NDA 209363/S-014
NDA 209363/S-016

SUPPLEMENT APPROVAL
FULFILLMENT OF POSTMARKETING REQUIREMENTS

Lupin Pharmaceuticals, Inc.
(A subsidiary of Lupin Inc.)
Attention: Kalpana Vanam, MBA
Senior Vice President, Regulatory Affairs
400 Campus Drive
Somerset, NJ 08873

Dear Ms. Vanam:

Please refer to your supplemental new drug applications (sNDAs) dated and received March 29, 2021 (S-014) and August 30, 2021 (S-016), and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Solosec (secnidazole) oral granules, 2 g.

These Prior Approval supplemental new drug applications provide for the addition of female patients 12 to less than 18 years of age to the approved indication for treatment of bacterial vaginosis (S-014) and the addition of patients 12 to less than 18 years of age to the approved indication for treatment of trichomoniasis caused by *Trichomonas vaginalis* (S-016).

APPROVAL & LABELING

We have completed our review of these applications, as amended. They are approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

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 FDA.gov.[1] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, and Instructions for Use), 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.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

Information on submitting SPL files using eList may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include 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 Microsoft Word format, that includes the changes approved in these supplemental applications, as well as annual reportable changes. To facilitate review of your submission(s), 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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

For the bacterial vaginosis indication, we waived the pediatric study requirement for females from birth to less than 12 years, premenarchal adolescent females from 12 years to less than 18 years of age, and for males of all age groups, because necessary studies are impossible or highly impracticable. This is because bacterial vaginosis is not associated with these pediatric groups.

For the trichomoniasis indication, we waived the pediatric study requirement for females and males from birth to less than 12 years of age, because necessary studies are impossible or highly impracticable. This is because trichomoniasis does not commonly occur in preadolescent males and females.

[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

FULFILLMENT OF POSTMARKETING REQUIREMENTS

We have received your submission dated March 29, 2021 (S-014), containing the final report for the following postmarketing requirement listed in the September 15, 2017, approval letter.

3249-1 Conduct an open label, multicenter, safety study of Solosec (secnidazole) oral granules in healthy postmenarchal adolescent females ages 12 years to less than 18 years of age with bacterial vaginosis.

We have also received your submission dated August 30, 2021 (S-016), containing the final report for the following postmarketing requirement listed in the June 30, 2021, approval letter.

4113-1 Deferred pediatric assessment under PREA for SOLOSEC (secnidazole) oral granules for the treatment of trichomoniasis in adolescent females and males ages 12 years to less than 18 years of age**.** In your submission, provide a rationale for extrapolating efficacy from clinical trials of SOLOSEC for the treatment of trichomoniasis in adults and safety data from the completed clinical study in adolescent women for the treatment of bacterial vaginosis: SYM-1219-401, "A multi-center, open-label study to evaluate the safety of a single oral dose of SOLOSEC (secnidazole) 2-gram oral granules in 40 post-menarchal adolescent women with bacterial vaginosis."

We have reviewed these submissions and conclude that the above requirements were fulfilled.

This completes all of your postmarketing requirements acknowledged in our September 15, 2017, and June 30, 2021, letters.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.

[21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

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, please call Deborah Kim, PharmD, RAC, Regulatory Project Manager at (301) 796-9053.

Sincerely,

{See appended electronic signature page}

Peter Kim, MD, MS
Director
Division of Anti-Infectives
Office of Infectious Diseases
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert
  - Instructions for Use

[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

PETER W KIM
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