CENTER FOR DRUG EVALUATION AND RESEARCH

Approval Package for:

APPLICATION NUMBER:

022542Orig1s008

Trade Name:	VIOKACE
Generic or Proper Name:	(pancrelipase)
Sponsor:	VIOKACE LLC.
Approval Date:	October 21, 2022
Indication:	VIOKACE® is a combination of porcine-derived lipases, proteases, and amylases. VIOKACE, in combination with a proton pump inhibitor, is indicated in adults for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy.

CENTER FOR DRUG EVALUATION AND RESEARCH

022542Orig1s008

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Reviews / Information Included in this NDA Review.

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APPLICATION NUMBER:

022542Orig1s008

APPROVAL LETTER

BLA 022542/S-008

APPROVAL LETTER

Aimmune LLC
Attention: Vandana Garikipati, PhD
8000 Marina Boulevard
Suite 300
Brisbane, CA 94005

Dear Dr. Garikipati:

Please refer to your supplemental biologics license application (sBLA) dated and received April 22, 2022, submitted under section 351(a) of the Public Health Service Act for Viokace (pancrelipase) tablet.

This "Changes Being Effected in 0 days" sBLA provides for revisions submitted to the referenced DMF (b) (4) pertaining to modifications to the qPCR methods for virus testing.

APPROVAL

We have completed our review of this sBLA. This supplement is approved.

This information will be included in your biologics license application file.

If you have any questions, call Melinda Bauerlien, Senior Regulatory Business Process Manager, at (301) 796 - 0906.

Sincerely,

{See appended electronic signature page}

Susan Kirshner, Ph.D.
Director
Division of Biotechnology Review and Research III
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Susan Kirshner

Digitally signed by Susan Kirshner
Date: 10/21/2022 02:43:42PM
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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022542Orig1s008

PRODUCT QUALITY REVIEW(S)

Memorandum of Assessment:

Submission Tracking Number (STN):	BLA 022542 SUPPL-8 (seq 0100)
Subject:	CBE-0: Modification to qPCR methods for virus testing in referenced DMF (b) (4)
Date Received:	April 22, 2022
Assessment/Revision Date:	October 21, 2022
Primary Assessor:	Tracy Denison, Ph.D., OBP/DBRR-III
Secondary Assessor:	Massod Rahimi, Ph.D., OBP/DBRR-III
RBPM:	Melinda Bauerlien
Consults:	None
Applicant:	Aimmune Therapeutics, Inc.
Product:	Viokace (pancrelipase), combination of porcine-derived lipases, proteases, and amylases
Indication:	In combination with a proton pump inhibitor for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy
Filing Action Date:	June 21, 2022
Action Due Date:	October 22, 2022

1. Summary Basis of Recommendation:

a. Recommendation: I recommend approval of this supplement.

b. Justification: Refer to the assessment memo for DMF (b) (4) Amendment received December 17, 2021 in DARRTS (uploaded on October 21, 2022).

2. Suggested Language for Action Letter:

Please refer to your Supplemental Biologics License Application (sBLA) dated and received April 22, 2022, submitted under section 351(a) of the Public Health Service Act for Viokace (pancrelipase) tablets.

This "Changes Being Effected in 0 Days" sBLA provides for revisions submitted to the referenced DMF (b) (4) pertaining to modifications to the qPCR methods for virus testing.

We have completed our review of this sBLA. This supplement is approved.

3. Assessment:

The assessment of the relevant DMF (b) (4) amendment dated December 17, 2021, and the assessment of related information request responses is located in DARRTS, uploaded by Tracy Denison on October 21, 2022.

4. Assessment Conclusions:

The CBE-0 is approvable as the cross-reference information in the DMF is found adequate in the context of this BLA supplement.

