

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

21-591

APPROVAL LETTER(S)



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 21-591

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

Dear Ms. Pant:

Please refer to your new drug application (NDA) dated November 13, 2002, received November 14, 2002, submitted under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Riomet (metformin HCl) Oral Solution 100 mg/mL.

We acknowledge receipt of your submissions dated January 13, February 3 and 12, June 26, August 5, 21, 26, 27 and 28, (2), 29 (2), and September 4, 2003.

This new drug application provides for the use of Riomet (metformin HCl) Oral Solution as monotherapy as an adjunct to diet and exercise to improve glycemic control in patients with type 2 diabetes mellitus.

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

The final printed labeling (FPL) must be identical to the labeling (text for the package insert, immediate container and carton labels), submitted September 10, 2003. Marketing the product with FPL that is not identical to the approved labeling text may render the product misbranded and an unapproved new drug.

Please provide an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. Alternatively, you may submit 20 paper copies of the FPL as soon as it is available but no more than 30 days after it is printed. Individually mount 15 of the copies on heavy-weight paper or similar material. For administrative purposes, designate this submission "FPL for approved NDA 21-591." Approval of this submission by FDA is not required before the labeling is used.

Based on the stability data provided, a shelf-life of 18-months is granted instead of _____ as requested.

Please submit three copies of the introductory promotional materials that you propose to use for this product. Submit all proposed materials in draft or mock-up form, not final print.

Send one copy to this Division, the Division of Metabolic and Endocrine Drug Products, HFD-510, and two copies of both the promotional materials and the package insert directly to:

Division of Drug Marketing, Advertising, and Communications, HFD-42
Food and Drug Administration
5600 Fishers Lane
Rockville, MD 20857

One market package of the drug product should be submitted when it is available

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

We also remind you that you must submit patent information on form FDA 3542, *Patent Information Submitted Upon and After Approval of an NDA or Supplement*, within 30 days of the date of this letter as required by 21 CFR 314.53(c)(2)(ii) and 314.53(d)(2) at the address provided by 21 CFR 314.53(d)(4). The form may be obtained at <http://www.fda.gov/opacom/morechoices/fdaforms/cder.html>. To expedite review of this patent declaration form, we request you submit an additional copy of the form to the Center for Drug Evaluation and Research "Orange Book" staff at:

Food and Drug Administration
Office of Generic Drugs, HFD-610
Orange Book Staff
7500 Standish Place
Metro Park North II
Rockville, MD 20855-2773

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 (draft package insert submitted September 10, 2003)

**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
9/11/03 03:15:10 PM