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(b) (6) ANALYTICAL METHOD REVIEW MEMO

To The file: STN 125869/0

From (b) (6)

Through (b) (6)

Product (b) (4)

Applicant Moderna TX, INC (Moderna)

Subject Review of Bioburden, Sterility, and Endotoxin Analytical Methods used for Influenza Vaccine, mRNA (MFLUSIVA, mRNA-1010)

Recommendation: Approval

Executive Summary

The bioburden, sterility, and bacterial endotoxin analytical methods used for testing and release of mRNA-1010 and the associated analytic method qualifications, were reviewed. The assays were adequately described and shown to be suitable for their intended purpose.

Conclusion: The analytical methods and their qualifications reviewed for MFLUSIVA (b) (4) drug product (DP) were found to be adequate for their intended use.

Documents Reviewed

Information in the original submission that describe control of (b) (4) DP (3.2.S.4 and 3.2.P.5, respectively), including descriptions of (b) (4) DP specifications, analytical procedures of (b) (4) DP, and the qualification of these analytical procedures were reviewed. In addition, the responses to CBER's information requests (IRs) received on April 03, 2026 (Amendment # 31) and June 02, 2026 (Amendment # 67), were also reviewed.

(b) (4)

2. Sterility (DP)

Introduction

Sterility testing is performed on mRNA-1010 DP at (b) (4)

Moderna (b) (4) (Moderna (b) (4)

. Acceptance criteria of 'No Growth' must be met for the lot release of mRNA-1010 DP.

Method

(b) (4)



The original submission lacked complete qualification reports. Therefore, an IR was sent requesting missing information and the response received on April 03, 2026 (Amendment # 31), which was determined to be acceptable and detailed below.

Sterility Test Qualification for DP

(b) (4) qualified their (b) (4) method for mRNA-1010 DP by performing B&F qualification studies to determine if the method is suitable under the actual conditions of use. The test performed using (b) (4) indicator microorganisms

(b) (4)



on (b) (4) batches (b) (4) of mRNA-1010 DP.

(b) (4)



Moderna (b) (4) qualified their (b) (4) method using (b) (4) lots (i.e., (b) (4)) of DP. The test was performed using the same procedure as (b) (4) described above.

(b) (4)



(b) (4)

Conclusion

The method suitability tests were performed and compliant with (b) (4) and the test results indicate there is no product interference from DP test samples, thus indicating the (b) (4) test method is appropriate under the actual conditions of use.

3. Endotoxin (b) (4) DP)

Introduction

Endotoxin testing is performed on the (b) (4) at ModernaTX (b) (4) is also tested at (b) (4). mRNA-1010 DP endotoxin testing in (b) (4) and Moderna (b) (4). The acceptance criteria: (b) (4) mRNA-1010 DP is (b) (4)

Method

(b) (4)

(b) (4)

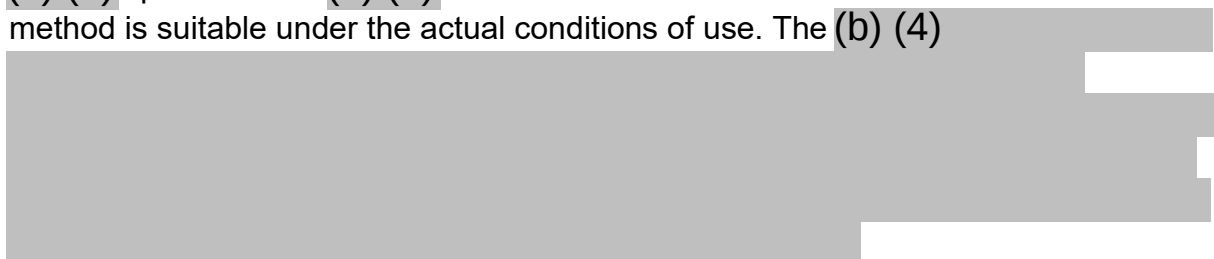
The original qualification reports for the endotoxin tests lacked sufficient information to complete the review. Therefore, IRs were sent requesting data and clarification to fulfill these deficiencies. Responses were received on April 03, 2026 (Amendment # 31) and June 2, 2026 (Amendment # 67), which were determined to be acceptable and explained below.

(b) (4)



(b) (4) Qualification for DP

(b) (4) qualified their (b) (4) method for mRNA-1010 DP to determine if the method is suitable under the actual conditions of use. The (b) (4)



(b) (4)



(b) (4)



Based on the results and to align with the global strategy for endotoxin testing, (b) (4) was selected for release testing for mRNA-1010 DP and CBER found that acceptable.

Conclusion

The method suitability tests were performed and in compliance with (b) (4). In addition, testing sites were qualified for their (b) (4) endotoxin test or because the site was qualified to perform the same test for a similar product in an approved BLA. Therefore, CBER determined their (b) (4) test methods are appropriate under the actual conditions of use.