NDA 216142

NDA APPROVAL

Baxter HealthCare Corporation
Hiren Gadhiya, MSc, RAC
Senior Manager, Global Regulatory Affairs
1 Baxter Parkway
Deerfield, IL 60015

Dear Hiren Gadhiya:

Please refer to your new drug application (NDA) dated and received November 30, 2022, and your amendments submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act for Micafungin in Sodium Chloride Injection, 50 mg/50 mL, 100 mg/100 mL and 150 mg/150 mL in single-dose Galaxy containers.

This NDA provides for the use of Micafungin in Sodium Chloride Injection for the following:

- Treatment of candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses in adult and pediatric patients 4 months of age and older for whom appropriate dosing with this formulation can be achieved
- Treatment of candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses ***without*** meningoencephalitis and/or ocular dissemination in pediatric patients younger than 4 months of age for whom appropriate dosing with this formulation can be achieved
- Treatment of esophageal candidiasis in adult and pediatric patients 4 months of age and older for whom appropriate dosing with this formulation can be achieved
- Prophylaxis of *Candida* infections in adult and pediatric patients 4 months of age and older undergoing hematopoietic stem cell transplantation (HSCT) for whom appropriate dosing with this formulation can be achieved

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.

WAIVER OF ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS

We are waiving the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information. This waiver applies to all future supplements containing revised labeling unless we notify you otherwise.

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) 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 via publicly available labeling repositories.

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to the enclosed carton and container labeling as soon as they are available, but no more than 30 days after they are printed. Please submit these labeling electronically according to the guidance for industry *SPL Standard for Content of Labeling Technical Qs & As.* For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 216142**." Approval of this submission by FDA is not required before the labeling is used.

DATING PERIOD

Based on the stability data submitted to date, the expiry dating period for Micafungin in Sodium Chloride Injection shall be 12 months from the date of manufacture when stored in the refrigerator at 2°C to 8°C (36°F to 46°F) in the original carton to protect from light.

PROPRIETARY NAME

If you intend to have a proprietary name for this product, the name and its use in the labeling must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of*

[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.

Proprietary Names. and *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027*.)

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. This application triggered PREA due to a new dosage form.

We are waiving the pediatric studies requirement in patients from birth to less than 4 months of age for the treatment of esophogeal candidiasis and prophylaxis of *Candida* infections in patients undergoing HSCT because necessary studies are impossible or highly impracticable. This is because patients in this age group rarely develop these conditions.

This product is appropriately labeled for use in adult and pediatric patients 4 months and older for the treatment of esophageal candidiasis and prophylaxis of *Candida* infections in patients undergoing HSCT. Therefore, no additional studies are needed in this pediatric group.

This product is appropriately labeled for use for the treatment of candidemia, acute disseminated candidiasis, *Candida* peritonitis and abscesses in all relevant pediatric populations. Therefore, no additional pediatric studies are needed at this time.

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]

As required under 21 CFR 314.81(b)(3)(i), you must submit final promotional materials, and the Prescribing Information, at the time of initial dissemination or publication, accompanied by a Form FDA 2253. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

COMPENDIAL STANDARDS

A drug with a name recognized in the official United States Pharmacopeia or official National Formulary (USP-NF) generally must comply with the compendial standards for strength, quality, and purity, unless the difference in strength, quality, or purity is plainly stated on its label (see FD&C Act § 501(b), 21 USC 351(b)). FDA typically cannot share application-specific information contained in submitted regulatory filings with third parties, which includes USP-NF. To help ensure that a drug continues to comply with compendial standards, application holders may work directly with USP-NF to revise official USP monographs. More information on the USP-NF is available on USP's website[6].

If you have questions, call Sheel Shah, Pharm D, Regulatory Project Manager, at (240) 402-3968.

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
- Carton and Container Labeling

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
09/29/2023 12:00:01 PM