NDA 209363/S-015

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:

Please refer to your supplemental new drug application (sNDA) dated and received April 30, 2021, 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 sNDA provides for the following revisions to the Prescribing Information (PI) as requested by the Agency in the February 26, 2021, supplement request letter.

(1) The **DOSAGE AND ADMINISTRATION (2)** section, **Instructions for the Preparation and Administration of SOLOSEC (2.2)** subsection**,** was updated to include the following text: *Avoid consumption of alcoholic beverages and preparations containing ethanol or propylene glycol during treatment with SOLOSEC and for at least 2 days after completing therapy.*

(2) The **ADVERSE REACTIONS (6)** section, **Postmarketing Experience (6.2)** subsection was revised to state that *Nausea, vomiting, diarrhea, abdominal pain, dizziness, and headache have been reported when SOLOSEC was taken concomitantly with alcohol.*

(3) Under the **DRUG INTERACTIONS (7)** section, an **Alcohol (7.2)** subsection was added to state *Alcoholic beverages and preparations containing ethanol or propylene glycol should be avoided during SOLOSEC therapy and for 2 days after treatment is stopped. Nausea, vomiting, diarrhea, abdominal pain, dizziness, and headache have been reported when SOLOSEC was taken concomitantly with alcohol.*

(4) In the **CLINICAL PHARMACOLOGY (12)** section, **Pharmacokinetics (12.3)** subsection, under the Drug Interaction Studies subheading, *Ethanol Metabolism*, was updated to state that *However, postmarketing observations of adverse reactions of nausea, vomiting, diarrhea, abdominal pain, dizziness, and headache with concomitant use of SOLOSEC and alcohol have been reported.*

(5) In the **PATIENT COUNSELING INFORMATION (17)** section, the Alcohol subheading was added to state *Advise patients to avoid consumption of alcoholic beverages and preparations containing ethanol or propylene glycol during SOLOSEC therapy and for 2 days afterward because nausea, vomiting, diarrhea, abdominal pain, dizziness, and headache may occur.*

Additionally, **PATIENT INFORMATION** and **INSTRUCTIONS FOR USE** were upated to be consistent with the PI and minor editorial revisions have been made throughout the labeling.

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.[1] 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*.[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 this supplemental application, as well as annual reportable changes. To facilitate review of your submission(s), provide a

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

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).

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}

Dmitri Iarikov, MD, PhD
Deputy 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

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/

DMITRI IARIKOV
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