NDA 209363/S-012

SUPPLEMENT APPROVAL

Lupin Pharmaceuticals, Inc.
A subsidiary of Lupin Inc.
Attention: Geetanjali Jaguste
Senior Manager, Regulatory Affairs
111 South Calvert Street
Harborplace Tower, 24th Floor
Baltimore, MD 21202

Dear Ms. Jaguste:[1]

Please refer to your supplemental new drug application (sNDA) dated August 31, 2020, received August 31, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for SOLOSEC (secnidazole) oral granules, 2 g.

This Prior Approval supplemental new drug application provides for a new indication, for the treatment of trichomoniasis caused by *Trichomonas vaginalis* in adults.

APPROVAL & LABELING

We have completed our review of this application, as amended. It is 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.[2] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information, Patient Package Insert, 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.

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*.[3]

[1] 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.
[2] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[3] 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.

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 this supplemental application, 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.

We are waiving 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.

We have determined that the following Postmarketing Requirement (PMR) for a deferred pediatric assessment is required for adolescent females and males from 12 years to less than 18 years of age for the treatment of trichomoniasis:

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.”

The timetable you submitted on June 29, 2021, states that you will submit this pediatric assessment according to the following schedule:

Final Report Submission: 08/2021

Reports of this required pediatric postmarketing assessment must be submitted as a supplement to your approved NDA with the proposed labeling changes you believe are warranted based on the data derived from this assessment. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

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.*[4]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 314.81(b)(3)(i)]. Form FDA 2253 is available at FDA.gov.[5] Information and Instructions for completing the form can be found at FDA.gov.[6]

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

Sincerely,

{See appended electronic signature page}

Adam Sherwat, MD
Deputy Director
Office of Infectious Diseases
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURES:

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

[4] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[6] 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/

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