



NDA 211155/S-008

SUPPLEMENT APPROVAL

Secura Bio, Inc.
Attention: Kate Rizzo
Global Regulatory Affairs Advisor
1995 Village Center Circle, Suite 128
Las Vegas, NV 89134

Dear Ms. Rizzo:

Please refer to your supplemental new drug application (sNDA) dated and received January 29, 2025, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Copiktra (duvelisib) capsules.

This Prior Approval sNDA provides for proposed modifications to the approved Copiktra (duvelisib) risk evaluation and mitigation strategy (REMS).

We have completed our review of this supplemental application, as amended. It is approved effective on the date of this letter.

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for Copiktra (duvelisib) was originally approved on September 24, 2018, and the most recent REMS modification was approved on February 2, 2022. The REMS consists of a communication plan and a timetable for submission of assessments of the REMS.

Your proposed modification to the REMS includes labeling changes approved on July 26, 2024. The labeling changes included a new Limitation of Use statement and changes to the Boxed Warning and Warnings and Precautions.

Your proposed modified REMS, submitted on January 29, 2025, amended and appended to this letter, is approved.

The timetable for submission of assessments of the REMS must be revised to submit REMS Assessments to FDA on September 24, 2025, and 1 year from the date of the REMS modification approval (July 28, 2025).

The revised REMS assessment plan must include, but is not limited to, the following:

1. An evaluation of healthcare providers' awareness and understanding of the risks of fatal and/or serious toxicities associated with the use of Copiktra including:

- a. Treatment-related mortality
 - b. Infections
 - c. Diarrhea or colitis
 - d. Cutaneous reactions
 - e. Pneumonitis
2. A description of the implementation of the communication plan (current reporting period and cumulative), including:
 - a. Number of HCPs targeted by the REMS
 - b. Number and name of professional societies targeted by the REMS
 - c. Number of REMS letters sent to healthcare providers and professional societies via email and via mail, and the dates the letters were sent
 - i. For letters sent via email,
 - 1) Include the number of letters successfully delivered and number of email letters opened by the recipients.
 - 2) Include the number of letters sent via mail because, the emailed letter was undeliverable or the email unknown.
 - ii. For letters sent by mail, include numbers of returned or undeliverable letters
 - d. The sources of the recipient lists
 - e. Names of professional societies that distributed the DHCP REMS Letters or content of the letter to their membership and dates distributed
 - f. Names and dates of scientific meetings and materials displayed at each
 - g. Date the REMS materials were available and updated through the website
 - h. Number of unique site visits to the Copiktra REMS website during each assessment period
 - i. Number of Fact Sheets disseminated by field-based sales and medical representatives during initial and/or follow-up details/visits with healthcare providers
 - j. Number of Patient Safety Wallet Cards disseminated by field-based sales and medical representatives during visits with healthcare providers
3. The requirements for assessments of an approved REMS under section 505-1(g)(3) include with respect to each goal included in the strategy, an assessment of the extent to which the approved strategy, including each element of the strategy, is meeting the goal or whether one or more such goals or such elements should be modified.

We remind you that in addition to the REMS assessments submitted according to the timetable in the approved REMS, you must include an adequate rationale to support a proposed REMS modification for the addition, modification, or removal of any goal or element of the REMS, as described in section 505-1(g)(4) of the FDCA.

We also remind you that you must submit a REMS assessment when you submit a supplemental application for a new indication for use, as described in section 505-1(g)(2)(A) of the FDCA. This assessment should include:

- a) An evaluation of how the benefit-risk profile will or will not change with the new indication.
- b) A determination of the implications of a change in the benefit-risk profile for the current REMS.
- c) *If the new indication for use introduces unexpected risks:* A description of those risks and an evaluation of whether those risks can be appropriately managed with the currently approved REMS.
- d) *If a REMS assessment was submitted in the 18 months prior to submission of the supplemental application for a new indication for use:* A statement about whether the REMS was meeting its goals at the time of that last assessment and if any modifications of the REMS have been proposed since that assessment.
- e) *If a REMS assessment has not been submitted in the 18 months prior to submission of the supplemental application for a new indication for use:* Provision of as many of the currently listed assessment plan items as is feasible.
- f) *If you propose a REMS modification based on a change in the benefit-risk profile or because of the new indication of use, submit an adequate rationale to support the modification, including:* Provision of the reason(s) why the proposed REMS modification is necessary, the potential effect on the serious risk(s) for which the REMS was required, on patient access to the drug, and/or on the burden on the health care delivery system; and other appropriate evidence or data to support the proposed change. Additionally, include any changes to the assessment plan necessary to assess the proposed modified REMS. *If you are not proposing REMS modifications,* provide a rationale for why the REMS does not need to be modified.

