Our STN: BL 125745/0

COMPLETE RESPONSE
January 15, 2025

Atara Biotherapeutics, Inc.
Attention: Jim Sesic
2380 Conejo Spectrum Street, Suite 200
Thousand Oaks, CA 91320

Dear Jim Sesic:

Please refer to your Biologics License Application (b) (4), for tabelecleucel(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 deficiency outlined below.

Chemistry, Manufacturing, and Controls

1. Corrections to FDA's inspectional observations issued to (b) (4) at the conclusion of the pre-license inspection conducted between (b) (4) of the facility located in (b) (4) have not been adequately demonstrated, may require additional review during a follow-up inspection, and, therefore, remain unresolved. At this time, CBER cannot determine pursuant to 21 CFR 601.20(a) and (d) that the product and establishment listed in the BLA comply with the standards established in the BLA and the requirements prescribed in FDA regulations, including current good manufacturing practice requirements.

Labeling

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

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