**DEPARTMENT OF HEALTH & HUMAN SERVICES**

Public Health Service

Food and Drug Administration
Rockville, MD 20857

NDA 17-556/S-038

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

Dear Ms. Sankaran:

Please refer to your supplemental new drug application(s) dated February 09, 2009, received February 10, 2009, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Halog® (halcinonide) Cream 0.1%.

This "Prior Approval" supplemental new drug application provides for the following change(s):

1) Addition of (b) (4) located in (b) (4) as an alternate source for drug substance

2) Change in finished drug product specifications for related substances

3) Additional packaging configuration of 216 gm jar for Halog Cream

We 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.

The final printed labeling (FPL) must be identical to the enclosed labeling and with the minor editorial revisions listed below (text for the package insert and immediate container labels) and/or submitted labeling (package insert submitted February 9, 2009 and immediate container labels submitted February 9, 2009).

We remind you to specify the location and printing method for the expiration date and lot number on all future submissions that include the immediate container labels.

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 submission "**FPL for approved supplement NDA 17-556/S-038**". 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

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

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/s/

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Jim Vidra

6/10/2009 04:08:15 PM