DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 09-112/S-022 **APPROVAL LETTER**

Ranbaxy Laboratories Inc.
Attention: Usha Sankaran
US Agent for Ranbaxy
600 College Road
Princeton, NJ 08540

Dear Ms. Sankaran:

Please refer to your supplemental new drug application dated October 27, 2008, received October 28, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Eurax® (crotamiton) Lotion, 10 %.

We acknowledge receipt of your submissions dated February 19, 2009, and March 12, 2009.

Your submission of March 12, 2009 constituted a complete response to our February 27, 2009, action letter.

This supplemental new drug application provides for addition of physician's sample packaging configuration of 0.5 oz (b) (4) bottle.

We completed our review of this application, as amended. This application 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 enclosed labeling (immediate container and carton labels) and submitted labeling (immediate container and carton labels submitted March 12, 2009).

Please submit an electronic version of the FPL according to the guidance for industry titled *Providing Regulatory Submissions in Electronic Format - NDA*. For administrative purposes, designate this submissions "**FPL for approved supplement NDA 09-112/S-022**." Approval of this submission by FDA is not required before the labeling is used.

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, call Swati Patwardhan, Regulatory Project Manager, at (301) 796-4085.

Sincerely,

{See appended electronic signature page}

James D. Vidra, Ph.D.
Branch Chief
Branch VII, Division of Post-Marketing Evaluation
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

Enclosure:

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

/s/

Jim Vidra

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