NDA 208083/S-006, S-007, S-008

SUPPLEMENT APPROVAL

Baxter Healthcare Corporation
Attention: Shruti Patel
Principal Specialist, Regulatory Affairs
One Baxter Parkway
Deerfield, IL 60015

Dear Ms. Patel:

Please refer to your supplemental new drug applications (sNDAs) dated and received March 22, 2021 (S-006), July 6, 2021 (S-007), and October 14, 2021 (S-008), and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Clindamycin Phosphate in Sodium Chloride injection.

These "Changes Being Effected" sNDAs provide for the revision of the drug product title throughout the prescribing information (PI) and the carton and container labeling (S-006), the addition of new safety information regarding acute renal failure (S-007), and updates to the PI with pediatric information in response to our September 14, 2021, supplement request letter in accordance with Section 409I of the Best Pharmaceuticals for Children Act (S-008). Specifically the following sections of the PI have been revised:

PRESCRIBING INFORMATION
The drug product name has been revised from Clindamycin in 0.9% Sodium Chloride Injection to Clindamycin Phosphate in Sodium Chloride injection and this change has been implemented throughout the PI.

1) **HIGHLIGHTS OF PRESCRIBING INFORMATION: RECENT MAJOR CHANGES** and **WARNINGS AND PRECAUTIONS**
2) **FULL PRESCRIBING INFORMATION:**
    a. **DOSAGE AND ADMINISTRATION (2)** section: **Dosage in Pediatric Patients (2.3)** subsection: Text was separated and placed under "Pediatric Patients (1 month of age to 16 years old)" and "Pediatric Patients (less than 1 month)" subheadings and Table 3, "Dosing Regimens for Pediatric Patients with PMA less than or equal to 32 weeks, or greater than 32 weeks to less than or equal to 40 weeks" added.
    b. **DOSAGE FORMS AND STRENGTHS (3)** section: drug product name has been added.
    c. **WARNINGS AND PRECAUTIONS (5)** section: A **Nephrotoxicity (5.3)** subsection has been added.
    d. **ADVERSE REACTIONS (6)** section: **Nephrotoxicity** has been added and the text under the **Renal** subheading revised to "acute kidney injury".

e. **DESCRIPTION (11)** section has been revised to more accurately describe the product.
f. **CLINICAL PHARMACOLOGY (12)** section: Under **Pharmacokinetics (12.3),** Specific Populations**,** a new subsection under *Pharmacokinetics in Pediatric Patients with PMA ≤32 weeks, or > 32 to ≤ 40 weeks* has been added. Additionally, under **Microbiology (12.4)**, Antimicrobial Activity, the nomenclature of "*Propionibacterium acnes"* was updated to "*Cutibacterium acnes."*
g. **HOW SUPPLIED /STORAGE AND HANDLING (16)** section has been updated to reflect drug product identifying characteristics.
h. **PATIENT COUNSELING INFORMATION (17)** section has been reordered, headings added and text updated.

Additionally, editorial updates have been made throughout the PI.

CARTON AND CONTAINER LABELING

The drug name in the product title has been revised from Clindamycin in 0.9% Sodium Chloride Injection to Clindamycin Phosphate in 0.9% Sodium Chloride Injection.

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.

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), 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).

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 *Providing Regulatory Submissions in Electronic Format — Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Final Printed Carton and Container Labeling for approved NDA 208083/S-006, S-007, and S008**." Approval of this submission by FDA is not required before the labeling is used.

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 [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]

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[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.
[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

PATENT LISTING REQUIREMENTS

Pursuant to 21 CFR 314.53(d)(2) and 314.70(f), certain changes to an approved NDA submitted in a supplement require you to submit patent information for listing in the Orange Book upon approval of the supplement. You must submit the patent information required by 21 CFR 314.53(d)(2)(i)(A) through (C) and 314.53(d)(2)(ii)(A) and (C), as applicable, to FDA on Form FDA 3542 within 30 days after the date of approval of the supplement for the patent information to be timely filed (see 21 CFR 314.53(c)(2)(ii)). You also must ensure that any changes to your approved NDA that require the submission of a request to remove patent information from the Orange Book are submitted to FDA at the time of approval of the supplement pursuant to 21 CFR 314.53(d)(2)(ii)(B) and 314.53(f)(2)(iv).

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 Alison Rodgers, Regulatory Project Manager, at 301-796-0797.

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

ENCLOSURE(S):

- 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/

DMITRI IARIKOV
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