DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 TEL: 973-331-4900	07/14/2025-07/18/2025
	FEI NUMBER 3004991673

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
Mark Piskadlo, Vice President, Cell Therapy, Summit West Campus Leader

TO: FIRM NAME	STREET ADDRESS
Celgene Corporation	556 Morris Avenue
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Summit, NJ 07901 USA	Drug Product 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 WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not followed. Specifically, aseptic processing of drug product is deficient. Through review of (b) (4) (b) (4) and process observation, the following examples of deficient aseptic processing were observed:

a. (b) (4) review identified that following manufacture of Breyanzi lot (b) (4) and Abecma lot (b) (4), your firm's biological safety cabinet (BSC) operators disinfected their (b) (4) (b) (4) with (b) (4) (without any subsequent manufacturing activities) immediately prior to performing personnel monitoring sampling. Specifically, the operators appear to thoroughly disinfect their (b) (4) with (b) (4), then they raise their (b) (4) to an (b) (4) prior to the ensuing personnel monitoring.

b. Through (b) (4) review, we observed your operator in the prevailing (b) (4) area in (b) (4) introduce materials into the (b) (4) BSC without disinfection of the respective materials throughout the manufacture of Breyanzi lot (b) (4) However, the governing DOC-721881 titled "SOP: Aseptic Techniques for Working in the BSCs (b) (4)," states that the following precautionary measures must be performed: (b) (4)

c. On July 14, 2025, we observed an (b) (4) operator (in (b) (4) used in the aseptic processing of Breyanzi) reach into the (b) (4) BSC without disinfecting their (b) (4) or taking any other special precautions to prevent contamination. A similar finding was noted in (b) (4) review of aseptic processing of Breyanzi lot (b) (4)

d. (b) (4) review identified that during the manufacture of Abecma lot (b) (4) we observed an operator don a (b) (4) of sterile (b) (4) in the (b) (4) area, and begin processing without disinfecting their (b) (4) which deviates from your established procedure. Per procedure DOC-

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Christian D. Lynch -S Digitally signed by Christian D Lynch -S Date 2025 07 18 17 27 23 -0400' MASSOUD MOTAMED -S ELVIRA R. ARGUS -S Digitally signed by ELVIRA R. ARGUS -S	Christian D. Lynch, Investigator Massoud Motamed, CSO Elvira R. Argus, Lead Biologist	07/18/2025

709743 titled "Standard Operating Procedure: (b) (4) for (b) (4) Manufacturing Areas," the operator must "Sanitize (b) (4) with (b) (4) and allow to dry" before engaging in manufacturing activities.

e. (b) (4) review identified that during the processing of Abecma lot (b) (4), we observed the (b) (4) operator remove their (b) (4) sterile (b) (4) and proceed to operate with their (b) (4) (b) (4) without first disinfecting them.

f. On July 15, 2025, during the manufacture of Breyanzi in (b) (4) an (b) (4) area operator was observed changing their (b) (4) and thereby exposing the underlying (b) (4) between the (b) (4) and the underlying (b) (4).

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has already been distributed. Specifically, insufficient risk assessment of deviations and inadequate review of appropriate documentation was performed to determine the impact on product quality due to a (b) (4) (b) (4) event that occurred on October 14, 2023, in which (b) (4) into (b) (4).

a. The impact on product quality of (b) (4) Breyanzi and Abecma lots affected by the (b) (4) event that occurred on October 14, 2023, was evaluated solely based on the sterility test results for the drug product lots, and the investigations did not account for lack of environmental control resulting from the (b) (4) event. For example, QE-140107 noted that Breyanzi and Abecma (b) (4) (b) (4) were moved between (b) (4) due to the (b) (4) event. Additionally, QE-140463 noted that on October 15, 2023, (b) (4) personnel exited (b) (4) after it was deemed out of service and subsequently entered (b) (4) without following the appropriate (b) (4) procedures while (b) (4) Abecma lots were being processed in (b) (4). However, the evaluation of risks to sterility assurance of the affected Breyanzi and Abecma lots did not comprehensively assess the impact of all deviations that occurred due to the (b) (4) event.

