



Our STN: BL 125806/0

COMPLETE RESPONSE

JUNE 14, 2024

Rocket Pharmaceuticals, Inc.
Attention: Sanchali Kasbekar, PharmD
9 Cedarbrook Drive
Cranbury, NJ 08512

Dear Dr. Kasbekar:

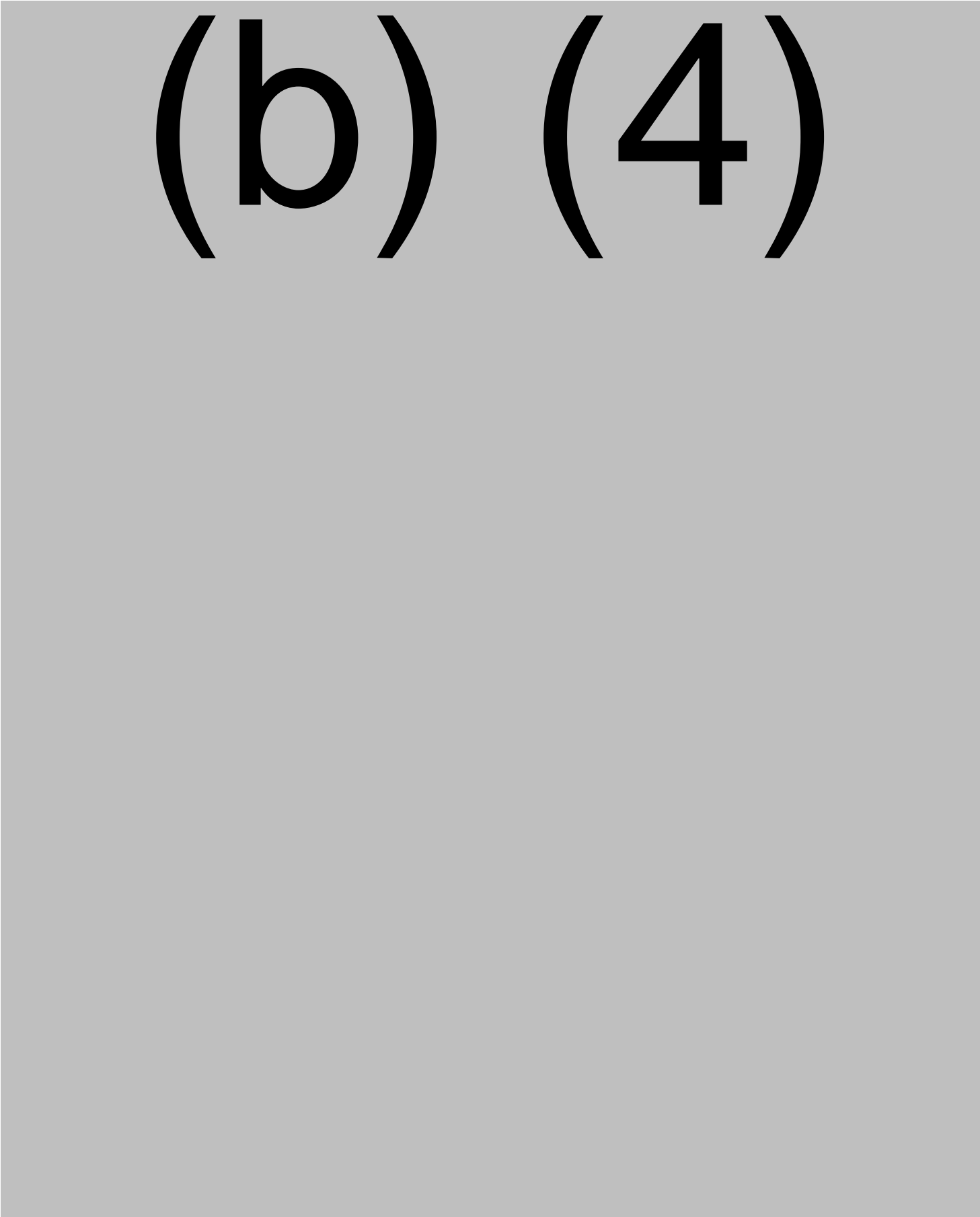
Please refer to your Biologics License Application (b) (4), for
marinetegrane autotemcel manufactured for Rocket Pharmaceuticals, Inc at the
(b) (4) (b) (4)

We have completed our review of all the submissions you have made relating to this
BLA. After our complete review, we have concluded that we cannot grant final approval
because of the deficiencies outlined below.

