



NDA 50-441/S-083  
NDA 50-639/S-041

## SUPPLEMENT APPROVALS

Pharmacia & Upjohn, a subsidiary of Pfizer, Inc.  
Attention: Mikhail Abarshalin  
Senior Manager, Pfizer Global Regulatory Affairs  
235 East 42<sup>nd</sup> Street  
New York, NY 10017-7555

Dear Mr. Abarshalin:

Please refer to your supplemental new drug applications (sNDA) dated January 9, 2020, received January 9, 2020, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

- CLEOCIN PHOSPHATE (clindamycin injection, USP) Solution [NDA 50-441]
- CLEOCIN PHOSPHATE (clindamycin injection in 5% dextrose) IV Solution in GALAXY Plastic Container [NDA 50-639]

These “Changes Being Effected” supplemental new drug applications provide for revisions to the package insert, **CLINICAL PHARMACOLOGY** section, **Specific Populations**, Obese Children and Obese Young Adults subsection, and the **DOSAGE AND ADMINISTRATION** section, **Pediatric patients 1 month of age to 16 years** subsection. These supplemental applications have been submitted in response to the December 10, 2019 Agency Supplement Request Letter related to the requirements of Section 409I of the Public Health Service Act, also known as the Best Pharmaceuticals for Children Act (BPCA).

### **APPROVAL & LABELING**

We have completed our review of these applications and they are 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.<sup>1</sup>

Content of labeling must be identical to the enclosed labeling (Package Insert), 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*.<sup>2</sup>

The SPL will be accessible from publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for these NDAs, 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).

## **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 J. Christopher Davi, MS, Senior Regulatory Project Manager, at (301) 796-0702.

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: Content of Labeling

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

<sup>2</sup> 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>.

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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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