

NDA 213036/S-008

## SUPPLEMENT APPROVAL

Amivas, Inc.  
c/o Fast-Track Drugs and Biologics, LLC  
Attention: Janet H. Ransom, PhD  
President  
20010 Fisher Avenue, Suite G  
Poolesville, MD 20837

Dear Dr. Ransom:

Please refer to your supplemental new drug application (sNDA) dated and received June 6, 2024, and your amendments, submitted pursuant to section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Artesunate for Injection.

This “Changes Being Effectuated” sNDA provides for Carton labeling revisions that include:

1. A red box containing the Attention statement, revised to “Attention: Retain vials in carton until time of use. Artesunate and Diluent vials must be protected from light and kept together for Preparation and Administration.”
2. The format of the expiry date is updated to “YYYY-MMM-DD” to be compliant with FDA Guidance for Industry: *Product Identifiers Under the Drug Supply Chain Security Act - Questions and Answers (June 2021)*.
3. A taper evident seal will also be placed on the end of the carton where the flap is inserted.

### **APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

### **CARTON AND CONTAINER LABELING**

Submit final printed carton and container labeling that are identical to the enclosed carton 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 213036/S-008.**” Approval of this submission by FDA is not required before the labeling is used.

## **PROPRIETARY NAME**

If you intend to have a proprietary name for this product, the name and its use in the labeling must conform to the specifications under 21 CFR 201.10 and 201.15. We recommend that you submit a request for a proposed proprietary name review. (See the guidance for industry *Contents of a Complete Submission for the Evaluation of Proprietary Names and PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 through 2027*.)

## **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, contact Gregory DiBernardo, Chief, Regulatory Project Management Staff, at (301) 796-4063 or [gregory.dibernardo@fda.hhs.gov](mailto:gregory.dibernardo@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Dmitri Iarikov, MD, PhD  
Deputy Director  
Division of Anti-Infectives  
Office of Infectious Diseases  
Office of New Drug  
Center for Drug Evaluation and Research

## **ENCLOSURE:**

- Carton Labeling

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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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