

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION						
DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417		DATE(S) OF INSPECTION 3/16/2026-3/25/2026* FEI NUMBER 3008821247				
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Liguo (NMI) Zhang, Vice Chairman						
FIRM NAME Dendreon Pharmaceuticals LLC		STREET ADDRESS 1700 Saturn Way				
CITY, STATE, ZIP CODE, COUNTRY Seal Beach, CA 90740-5618		TYPE ESTABLISHMENT INSPECTED Biological Drug 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 Written records of investigations into unexplained discrepancies and the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up. Although your firm's Quality Unit approved a written procedure, SOP-11058.33, entitled "<i>Nonconformance Reporting</i>," effective August 9, 2025, which defines the nonconformance management process, investigation, assessment of impact, determination of root cause, implementation of corrections, identification of corrective actions, documentation, and reporting of process nonconformities, your firm failed to thoroughly investigate the following: a) Non-conformance NC-2025-0053, initiated on May 23, 2025, investigated the visual inspection failure of final product bags with lot number (b) (4). The final product bags from this lot did not meet the required visual inspection criteria: (b) (4) units contained embedded particulates on the product (b) (4) surface, and (b) (4) units contained embedded particulates on the (b) (4) product (b) (4) surface. Despite these findings, the lot was approved for use by Supplier Quality Assurance (SQA). This lot was subsequently used in the manufacturing of (b) (4) final product batches of Sipuleucel-T and remains the current lot in use for finished product. b) For critical material, (b) (4), Lot # (b) (4) were rejected during the (b) (4) packaging operation post-sterilization due to defects such as cracked (b) (4) and (b) (4). However, Quality Unit did not investigate the defects. c) For critical material, (b) (4) Lot # (b) (4) were rejected during the (b) (4)						
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packaging operation post-sterilization due to defects such as (b) (4) and (b) (4). However, Quality Unit did not investigate the defects.

d) For critical material, (b) (4) Lot # (b) (4) were rejected during the (b) (4) packaging operation post-sterilization due to defects such as (b) (4) and (b) (4).

e) Non-conformance NC-25007 dated April 7, 2025, investigated the failure of (b) (4) samples from (b) (4) and (b) (4) that failed the (b) (4) stability test for density. The (b) (4) sample results were out of specification (OOS) for the required density range for (b) (4). The investigation concluded that the (b) (4) needed to be (b) (4) testing. New samples from the batches were tested for density, the results passed, and the conclusion stated that there was no impact on the (b) (4) batches. The non-conformance failed to thoroughly investigate the stability failure in that there was no evaluation on the impact on the final drug product. (b) (4) lot (b) (4) was used to manufacture approximately (b) (4) units of your Sipuleucel-T final drug product, including lot number (b) (4) which was released on (b) (4).

f) Laboratory Investigation LIR-2023-0144 dated Nov 17, 2023, examined a Day (b) (4) BactT alarm for an (b) (4) at (b) (4) for batch (b) (4) final product. Preliminary (b) (4) (b) (4). The investigation used a (b) (4) BactT (b) (4) that had been (b) (4) for (b) (4), violating work instruction WI-000496.1, entitled "Work Instruction for the Completion of Sterility Test Laboratory Investigations" effective January 31, 2023, which requires (b) (4) per SOP-11002. The firm concluded the BacT alarm and (b) (4) were (b) (4), without justification, changed results from "(b) (4)" to "(b) (4)" and issued a new Sterility CoA

Since February 2024, your firm has manufactured approximately (b) (4) of (b) (4) and approximately (b) (4) of (b) (4). Of those manufactured (b) (4) approximately (b) (4) have been shipped to your sister location in Georgia. The (b) (4) solutions are used to (b) (4) the target cells during your Sipuleucel-T manufacturing

