

NDA 050608/S-056

SUPPLEMENT APPROVAL

Pfizer, Inc.
Attention: Mikhail Abarshalin
Director, Global Regulatory Sciences
66 Hudson Boulevard East
New York, NY 10001

Dear Mikhail Abarshalin:

Please refer to your supplemental new drug application (sNDA) dated and received July 25, 2024, and your amendments dated December 13, 2024, and January 10, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Unasyn (ampicillin sodium/sulbactam sodium) Injection.

This “Changes Being Effected” sNDA provides for the following updates to the prescribing information (PI) for Unasyn and Unasyn Pharmacy Bulk Package:

Unasyn and Unasyn Pharmacy Bulk Package

- The list of organisms in the **MICROBIOLOGY** section was updated to reflect the current names as follows: *Enterococcus faecalis*, *Streptococcus pneumoniae*, and *Moraxella catarrhalis*. *Streptococcus faecalis* and *D. pneumoniae* were removed.
- The **WARNINGS** section, **Severe Cutaneous Adverse Reactions** subsection, was updated to include information on drug reaction with eosinophilia and systemic symptoms (DRESS).
- In the **ADVERSE REACTIONS** section:
 - Arthralgia was added to the **Musculoskeletal and Connective Tissue Disorders** subsection;
 - Drug reaction with eosinophilia and systemic symptoms (DRESS) was added to the **Skin and Subcutaneous Tissue Disorders** subsection.

Additionally, the document code and the revision date at the end of the PI were updated and minor editorial changes were made throughout the PI. Additionally, the following edit was made to the PI for the **Pharmacy Bulk Package**:

- Addition of the following statement to the **DESCRIPTION** section regarding the quantitative information of sodium: “Each 1.5 g of UNASYN (1 g ampicillin as the sodium salt plus 0.5 g sulbactam as the sodium salt) parenteral contains approximately 115 mg (5 mEq) of sodium.”

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.

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 (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 this NDA, 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 this supplemental application, 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).

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>.

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, please contact Jennifer Grant, MSHS, Regulatory Project Manager, at jennifer.grant@fda.hhs.gov or (301) 796-0480.

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 for Unasyn for injection
 - Prescribing Information for Unasyn Pharmacy Bulk Package

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
01/31/2025 02:04:17 PM