DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 18-738/S-009

Ranbaxy Laboratories, Inc.
Attn: Usha Sankaran
Manager, Regulatory Affairs
600 College Road East
Princeton, NJ 08540

Dear Ms. Sankaran:

Please refer to your supplemental new drug application (sNDA) dated October 27, 2008, received October 29, 2008, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act for Exelderm® (sulconazole nitrate) Solution, 1%.

We acknowledge receipt of your submission dated April 16, 2009, which constituted a complete response to our February 27, 2009 action letter.

This supplemental new drug application provides for an additional packaging configuration for a proposed 5 mL plastic bottle (physician's sample).

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.

CONTENT OF LABELING

As soon as possible, but no later that 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 enclosed labeling (text for the package insert and text for the patient information leaflet). 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 supplement NDA 18-738/S-009.

LETTERS TO HEALTH CARE PROFESSIONALS

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
Suite 12B05
5600 Fishers Lane
Rockville, MD 20857

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, call Catherine Carr, Regulatory Project Manager, at (301) 796-2110.

Sincerely,

{See appended electronic signature page}

Stanka Kukich, M.D.
Deputy Director
Division of Dermatology and Dental Products
Office of Drug Evaluation III
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/

Stanka Kukich

7/8/2009 09:30:56 AM