



NDA 211415/S-001

## SUPPLEMENT APPROVAL

JDP Therapeutics LLC  
520 Lake Cook Road, Suite 500  
Deerfield, IL 60015

Attention: Jay Ford  
Vice President, Regulatory Affairs

Dear Mr. Ford:

Please refer to your supplemental new drug application (sNDA) dated November 13, 2019, received submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Quzyttir (cetirizine solution) for intravenous injection, 10 mg/mL.

This "Changes Being Effected" supplemental new drug application provides for corrections to the carton and vial container labeling.

This supplemental new drug application provides for revisions to the labeling for Quzyttir (cetirizine solution) for intravenous injection, 10 mg/mL.

### **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 carton/vial labeling.

The carton and vial containers contain the following modifications per the Agency's request:

- The addition of "sodium chloride for tonicity adjustment" (for carton and vial)
- The addition of "excursions permitted to 15°-30°C (59° – 86°F)" (for carton only)

### **CARTON AND CONTAINER LABELING**

We acknowledge your November 13, 2019, submission containing final printed carton and container labeling.

### **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.

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

## **PROMOTIONAL MATERIALS**

You may request advisory comments on proposed introductory advertising and promotional labeling. To do so, submit the following, in triplicate, (1) a cover letter requesting advisory comments, (2) the proposed materials in draft or mock-up form with annotated references, and (3) the Prescribing Information to:

OPDP Regulatory Project Manager  
Food and Drug Administration  
Center for Drug Evaluation and Research  
Office of Prescription Drug Promotion (OPDP)  
5901-B Ammendale Road  
Beltsville, MD 20705-1266

Alternatively, you may submit a request for advisory comments electronically in eCTD format. For more information about submitting promotional materials in eCTD format, see the draft guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs*.<sup>1</sup>

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](http://FDA.gov).<sup>2</sup> Information and Instructions for completing the form can be found at [FDA.gov](http://FDA.gov).<sup>3</sup> For more information about submission of promotional materials to the Office of Prescription Drug Promotion (OPDP), see [FDA.gov](http://FDA.gov).<sup>4</sup>

## **REPORTING REQUIREMENTS**

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

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<sup>1</sup> When final, this guidance will represent the FDA's current thinking on this topic. For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/RegulatoryInformation/Guidances/default.htm>.

<sup>2</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

<sup>3</sup> <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

<sup>4</sup> <http://www.fda.gov/AboutFDA/CentersOffices/CDER/ucm090142.htm>

If you have any questions, call Susan Rhee, Regulatory Project Manager, at 301-796-2402.

Sincerely,

*{See appended electronic signature page}*

Sally Seymour, MD  
Director  
Division of Pulmonary, Allergy, and  
Rheumatology Products  
Office of Drug Evaluation II  
Center for Drug Evaluation and Research

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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.**  
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/s/  
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SALLY M SEYMOUR  
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