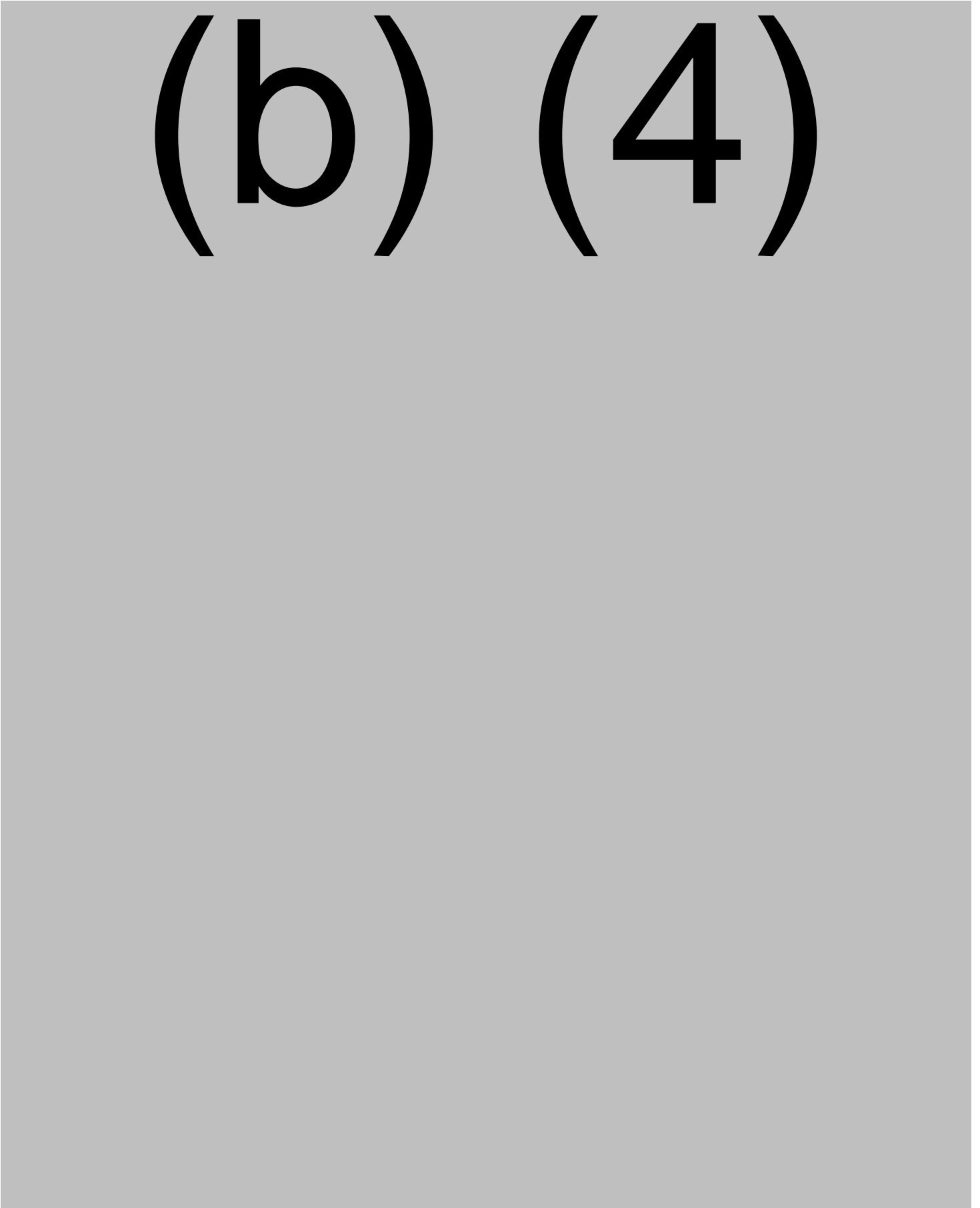
Chemistry, Manufacturing, and Controls

(b) (4)

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LABELING

12. We reserve comment on the proposed labeling until the application is otherwise acceptable. We may have comments when we see the proposed final labeling.

ADDITIONAL COMMENTS

Chemistry, Manufacturing, And Controls (CMC)

(b) (4)

(b) (4)

19. During the interactive review of this BLA, there were many revisions and corrections that were confirmed in your responses to information requests but that were not formally updated in the documents within the BLA. These include, , typographical errors in method SOPs, data and/or calculation errors reported in validation report

tables, and changes to SSC, AC, or validated assay ranges that were agreed upon during the review cycle. These changes must be appropriately corrected within the BLA submission, and revisions to documents or data must be adequately documented with red-lined versions included in tandem. Please submit all updated, corrected, or revised information discussed during the review cycle with your resubmission. Please also provide a tabulated summary of all changes made, including the affected document or module, nature of the updated information, the information request and amendment number within which the change was discussed, and any other pertinent information that may facilitate review of the revised documents.

Within one year after the date of this letter, you are required to resubmit or withdraw the application (21 CFR 601.3(b)). If you do not take one of these actions, we may consider your lack of response a request to withdraw the application under 21 CFR 601.3(c). You may also request an extension of time in which to resubmit the application. A resubmission must fully address all the deficiencies listed. A partial response to this letter will not be processed as a resubmission and will not start a new review cycle.

You may request a meeting or teleconference with us to discuss the steps necessary for approval.

Please submit your meeting request as described in the guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products* at <https://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM590547.pdf>, and CBER's SOPP 8101.1 *Scheduling and Conduct of Regulatory Review Meetings with Sponsors and Applicants* at <http://www.fda.gov/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/ProceduresSOPPs/ucm079448.htm>.

If you have any questions regarding the above, please contact the (b) (4)

Sincerely,

(b) (4)

Center for Biologics Evaluation and Research