NDA 050564/S-059
NDA 050575/S-048
NDA 050597/S-051
NDA 050720/S-033
NDA 050725/S-035
NDA 050726/S-026

SUPPLEMENT APPROVAL

USAntibiotics, LLC
Attention: Linda K. Robbins
Vice President, Quality and Regulatory Affairs
201 Industrial Drive
Bristol, TN 37620

Dear Ms. Robbins:

Please refer to your supplemental new drug applications (sNDAs) dated and received March 07, 2022, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for the following:

NDA #/SUPPLEMENT #	PRODUCT NAME
NDA 050564/S-059	Augmentin (amoxicillin and clavulanate potassium) tablets, 250 mg/125 mg and 500 mg/125 mg
NDA 050575/S-048	Augmentin (amoxicillin and clavulanate potassium) for oral suspension, 125 mg/31.25 mg per 5 mL and 250 mg/62.5 mg per 5 mL
NDA 050597/S-051	Augmentin (amoxicillin and clavulanate potassium) chewable tablets, 125 mg/31.25 mg and 250 mg/62.5 mg
NDA 050720/S-033	Augmentin (amoxicillin and clavulanate potassium) tablets, 875 mg/125 mg
NDA 050725/S-035	Augmentin (amoxicillin and clavulanate potassium) for oral suspension, 200 mg/28.5 mg per 5 mL and 400 mg/57 mg per 5 mL
NDA 050726/S-026	Augmentin (amoxicillin and clavulanate potassium) chewable tablets, 200 mg/28.5 mg and 400 mg/57 mg

These “Changes Being Effected” sNDAs provide for the revisions to the following sections of the Prescribing Information (PI).

1. HIGHLIGHTS OF PRESCRIBING INFORMATION

A. The **INDICATIONS AND USAGE** section was revised to update the regulatory required statement for the labeling of systemic antibacterial drug products.

B. The **HIGHLIGHTS OF PRESCRIBING INFORMATION** was updated to reflect changes to the **FULL PRESCRIBING INFORMATION** described below as appropriate.

2. FULL PRESCRIBING INFORMATION

A. The **DOSAGE AND ADMINISTRATION** (2) section, **Adult Patients** (2.2), **Pediatric Patients** (2.3), and **Patients with Renal Impairment** (2.4), subsections were revised to be presented in tabular format to improve readability.

B. The **WARNINGS AND PRECAUTIONS** (5) section was revised to include the **Severe Cutaneous Adverse Reactions** (5.2) subsection. The **ADVERSE REACTIONS** (6) section and the **PATIENT COUNSELING INFORMATION** (17) section were updated to reflect these changes.

C. The **ADVERSE REACTIONS** (6) section, **Postmarketing Experience** (6.2) subsection, was revised to include aseptic meningitis under **Central Nervous System**.

D. The **DESCRIPTION** (11) section was updated to add an equivalency statement per *Guidance for Industry: Naming of Drug Products Containing Salt Drug Substances (June 2015)*. In addition, the descriptor “trihydrate” was added throughout the PI to reflect that amoxicillin exists as the trihydrate form in the drug product formulation.

E. The **HOW SUPPLIED/STORAGE AND HANDLING** (16) section was updated to revise the National Drug Codes (NDC).

F. *Clostridium difficile* was replaced with *Clostridioides difficile* throughout the PI.

G. The term antibiotic(s) was replaced with antibacterial(s) throughout the PI.

H. Editorial updates have been made throughout the PI to improve readability, provide clarity and to be consistent with labeling regulatory requirements.

3. CARTON AND CONTAINER LABELING

The container labels and carton labeling have been updated to be consistent with the PI.

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.

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 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

[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.

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 the following approved NDAs: NDA 050564/S-059, NDA 050575/S-048, NDA 050597/S-051, NDA 050720/S-033, NDA 050725/S-035, and NDA 050726/S-026.** Approval of these submissions by FDA is not required before the labeling is used.

All promotional materials that include representations about your drug product must be promptly revised to be consistent with the labeling changes approved in this supplement, including any new safety- related information [21 CFR 314.70(a)(4)]. The revisions in your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 314.70(a)(4).

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 Kristine Park, PhD, RAC, Senior Regulatory Health Project Manager, at (301) 796-0471.

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

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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