5. Future Inspection Items: None.

APPEARS THIS WAY ON ORIGINAL

Tracy Denison

Digitally signed by Tracy Denison
Date: 10/21/2022 02:16:14PM
GUID: 53725fbb0005b7b3ff10aa8a0ade1295

Massod Rahimi

Digitally signed by Massod Rahimi
Date: 10/21/2022 02:30:53PM
GUID: 542e18bc0004452462912a2ae67666a9

Product Quality (Biotechnology)
Filing Assessment for BLA/NDA supplements

Application Type (BLA or NDA): BLA
Submission Number and Type: 22542/8 CBE-0
Stamp Date: 4/22/22
Filing Date: 6/21/22
Goal date: 10/22/22
Established/Proper Name: Viokace (pancrelipase)
Applicant: Aimmune LLC
Indication: In combination with a proton pump inhibitor for the treatment of exocrine pancreatic insufficiency due to chronic pancreatitis or pancreatectomy

Initial overview of the BLA/NDA Supplement for filing:

i) Brief description of the change(s) proposed:

The supplement provides for modification to the quantitative polymerase chain reaction (qPCR) methods used for virus detection. The update occurs via a submission to the referenced DMF (b) (4) (SN0015, submitted 12/17/2021), and a letter of authorization is provided to reference to DMF. The DMF amendment referenced provides updated section 3.2.S.4.2 describing the analytical method modifications. Other updates to sections in the DMF are also provided regarding batch analysis, stability, and adventitious agent safety evaluation.

ii) The following was submitted in support of the change (check all that apply):

☒	A detailed description of the proposed change.
☒	Identification of the product(s) involved.
☒	A description of the manufacturing site(s) or area(s) affected.
☒	A description of the methods used and studies performed to evaluate the effect of the change on the identity, strength, quality, purity, or potency of the product as they may relate to the safety or effectiveness of the product.
☒	The data derived from any studies conducted.
☐	Relevant validation protocols and data.
☐	A reference list of relevant standard operating procedures (SOPs)
☒	A reference to DMF(s)
☐	A statement for GMP inspection of the facility

Is the Product Quality section of the supplement fileable? ☒ Yes; ☐ No

If the supplement is not fileable from the product quality perspective, identify potential filing issue(s) and provide comments to be sent to the applicant.

If fillable, identify and list any potential assessment issues, not including the filing comments to be forwarded to the Applicant for the 74-day letter.

APPEARS THIS WAY ON ORIGINAL

Tracy Denison

Digitally signed by Tracy Denison
Date: 6/16/2022 02:21:01PM
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Massod Rahimi

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Date: 6/16/2022 03:35:15PM
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CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

022542Orig1s008

ADMINISTRATIVE AND CORRESPONDENCE DOCUMENTS

BLA 022542/S-008

CBE CMC SUPPLEMENT - ACKNOWLEDGEMENT

Aimmune LLC
Attention: Vandana Garikipati, PhD
8000 Marina Boulevard
Suite 300
Brisbane, CA 94005

Dear Dr. Garikipati:[1]

We have received your Supplemental Biologics License Application (sBLA) submitted under section 351(a) of the Public Health Service Act for the following:

BLA SUPPLEMENT NUMBER:	022542/S-008
PRODUCT NAME:	Viokace (Pancrelipase) Tablet
DATE OF SUBMISSION:	April 22, 2022
DATE OF RECEIPT:	April 22, 2022

This acknowledgment recognizes that your submission is in the form of a **"Supplement--Changes Being Effected"** as described under 21 CFR 601.12(c)(5). Continued use of the changes is subject to final approval of this supplement.

This supplemental application, submitted as a “Changes Being Effected” supplement, proposes the following change: to notify the Agency of a quality amendment submitted to the drug substance manufacturer’s [redacted] (b) (4) Drug Master File (DMF) (b) (4) regarding the addition of an alternate analytical procedure used for viral infectivity testing..

Unless we notify you within 60 days of the receipt date that the application is not sufficiently complete to permit a substantive review, we will file the application on June 21, 2022, in accordance with 21 CFR 601.2(a).

If the application is filed, the user fee goal date will be October 22, 2022.

This acknowledgment does not mean that this supplement has been approved nor does it represent any evaluation of the adequacy of the data submitted. Following a review of this submission, we shall advise you in writing as to what action has been taken and request additional information if needed.

If you have any questions, please contact Melinda Bauerlien, Regulatory Business Process Manager, at (301) 796 - 0906 or melinda.bauerlien@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Melinda Bauerlien, MS
Regulatory Business Process Manager
Division of Regulatory and Business Process Management I (DRBPMI)
Office of Program and Regulatory Operations
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Melinda Bauerlien

Digitally signed by Melinda Bauerlien
Date: 4/27/2022 11:38:22AM
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