental new drug application provides for labeling revisions as requested in our communication dated December 11, 2009, and included changes to the **DESCRIPTION** section, **CLINICAL PHARMACOLOGY** section, **Distribution** subsection, **CLINICAL STUDIES** section, **INDICATIONS AND USAGE** section, **PRECAUTIONS** section, **Drug Interactions** subsection, **PRECAUTIONS** section, **Carcinogenesis, Mutagenesis, Impairment of Fertility, Pregnancy, and Nursing Mothers** subsections, **HOW SUPPLIED** and **STORAGE** sections.

We have completed our review of this supplemental application. It is **approved**, effective on the date of this letter, for use as recommended in the enclosed, agreed-upon labeling text.

We note that your June 9, 2009, submission includes final printed labeling (FPL) for your package insert. You are responsible for assuring that the wording in this printed labeling is identical to that of the approved content of labeling in the structured product labeling (SPL) format.

As soon as possible, but no later than 14 days from the date of this letter, submit, using the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format, as described at <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>, that is identical to the enclosed labeling (text for the package insert) and include the labeling changes proposed in any pending “Changes Being Effected” (CBE) supplements and any annual reportable changes not included in the enclosed labeling.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled “SPL Standard for Content of Labeling Technical Qs and As” at <http://www.fda.gov/downloads/DrugGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf>.

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications for this NDA, including CBE supplements for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 314.50(l)(1)(i)] in MS Word format that includes the changes approved in this supplemental application.

LETTERS TO HEALTH CARE PROFESSIONALS

If you decide to issue a letter communicating important safety-related information about this drug product (i.e., a “Dear Health Care Professional” letter), we request that you submit, at least 24 hours prior to issuing the letter, an electronic copy of the letter to this NDA to the following address:

MedWatch Program
Office of Special Health Issues
Food and Drug Administration
10903 New Hampshire Ave
Building 32, Mail Stop 5353
Silver Spring, MD 20993

REPORTING REQUIREMENTS

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 and Endocrinology Products
Office of Drug Evaluation II
Center for Drug Evaluation and Research

Enclosure: Package Insert

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

/s/

MARY H PARKS
12/06/2010