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process. THIS IS A REPEAT OBSERVATION OBSERVATION 2 Laboratory records do not include the initials or signature of a second person showing that the original records have been reviewed for accuracy. Your firm's test method, (b) (4) entitled (b) (4) effective June 29, 2022, for Sipuleucel-T release lacks adequate independent verification of microbial contamination results. The procedure requires (b) (4) (b) (4) entitled "(b) (4)" effective March 10, 2026, no microscopic examination of (b) (4) by QC reviewers. On March 19, 2026, this was confirmed when an analyst performed (b) (4) for batches (b) (4) and (b) (4), and a (b) (4) analyst stated reviewers verify only (b) (4). This test is used for product release before final sterility testing is completed. OBSERVATION 3 Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established and followed. 1. Your written procedures (b) (4)-100448.13, entitled, "Cleaning of the ISO Classified and CNC Areas at the Seal Beach Facility," effective July 19, 2025, and (b) (4) 100168. 12, entitled "Cleanroom Behavior at the...Manufacturing Facilities," effective May 23, 2024, are inadequate in that they lack detailed instructions to prevent contamination of sterile biological drug products and to perform aseptic manufacturing and cleaning of classified areas. The following deficiencies were observed during manufacturing activities for Sipuleucel-T: A. On March 18, 2026, we observed the following deficiencies during the culture bag filling operation of a Sipuleucel-T, Day (b) (4) processing for batch (b) (4) at workstation (b) (4):						
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- I. An operator (b) (6), (b) (7)(C) was observed not sanitizing (b) (6), (b) (7)(C) hands before entering and exiting the biological safety cabinet, ISO (b) (4) environment on multiple instances during the processing of Sipuleucel-T
- II. The (b) (4) and (b) (4) used in processing are not always sanitized (b) (4) moving from manufacturing module ISO (b) (4) environment to ISO (b) (4) Biological Safety Cabinet (BSC).
- B. On March 18, 2026, we observed the following deficiencies during the culture bag filling operation of a Sipuleucel-T, Day (b) (4) processing for batch (b) (4) at workstation (b) (4)
 - I. The operator (b) (6), (b) (7)(C) was observed entering and exiting the ISO (b) (4) Biological Safety Cabinet (BSC) from the ISO (b) (4) environment without sanitizing hands with (b) (4)
 - II. The operator (b) (6), (b) (7)(C) was observed entering and exiting the ISO (b) (4) BSC quickly, transferring materials into BSC without sanitizing hands with (b) (4).
- C. On March 19, 2026, we observed the following deficiency during the cell harvest operation of a Sipuleucel-T, Day (b) (4) processing for batch (b) (4) at workstation (b) (4). The (b) (4) and (b) (4) used in processing are not always completely sanitized (b) (4) moving from manufacturing module ISO (b) (4) environment to ISO (b) (4) Biological Safety Cabinet. The Operator (b) (6), (b) (7)(C) did not completely cover the surface at the bottom of the centrifuge (b) (4) and (b) (4) (b) (4) with (b) (4).
- D. On March 19, 2026, we observed the following deficiencies during the cell harvest operation of a Sipuleucel-T, Day (b) (4) processing for batch (b) (4) at workstation (b) (4):
 - I. The operator (b) (6), (b) (7)(C) was observed entering and exiting the ISO (b) (4) biological safety cabinet (BSC) from the ISO (b) (4) environment without sanitizing hands with (b) (4)
 - II. The operator (b) (6), (b) (7)(C) was observed entering and exiting the BSC quickly by (b) (4) (b) (4) while transferring materials into BSC without sanitizing hands with (b) (4).
 - III. The operator (b) (6), (b) (7)(C) was observed leaving the ISO (b) (4) BSC and workstation (b) (4) for extended periods of time while the product was in the centrifuge.
 - IV. After the setup, before and throughout the processing time, we observed an (b) (4), which appear to be like a (b) (4) on the (b) (4) the BSC in an ISO (b) (4) environment

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2. Your firm's environmental monitoring program does not address the following: In-process monitoring of BSC on March 18, 2026, during Day ^{(b) (4)} manufacturing activities for Sipuleucel-T batch number (b) (4) did not include sampling of the (b) (4) of the BSC as per instructions in procedure SOP-11386.27 entitled "In-Process Environmental Monitoring at Manufacturing Facilities", effective October 4, 2024. On March 18, 2026, it was observed that all (b) (4) Environmental Monitoring surface samples from the BSC were collected at the (b) (4) of the working surface of the Biologic Safety Cabinet (Equipment Number (b) (4)).

