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	6/1/2026-6/12/2026* FEI NUMBER 3002836339

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Douglas T. Kennedy, Senior Vice President of Operations

FIRM NAME	STREET ADDRESS
Vericel Corporation	64 Sidney St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Cambridge, MA 02139-4170	Cell Therapy and Medical Device Manufacturer

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 I OBSERVED:

OBSERVATION 1

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,
A. Your firm's investigations into the following events involving leaks in (b) (4) bottles of MACI and liquid/fluid observed inside the secondary packaging pouch, were not adequate:

i. MACI Lot (b) (4) : Complaint 23-0061 received regarding *MACI Bottle Leakage,* (b) (4) Bottle Lot (b) (4) ; BPDR reported 9/25/2023

ii. MACI Lot (b) (4) : Complaint 23-0084 received regarding *Liquid Drops in the Self-Seal Pouch,* (b) (4) Bottle Lot (b) (4) ; BPDR reported 12/22/2023

iii. MACI Lot (b) (4) Complaint 25-0029 received regarding *Trace Fluid Observed Inside Inner Pouch of the Final Product Bottle,* (b) (4) Bottle Lot (b) (4) ; BPDR reported 5/15/2025

iv. MACI Lot (b) (4) ; Complaint 25-0070 received regarding *Liquid Droplets Inside the MACI Final Product Pouch,* (b) (4) Bottle Lot (b) (4) ; BPDR reported 10/2/2025

Your firm's investigations into these events did not evaluate the (b) (4) bottle lots used in manufacturing the affected MACI lots. For example, the investigations were not expanded to

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identify other MACI lots that were filled in bottles from the implicated (b) (4) lots.
A CAPA initiated in response to the leakage complaints revealed leakage complaints since implementation of a corrective action, and found that (b) (4) bottle lot (b) (4) was a common factor, prompting quarantine of (b) (4) bottles on August 19, 2025. Upon identifying and quarantining (b) (4) bottle lot (b) (4) , your firm did not extend the investigation to identify other impacted product.

Event #	Product	Lot Number	Date Received by QA	Event Description	Date Closed
(b) (4) 25-0056	MACI	(b) (4)	August 2, 2025	Implant bottle leaked into shipping bags and was discovered by the rep. Surgeon cancelled the implant.	September 16, 2025
25-0067	MACI	(b) (4)	August 19, 2025	Taken from Product Event form: The MACI bottle associated with lot (b) (4) was leaking. The surgeon	October 5, 2025

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				decided not to proceed with the implant due to infection concerns.	
25-0070	MACI	(b) (4)	August 22, 2025	Droplets were inside the inner pouch. Surgeon proceeded with the implant.	October 2, 2025

Additionally, Product Complaints (b) (4) 25-0056 and 25-0067 were not reported as BPDRs.

B. Aseptic process simulation (APS) for Grade (b) (4) room (b) (4) where critical MACI manufacturing steps are performed, was conducted on November 12, 2025. Growth promotion testing of the (b) (4) media used in the APS included (b) (4) microorganisms; all exhibited growth except for the in-house (b) (4) An investigation was initiated, which concluded that that the (b) (4) media exhibited no inhibitory properties since the (b) (4) isolates exhibited growth, and a potential root cause was QC analyst error. However, no interviews were conducted with the analyst nor was retraining conducted. Growth promotion retest was performed using only the in-house gram-positive cocci; growth was exhibited. No repeat of the media fill was conducted.

C. Event 33855 (opened October 22, 2024) was initiated in response to the use of expired (b) (4), (b) (4) and standards to qualify standards used in the qualification of Primary Human

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Chondrocyte Reference Cell Strain (b) (4) as a (b) (4). This strain, qualified on June 3, 2025, was shipped to your headquarters for use in (b) (4) Process Evaluations for the MACI combination product manufacturing process. The investigation is deficient as there is no justification to support using expired reagents.

D. Event 334155 regarding lapsed routine calibration of (b) (4) did not include a thorough investigation. Event 334155 was opened on November 12, 2024 to investigate the failure to perform (b) (4) calibration of GMP critical (b) (4) in Grade (b) (4) Biosafety Cabinet (BSC) (b) (4) in February 2024, which is used in the manufacture of Epicel cultured epithelial autograft. From March 1, 2024 to November 15, 2024, (b) (4) was used to conduct critical manufacturing steps of approximately (b) (4) batches of Epicel cultured epithelial autograft designated for distribution throughout the United States. However, the investigation failed to identify the batches manufactured during the subject timeframe to perform a risk assessment.

OBSERVATION 2

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

A. On June 1, 2026, your firm's laboratory personnel demonstrated that the raw data generated from the instrument (b) (4) can be potentially modified and deleted by any personnel with local login accounts to the computer connected to the instrument. This instrument is used by your laboratory for MACI combination product release testing for Identity, Potency, and Mycoplasma.

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B. Your firm's written procedure SOP QC2-133 "Chondrocyte ID and Product (b) (4) (b) (4) Assays" Version 34, Effective Date 9/3/2025 governs testing of Identity for MACI using the (b) (4) instrument and specifies the drive locations containing the testing template and source data files. However, upon inspection of folder locations on June 1, 2026, it was found that your firm does not store the testing template or source data files in the drive locations required by SOP QC2-133.

OBSERVATION 3

The batch records do not record the distinctive identification number to identify major equipment to show the specific equipment used in the manufacture of a batch of a drug product.

Specifically, the system your firm uses to maintain electronic batch records, (b) (4) (b) (4) does not capture changes to (b) (4) used during cell culture (b) (4) of patient cells for the manufacture of MACI combination product.

Deviation 340429 was created on March 10, 2026 to investigate a (b) (4) Excursion on March 9, 2026 for (b) (4), which is used for (b) (4) of patient cells. Approximately (b) (4) patient cell lots of MACI were in (b) (4) at the time of the (b) (4) excursion, which lasted at least 10 minutes. Per Deviation 340429, on March 9, 2026, at 11:43AM, all approximately (b) (4) patient cell lots were transferred from (b) (4) to another (b) (4). However, your firm's electronic batch records for each of the implicated MACI patient cell lots do not reflect this transfer of patient cells between (b) (4).

OBSERVATION 4

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed.

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Specifically, on June 1, 2026, during inspectional walkthrough of your firm's (b) (4) ((b) (4)) corridor number (b) (4), multiple gowning materials, that are used by manufacturing personnel in cleanrooms, were observed to be expired. Expired gowning materials observed include the following: (b) (4) Lot (b) (4) expired 4/15/2026 and (b) (4) Lot (b) (4) (b) (4) expired 12/11/2025.

***DATES OF INSPECTION**

6/01/2026(Mon), 6/02/2026(Tue), 6/03/2026(Wed), 6/04/2026(Thu), 6/05/2026(Fri), 6/08/2026(Mon), 6/09/2026(Tue), 6/10/2026(Wed), 6/11/2026(Thu), 6/12/2026(Fri)

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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."