DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

NDA 21951/S-001

SUPPLEMENT APPROVAL
FULLFILLMENT OF POSTMARKETING COMMITMENT

Ranbaxy Inc.
Attention: Sameer Manan
Senior manager, Regulatory Affairs
600 College Road East
Princeton, NJ 08540

Dear Mr. Manan:

Please refer to your Supplemental New Drug Application (sNDA) dated March 18, 2013, received March 19, 2013, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Absorica (isotretinoin) Capsules.

We acknowledge receipt of your amendments dated March 27, 2013, March 31, 2014, May 2, 2014, and July 25, 2014.

This "Changes Being Effected in 30 days" supplemental new drug application provides for revised dissolution methodology which is a minor change in line with the USP Dissolution Test 3 of the USP monograph for the 10 mg, 20 mg, 30 mg and 40 mg isotretinoin capsules.

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

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit the content of labeling [21 CFR 314.50(l)] in structured product labeling (SPL) format using the FDA automated drug registration and listing system (eLIST), as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Content of labeling must be identical to the enclosed labeling with the addition of any labeling changes in pending "Changes Being Effected" (CBE) supplements, as well as 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/DrugsGuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that includes labeling changes 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, as well as annual reportable changes and annotate each change. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submission dated March 18, 2013, March 31, 2014, May 2, 2014, and July 25, 2014, containing the final report for the following postmarketing commitment listed in the May 25, 2012, approval letter.

1896-1 Conduct an *in vitro* dissolution method development study to define final test method parameters for quality control. Evaluate the utility of a two-tiered dissolution method (e.g., USP dissolution test 1 for isotretinoin capsules), identify different parameters that allow for enzyme use in accordance with USP guidelines, and identify a suitable surfactant that can be used at lower concentrations, ideally <2%. Other test method parameters may be evaluated, as desired, to assure the development of a robust dissolution test in line with the principles of USP <711> and <1092>. The optimal dissolution test method for your isotretinoin capsules should allow for reproducible product profiles (RSDs <10%).

FDA will make a decision on the final dissolution method for your isotretinoin capsules after reviewing your dissolution method report. Once an agreement is reached on the final test method, use the final test method to propose final dissolution acceptance criteria for your isotretinoin capsules. Your proposal should be supported by dissolution data from at least the first three (3) validation-lots of each capsule strength, and two (2) additional commercial batches of each strength. If the dissolution report provides for a new faster-release dissolution method (i.e., complete release/dissolution for all the strengths in < 90 minutes) and the provided data support the approval of this method, you may propose the implementation of a single-point dissolution criterion. Otherwise, implement at least a two-point criteria, with the first time point being a range of appropriate variability (ideally +/- 10%).

We have reviewed your submission and conclude that the above commitment was fulfilled.

This completes all of your postmarketing commitments acknowledged in our May 25, 2012, letter.

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 Olga Simakova, Regulatory Project Manager, at (240) 402-3814.

Sincerely,

{See appended electronic signature page}

Thomas F. Oliver, PhD
Branch Chief, Branch VI
Division of New Drug Quality Assessment II
Office of New Drug Quality Assessment
Center for Drug Evaluation and Research

ENCLOSURE(S):
Content of Labeling

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

/s/

THOMAS F OLIVER
07/30/2014