Since August 4, 2023, to March 16, 2026, your firm has manufactured and distributed approximately (b) (4) batches of Sipuleucel-T product.

OBSERVATION 4

The responsibilities and procedures applicable to the quality control unit are not fully followed.

- A. Your firm uses a contract manufacturer to (b) (4) (b) (4) of your (b) (4). Your firm's quality control unit does not ensure that the final visual inspection for the (b) (4) solution is completed and acceptable for release. For example, your quality control unit did not document the reason for rejection provided by the contract manufacturer for the following and did not conduct investigations of the rejections. Your contract manufacturer rejected the following:

- (b) (4) rejected (b) (4) (approximately 16% total batch)
- (b) (4) rejected (b) (4) (approximately 8% of total batch)
- (b) (4) rejected (b) (4) (approximately 30% of total batch)
- (b) (4) rejected (b) (4) (approximately 99% of total batch)
- (b) (4) rejected (b) (4) (approximately 34% of total batch)

- B. Your firm uses a (b) (4) with (b) (4) solution for manufacturing of your (b) (4). The information for use (71500870 AF V:6 09/2020) states "the products are intended for (b) (4)"

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(b) (4). Where your procedures require sterile products, (b) (4).
However, your QC unit has not evaluated the risk of using this material, which is intended for research use only, to manufacture the (b) (4) Solutions.

Since February 2024, your firm has manufactured approximately (b) (4) of (b) (4) and approximately (b) (4) of (b) (4). Of those manufactured (b) (4), approximately (b) (4) have been shipped to your sister location in Georgia. The (b) (4) solutions are used to (b) (4) the target cells during your Sipuleucel-T manufacturing process.

OBSERVATION 5

The batch production and control records are deficient in that they do not include documentation of the accomplishment of each significant step in processing and packing. Electronic records are used, but they do not meet requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

- A. On March 17, 2026, it was observed that the workstation used in the manufacturing process have a (b) (4) to document in the electronic batch record for Sipuleucel-T manufacturing (Master Batch record number (b) (4)). The (b) (4) make it potentially impossible to identify the employee that performed each step during manufacturing. Additionally, the Manager for Manufacturing Operations explained that (b) (4) verifier can assist (b) (4) workstations simultaneously performing manufacturing operations for Sipuleucel-T.
- B. The (b) (4) batch record does not contain detailed documentation describing the reason (b) (4) are rejected during filling and capping. For example:
- (b) (4) had (b) (4) rejected due to "volume filling error," the batch record does not describe what the reason for the error was or how the error occurred.
 - (b) (4) had (b) (4) rejected due to "volume filling error," the batch record does not describe what the reason for the error was or how the error occurred.
 - (b) (4) had (b) (4) rejected due to "volume filling error," the batch record does

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not describe what the reason for the error was or how the error occurred.

Since February 2024, your firm has manufactured approximately (b) (4) of (b) (4) and approximately (b) (4) of (b) (4). Of those manufactured (b) (4), approximately (b) (4) have been shipped to your sister location in Georgia. The (b) (4) solutions are used to (b) (4) the target cells during your Sipuleucel-T manufacturing process.

OBSERVATION 6

Control procedures are not established which validate the performance of those manufacturing processes that may be responsible for causing variability in the characteristics of in-process material and the drug product.