b. The transfer of Breyanzi and Abecma (b) (4) between (b) (4) due to a (b) (4) event that occurred on October 14, 2023, was not consistently documented in production batch records for all affected lots. For example, moving of (b) (4) from (b) (4) to (b) (4) was not documented in batch records for Breyanzi lots (b) (4) and (b) (4). Additionally, moving of (b) (4) from (b) (4) to (b) (4) was not documented for Abecma lot (b) (4)

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OBSERVATION 3

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. For example:

a. Procedure DOC-721912 titled "Routine Operation of the (b) (4) Particle Counter for Environmental Monitoring," states (b) (4) excursions for non-viable particulate monitoring are only deemed (b) (4) should the non-viable excursion persist into subsequent sampling. Therefore, (b) (4) sample (b) (4) is not investigated nor considered to be a deviation, should further testing meet the (b) (4) As of 2023, there have been (b) (4) Abecma and (b) (4) Breyanzi affected batches that exhibited an (b) (4) excursion in non-viable particulate samples that were not investigated.

b. On July 14, 2025, we observed that (b) (4) utilized in (b) (4) (for the manufacture of Breyanzi) were not positioned to be (b) (4) to the airflow and appeared to be at an (b) (4) to the (b) (4), potentially causing an underreporting of (b) (4) particulates.

c. Document DOC-734421 titled "SOP: Environmental Monitoring for Production Areas (b) (4) (b) (4) addresses non-conformance management of environmental monitoring. This procedure delineates that a deviation is indicated for (b) (4) recovery in the (b) (4) areas in the following situations: (b) (4) (b) (4) exhibited seven such (b) (4) recoveries that were not the subject of a deviation. (b) (4) also exhibited seven such (b) (4) recoveries that were not the subject of a deviation.

d. The aforementioned provisions were applied to cancel deviations pertaining to environmental excursions, including deviations QE-172740, QE-212936, and QE-212936.

e. Qualification of the Abecma production (b) (4) is deficient. Specifically, the (b) (4) environmental monitoring performed under dynamic conditions for the (b) (4) (b) (4) conducted in (b) (4) to address the (b) (4) of (b) (4) was performed concurrently with (b) (4) (b) (4) Execution of the (b) (4) in concurrence with the (b) (4) did not

accurately simulate production conditions (b) (4) and failed to provide sufficient baseline data for qualification of (b) (4) following the October 2023 (b) (4) event and subsequent (b) (4) of this (b) (4)

OBSERVATION 4

Written records of investigations into unexplained discrepancies do not include the conclusions and follow-up. Specifically, your firm improperly cancels deviations and failed to retrospectively evaluate the impact of canceled deviations.

a. Your (b) (4) electronic quality management system shows that your firm canceled 458 deviations between June 05, 2023 and July 16, 2025. A number of the canceled deviations pertain to missing information and/or documentation (e.g., QE-224345, QE-216748, QE-210383, QE-206227, QE-188380, and QE-172051). By canceling the deviations, your firm failed to identify the genesis of the missing documents and rectify the root cause. Additional examples of canceled deviations pertain to particulates. For instance,
   i. QE-167380 pertained to " (b) (4) found in (b) (4) with (b) (4) ((b) (4) (b) (4)) Internal Lot – (b) (4) Supplier Lot – (b) (4) during execution of (b) (4) (b) (4) of (b) (4)
   ii. Moreover, deviation QE-162273 also pertained to particles and was canceled despite a subject of " (b) (4) on (b) (4) (Item#: (b) (4), Vendor Lot#: (b) (4) Internal Lot#: (b) (4) Quantity: (b) (4) found prior to use during execution of (b) (4) workflow (b) (4) at step (b) (4)
b. Your firm applies work orders to rectify equipment utilized in the manufacture of drug product. There are repeated work orders pertaining to defects (b) (4), including (b) (4) addressing (b) (4) specifying " (b) (4) (b) (4) and (b) (4) stipulating " (b) (4) . It's not always (b) (4) depending on (b) (4) ." The (b) (4) are used to (b) (4) between (b) (4) in the Abecma drug product manufacturing process. However, continued functional issues persist with (b) (4) despite repeat maintenance/open work orders. Further, there was not an ensuing evaluation of prior drug product lots manufactured with (b) (4) .