If the assessment instruments and methodology for your REMS assessments are not included in the REMS supporting document, or if you propose changes to the submitted assessment instruments or methodology, you should update the REMS supporting document to include specific assessment instrument and methodology information at least 90 days before the assessments will be conducted. Updates to the REMS supporting document may be included in a new document that references previous REMS supporting document submission(s) for unchanged portions. Alternatively, updates may be made by modifying the complete previous REMS supporting document, with all changes marked and highlighted.

Prominently identify the submission containing the assessment instruments and methodology with the following wording in bold capital letters at the top of the first page of the submission:

NDA 211155 REMS ASSESSMENT METHODOLOGY

(insert concise description of content in bold capital letters, e.g.,

ASSESSMENT METHODOLOGY, PROTOCOL, SURVEY METHODOLOGIES, AUDIT PLAN, DRUG USE STUDY)

An authorized generic drug under this NDA must have an approved REMS prior to marketing. Should you decide to market, sell, or distribute an authorized generic drug under this NDA, contact us to discuss what will be required in the authorized generic drug REMS submission.

Prominently identify any submission containing the REMS assessments or proposed modifications of the REMS with the following wording in bold capital letters at the top of the first page of the submission as appropriate:

NDA 211155 REMS ASSESSMENT

or

**NEW SUPPLEMENT FOR NDA 211155/S-000
CHANGES BEING EFFECTED IN 30 DAYS
PROPOSED MINOR REMS MODIFICATION**

or

**NEW SUPPLEMENT FOR NDA 211155/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED MAJOR REMS MODIFICATION**

or

**NEW SUPPLEMENT FOR NDA 211155/S-000
PRIOR APPROVAL SUPPLEMENT
PROPOSED REMS MODIFICATIONS DUE TO SAFETY LABELING
CHANGES SUBMITTED IN SUPPLEMENT XXX**

or

**NEW SUPPLEMENT (NEW INDICATION FOR USE)
FOR NDA 211155/S-000
REMS ASSESSMENT
PROPOSED REMS MODIFICATION (if included)**

Should you choose to submit a REMS revision, prominently identify the submission containing the REMS revisions with the following wording in bold capital letters at the top of the first page of the submission:

REMS REVISIONS FOR NDA 211155

To facilitate review of your submission, we request that you submit your proposed modified REMS and other REMS-related materials in Microsoft Word format. If certain documents, such as enrollment forms, or website screenshots are only in PDF format, they may be submitted as such, but Word format is preferred.

SUBMISSION OF REMS DOCUMENT IN SPL FORMAT

As soon as possible, but no later than 14 days from the date of this letter, submit the REMS document in Structured Product Labeling (SPL) format using the FDA automated drug registration and listing system (eLIST). Content of the REMS document must be identical to the approved REMS document. The SPL will be publicly available.

Information on submitting REMS in SPL format may be found in the guidance for industry *Providing Regulatory Submission in Electronic Format – Content of the Risk Evaluation and Mitigation Strategies Document Using Structured Product Labeling*.

For more information on submitting REMS in SPL format, please email FDAREMSwebsite@fda.hhs.gov.

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because none of these criteria apply to your supplemental application, you are exempt from this requirement.

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 Jessica Kim, Safety Regulatory Project Manager, at 240-402-0883, or via email at Jessica.Kim1@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Shan M. Pradhan, M.D.
Associate Director for Safety
Office of Oncologic Diseases
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE(S):

- REMS

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/

SHAN PRADHAN
07/28/2025 10:43:35 AM