DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	5/22/2026-5/29/2026* FEI NUMBER 3007222218

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stephen M. Blash, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Biomedical Research Models, Inc. d/b/a Biomere	57 Union St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Worcester, MA 01608-1114	Nonclinical Laboratory

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:
The following observations relate to review of study records specific to non-clinical study protocol (b)(4): Study to Evaluate the Safety and Efficacy of (b)(4) (b)(4).

OBSERVATION 1

The study director failed to assure that all experimental data, including observations of unanticipated responses of the test system, were accurately recorded and verified.

Specifically,

A. The Pathology Report documents (b)(4) exhibited evidence of residual (b)(4) in tissues collected from within the (b)(4) site area at necropsy per protocol amendment 9; however, raw data documents tissue was collected from within the (b)(4) site area for only (b)(4) animals.

B. The Pathology Report documents evidence of residual (b)(4) tissue was observed in the tissues collected from the (b)(4) sites for Animals (b)(4); however, there is no documentation in raw data that tissue was collected from within the (b)(4) site area at necropsy for these animals.

1. The Pathology Report documents residual (b)(4) tissue with (b)(4) involution for Animal (b)(4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Agata E Libera, Investigator Kent A Conforti, Investigator	X Agata E Libera Investigator Signed By: AGATA E. LIBERA -S Date Signed: 05-29-2026 09:31:12	5/29/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	5/22/2026-5/29/2026* FEI NUMBER 3007222218

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Stephen M. Blash, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Biomedical Research Models, Inc. d/b/a Biomere	57 Union St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Worcester, MA 01608-1114	Nonclinical Laboratory

The Microscopic Raw Data documents Slides (b)(4) were examined with a finding of (b)(4) (b)(4) involution, but does not specify which slide the finding pertains to. The Histology Processing Record documents Block/Slide (b)(4) was collected on Day (b)(4) The Histology Processing Record documents Block/Slide (b)(4) tissue is (b)(4) collected at Day (b)(4) The Study Director stated (b)(4) is not collected during Day (b)(4) surgery and surgical records do not document collection of (b)(4) at Day (b)(4).

2. The Pathology Report documents residual (b)(4) tissue with (b)(4) involution for Animal (b)(4). The Microscopic Raw Data documents Slide (b)(4) was examined with a finding of (b)(4) involution. The Histology Processing Record documents Block/Slide (b)(4) was (b)(4) collected on Day (b)(4).

3. The Pathology Report documents residual (b)(4) tissue with (b)(4) involution for Animal (b)(4). The Microscopic Raw Data documents Slide (b)(4) was examined with a finding of (b)(4) involution. The Histology Processing Record documents Slide (b)(4) was (b)(4) collected on Day (b)(4).

C. The Pathology Report documents evidence of residual (b)(4) tissue with (b)(4) involution was observed in the tissue collected from the (b)(4) site for Animal (b)(4). The Microscopic Raw Data documents Slide (b)(4) was examined with an observation of (b)(4) involution; however, the Histology Processing Record documents Block/Slide (b)(4) is the (b)(4) collected on Day (b)(4) not tissue collected from the (b)(4) site during necropsy.

D. The Pathology Report documents evidence of residual (b)(4) tissue with (b)(4) involution was observed in the tissue collected from the (b)(4) site for Animal (b)(4). The Microscopic Raw Data documents Slide (b)(4) and Slide (b)(4) were reviewed with a finding of (b)(4) involution, but does

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Agata E Libera, Investigator Kent A Conforti, Investigator	X Agata E Libera Investigator Signed By: AGATA E. LIBERA -S Date Signed: 05-29-2026 09:31:12	5/29/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
109 Holton Street Winchester, MA 01890 (781)587-7500 Fax:(781)587-7556	5/22/2026-5/29/2026* FEI NUMBER 3007222218

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Stephen M. Blash, Chief Operating Officer	
FIRM NAME	STREET ADDRESS
Biomedical Research Models, Inc. d/b/a Biomere	57 Union St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Worcester, MA 01608-1114	Nonclinical Laboratory

not specify which slide the observation pertains to. The Histology Processing Record documents Block/Slide (b)(4) is tissue collected from within the (b)(4) site during necropsy. The Accessioning Record documents Block/Slide (b)(4) is the (b)(4) collected on Day (b)(4).

***DATES OF INSPECTION**

5/22/2026(Fri), 5/26/2026(Tue), 5/27/2026(Wed), 5/28/2026(Thu), 5/29/2026(Fri)

X Kent A Conforti
Investigator
Signed By: KENT A. CONFORTI -S
Date Signed: 05-29-2026 09:31:37

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Agata E Libera, Investigator Kent A Conforti, Investigator	X Agata E Libera Investigator Signed By: AGATA E. LIBERA -S Date Signed: 05-29-2026 09:31:12	5/29/2026

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."