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OBSERVATION 5

Buildings used in the manufacturing of a drug product are not maintained in a good state of repair. For example, throughout the inspection, the following was observed:

a. Throughout the inspection, the (b) (4) flooring of (b) (4) and (b) (4) used in the production of Abecma and Breyanzi, respectively, (b) (4) in the (b) (4) rendering the (b) (4) difficult to clean. This area is classified as (b) (4) Work orders pertaining to (b) (4) (b) (4) including (b) (4) opened May 22, 2023, (b) (4) opened July 03, 2023, (b) (4) opened August 10, 2023, and (b) (4) opened April 01, 2024 had previously been opened due to similar findings; however, (b) (4) persist.
b. On July 14, 2025, the (b) (4) to Room (b) (4), (b) (4) exhibited (b) (4) along the (b) (4) rendering a difficult to clean (b) (4) Further, the (b) (4) in (b) (4) (b) (4) (b) (4) exhibited a (b) (4) and (b) (4) (b) (4) The finding of (b) (4) continues to be identified, despite work orders being opened due to similar findings (b) (4) opened May 23, 2024, (b) (4) opened September 25, 2024, (b) (4) opened October 02, 2024, and (b) (4) opened February 04, 2025).
c. On July 14, 2025, (b) (4) of BSC (b) (4) (b) (4) in (b) (4) was observed. The BSC (b) (4) in the (b) (4) area and is used in the manufacture of Abecma.
d. On July 16, 2025, the (b) (4) space (b) (4) (b) (4) and (b) (4) used in the production of Abecma and Breyanzi, respectively, exhibited (b) (4). The accumulated (b) (4). The respective (b) (4) are not maintained in a good state of repair and appear to exhibit physical damage. For example, (b) (4) for the (b) (4) in the (b) (4) space (b) (4) (b) (4) and (b) (4) exhibit (b) (4) that is visible on and around the (b) (4) which appear to be (b) (4) The (b) (4) for the (b) (4) in the (b) (4) space (b) (4) (b) (4) and (b) (4) show visible signs of wear (b) (4) and appear to be (b) (4)
e. On July 14 and 15, 2025, we observed (b) (4) to the controlled not classified corridor. Your firm was unable to produce documentation pertaining to details of the event,

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Christian D. Lynch -S Digitally signed by Christian D. Lynch -S Date: 2025.07.18 17:23:24 -04'00' MASSOUD MOTAMED -S Digitally signed by MASSOUD MOTAMED -S Date: 2025.07.18 17:09:12 -04'00' ELVIRA R. ARGUS -S Digitally signed by ELVIRA R. ARGUS -S Date: 2025.07.18 17:13:09 -04'00'	Christian D. Lynch, Investigator Massoud Motamed, CSO Elvira R. Argus, Lead Biologist	07/18/2025

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including the reason for the (b) (4) state of the facility prior to the (b) (4) and number of (b) (4)

OBSERVATION 6

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use. Specifically, qualification of equipment and utility systems are deficient. For example:

a. Changes were made to the (b) (4) system in (b) (4) that is used to supply (b) (4) to the cell culture incubators to ensure (b) (4). Although changes including (b) (4) to the (b) (4), addition of new (b) (4) (b) (4) and (b) (4), were made, all (b) (4) used in the incubators for the manufacture of drug product were not qualified. Furthermore, utilization of (b) (4) has continued in the absence of a complete qualification of the system.
b. Equipment was not fully qualified or verified for functionality (b) (4) of the equipment in conjunction with a (b) (4) event (QE-140463). For example, refrigerators and incubators were not comprehensively assessed for functionality following (b) (4) (b) (4) and (b) (4) to a (b) (4).

***DATES OF INSPECTION**
07/14/2025 (Mon), 07/15/2025 (Tue), 07/16/2025 (Wed), 07/17/2025 (Thu), 07/18/2025 (Fri)

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SEE REVERSE OF THIS PAGE	Christian D. Lynch -S Digitally signed by Christian D. Lynch -S Date: 2025.07.18 17:21:51 -04'00' MASSOUD MOTAMED -S Digitally signed by MASSOUD MOTAMED -S Date 2025 07 18 17 09 38 -04'00' ELVIRA R. ARGUS -S Digitally signed by ELVIRA R. ARGUS -S Date 2025 07 18 17 13 45 -04'00'	Christian D. Lynch, Investigator Massoud Motamed, CSO Elvira R. Argus, Lead Biologist	07/18/2025

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."