NDA 050542/S-031
NDA 050754/S-021
NDA 050760/S-021
NDA 050761/S-018

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 July 19, 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 050542/S-031	Amoxil (amoxicillin) chewable tablets, 125 mg and 250 mg
NDA 050754/S-021	Amoxil (amoxicillin) tablets, 500 mg and 875 mg
NDA 050760/S-021	Amoxil (amoxicillin) for oral suspension, 200 mg/5 mL and 400 mg/5 mL
NDA 050761/S-018	Amoxil (amoxicillin) chewable tablets, 200 mg and 400 mg

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

1. HIGHLIGHTS OF PRESCRIBING INFORMATION

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

Updated to reflect changes to the **FULL PRESCRIBING INFORMATION** described below as appropriate

2. FULL PRESCRIBING INFORMATION:

The **DOSAGE AND ADMINISTRATION** (2) section, was revised to present the dosage and administration information for adult patients, pediatric patients and adult and pediatric patients with renal impairment in tabular format to improve readability.

The **DOSAGE FORMS AND STRENGTHS** (3) section and the **DESCRIPTION (11)** section were revised to include the Chewable Tablets.

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

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

The **CLINICAL PHARMACOLOGY (12)** section, **Microbiology (12.4)** subsection was revised to update labeling requirements for susceptibility test interpretive criteria for prescription systemic antibacterial and antiungal drugs.

The **HOW SUPPLIED/STORAGE AND HANDLING (16**) section was updated to revise the National Drug Codes and to include Chewable Tablets.

Additional Changes Include:
Clostridium difficile was replaced with *Clostridioides difficile* throughout the PI.

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 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 050542/S-031,**

[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.

NDA 050754/S-021, NDA 050760/S-021, and NDA 050761/S-018". Approval of these submissions 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]

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).

[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

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 Regulatoy 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
Office of New Drugs
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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