Specifically, since February 2024, your firm has manufactured (b) (4) and (b) (4), in house. A comparison study was conducted to demonstrate the comparability between your in-house manufacturing process and the prior contract manufacturer's process. Your current manufacturing process significantly differs from the contract manufacturer's process in the following parameters:

- I. Lot Size
- II. Mixing Conditions
- III. Hold times
- IV. Elimination of (b) (4) step
- V. Filling Environment ISO (b) (4) to ISO (b) (4)
- VI. Method of (b) (4) Sterilization
- VII. Different (b) (4) Composition

The manufacturing validation and comparability study did not fully address the impact of the changes above. Your firm did not ensure the reproducibility and effectiveness of the manufacture of the (b) (4) solutions, (b) (4). Your (b) (4) are a critical component in your Sipuleucel-T manufacturing process as they are used to (b) (4) the target cells.

Since February 2024, your firm has manufactured approximately (b) (4) of (b) (4) and approximately

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(b) (4) of (b) (4). Of those manufactured (b) (4), approximately (b) (4) have been shipped to your sister location in Georgia. The (b) (4) solutions are used to (b) (4) the target cells during your Sipuleucel-T manufacturing process.

OBSERVATION 7

Drug product (b) (4) are (b) (4) so as to alter the safety, identity, strength, quality, and purity of the drug beyond the official or established requirements.

Specifically, since February 2024, your firm started using (b) (4) for the in-house manufacturing of (b) (4) instead of (b) (4) (b) (4) which were used by the CMO's formulation. However, your stability study with (b) (4) in the (b) (4) position does not evaluate potential leachable, extractables, and seal integrity or if the formulation degrades when in direct, long-term contact with the (b) (4) or (b) (4) over time.

OBSERVATION 8

Employees engaged in the manufacture, processing and packing of a drug product lack the experience required to perform their assigned functions.

Your firm's quality unit approved written procedure, SOP-10046.20, entitled "General Visual Inspection," effective June 13, 2025, outlines the training and qualification requirements for personnel performing visual inspections. The quality unit failed to provide documents and demonstrate visual inspection test kits or library of defective samples as part of visual inspection training for employees performing 100% visual inspection. Furthermore, your firm relies on visual inspection to ensure the following materials do not contain particulates and are acceptable for use in manufacturing of your Sipuleucel-T drug product:

1. (b) (4)
2. (b) (4)
3. (b) (4)
4. (b) (4)

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5. (b) (4)
6. (b) (4)
7. (b) (4)
8. (b) (4)

OBSERVATION 9

Reprocessing was performed without the review and approval of the quality control unit.

Specifically, employees engaging in the manufacturing operation of your (b) (4) determines whether a (b) (4) should be reprocessed during packaging operations. Reprocessing can occur because of (b) (4), (b) (4), or incorrect color (b) (4). Furthermore, your firm does not have a written procedure for reprocess or rework.

For example:

- a) (b) (4) Lot # (b) (4) had (b) (4) reprocessed inline during the packaging operation.
- b) (b) (4) Lot # (b) (4) had (b) (4) reprocessed inline during the packaging operation.
- c) (b) (4) Lot # (b) (4) had (b) (4) reprocessed inline during the packaging operation.

There is no quality unit oversight for approval of reprocessing of the (b) (4).

***DATES OF INSPECTION**

3/16/2026(Mon), 3/17/2026(Tue), 3/18/2026(Wed), 3/19/2026(Thu), 3/20/2026(Fri), 3/23/2026(Mon), 3/24/2026(Tue), 3/25/2026(Wed)

X Emily B Camire
Investigator
Signed By: EMILY B. CAMIRE -S
Date Signed: 03-25-2026 19:29:34

X Esther A Ofori
Investigator
Signed By: Esther A. Ofori -S
Date Signed: 03-25-2026 19:30:29

X Lizaida Perez
Investigator
Signed By: 2004213019
Date Signed: 03-25-2026 19:31:32

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Sony Mathews, Investigator - Drug Specialist
Esther A Ofori, Investigator
Lizaida Perez, Investigator
Emily B Camire, Investigator

X Sony Mathews
Investigator - Drug Specialist
Signed By: 2000368493
Date Signed: 03-25-2026 19:39:35

DATE ISSUED

3/25/2026

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."