

CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

216109Orig1s000

Trade Name:

Generic or Proper Name: Cefazolin for Injection, 2 gram/vial and 3 gram/vial

Sponsor: Hikma Pharmaceuticals USA, Inc.

Approval Date: October 7, 2022

Indication:

1) Treatment of the following infections caused by susceptible isolates of the designated microorganisms in adult and pediatric patients 1 month of age and older for whom appropriate dosing with this formulation can be achieved:

- Respiratory tract infections
- Urinary tract infections
- Skin and skin structure infections
- Biliary tract infections
- Bone and joint infections
- Genital infections
- Septicemia
- Endocarditis

2) Perioperative prophylaxis in adult patients.

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APPROVAL LETTER



NDA 216109

NDA APPROVAL

Hikma Pharmaceuticals USA, Inc.
Attention: Venkata Sai Tankashala
Associate Director, Regulatory Affairs
2 Esterbrook Lane
Cherry Hill, NJ 08003

Dear Mr. Tankashala:

Please refer to your new drug application (NDA) dated and received December 7, 2021, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA), for Cefazolin for Injection, 2 gram/vial and 3 gram/vial.

This NDA provides for the use of Cefazolin for Injection, 2 gram/vial and 3 gram/vial, for the following indications:

1) Treatment of the following infections caused by susceptible isolates of the designated microorganisms in adult and pediatric patients 1 month of age and older for whom appropriate dosing with this formulation can be achieved:

- Respiratory tract infections
- Urinary tract infections
- Skin and skin structure infections
- Biliary tract infections
- Bone and joint infections
- Genital infections
- Septicemia
- Endocarditis

2) Perioperative prophylaxis in adult patients.

APPROVAL & LABELING

We have completed our review of this application. 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 216109.**” 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 Cefazolin for Injection, USP, 2 gram/vial, and 3 gram/vial, shall be 24 months from the date of manufacture when stored at 20°C to 25°C (68°F to 77°F) [see USP Controlled Room Temperature]. Protect from light.

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

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>.

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.

Because none of these criteria apply to your application, you are exempt from this requirement.

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 Proprietary Names*, and *PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 through 2022*.)

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

REPORTING REQUIREMENTS

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

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>

If you have any questions, call Eva Zuffova, MS, PhD, Regulatory Project Manager, at (301) 796-0697

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
10/07/2022 09:32:33 AM