



BLA 761451

COMPLETE RESPONSE

AstraZeneca Pharmaceuticals LP
Attention: Osamah Al-Qaysi
Associate Regulatory Affairs Director
One MedImmune Way
Gaithersburg, MD 20878

Dear Osamah Al-Qaysi:

Please refer to your biologics license application (BLA) dated and received

(b) (4) for
anifrolumab.

We have completed our review of this application and have determined that we cannot approve this application in its present form. We have described our reasons for this action below and, where possible, our recommendations to address these issues.

The amendment dated (b) (4), with the corrected interim dataset for study D3465C00001 was submitted late in the review cycle. This amendment identifies critical data quality issues that affect key analyses, including the primary endpoint, indicating specific deficiencies related to errors in the data submitted at the beginning of the review cycle. You may submit the correct study data with supporting datasets and corrected labeling for consideration in a new review cycle.

Clinical/Statistical

1. Provide the following information for Study D3465C00001:
 - a. Corrected interim Clinical Study Report.
 - b. Corrected ADaM and SDTM datasets based on the interim analysis, corresponding to any datasets submitted in the original submission, as well as corresponding to datasets that were submitted as a part of subsequent responses to Information Requests (IRs), such as adeff710 and adice710 datasets submitted on (b) (4).
 - c. If any tables/figures that you submitted as parts of responses to IRs were impacted, corrected versions of these tables/figures should be also submitted.
 - d. Corrected SAS programs.
 - e. Final ADaM and SDTM datasets based on the final analysis.

2. Address the following:
 - a. Provide a detailed discussion of what led to the errors in the locked database being found.
 - b. Clarify whether the SDTM data remain unchanged.
 - c. Provide a subject-level listing of all the changes in all the datasets along with the reason for each change.

OTHER

Within one year after the date of this letter, you are required to resubmit or take other actions available under 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 in this letter and should be clearly marked with "**RESUBMISSION**" in large font, bolded type at the beginning of the cover letter of the submission. The cover letter should clearly state that you consider this resubmission a complete response to the deficiencies outlined in this letter. 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 what steps you need to take before the application may be approved. If you wish to have such a meeting, submit your meeting request as described in the draft guidance for industry *Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products*.

The product may not be legally marketed until you have been notified in writing that this application is approved.

If you have any questions, contact

(b) (4)

Sincerely,

{See appended electronic signature page}

(b) (4)

Center for Drug Evaluation and Research

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/

(b) (4)

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