DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410)779-5455 Fax:(410)779-5707	4/1/2025-4/9/2025* FEI NUMBER 3015558590

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Kennita N. Riddick, Director of Quality Management Systems

FIRM NAME	STREET ADDRESS
Catalent Maryland, Inc.	801 W Baltimore St Ste 600
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Baltimore, MD 21201-1190	Biological 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 I OBSERVED:

OBSERVATION 1

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

Specifically, on APR-03-2025, while observing filling operations for delandistrogene moxeparvovec-rokl (ELEVIDYS) drug product batch number (b)(4), your operator did not follow SOP 05.0105 (titled "*Aseptic Techniques and Personnel Behavior in the Aseptic Filling Suite*", Revision 05, Effective Date: OCT-05-2023) while performing (b)(4) checks and an intervention requiring repeated opening of and reaching into the RABS surrounding the filling equipment during filling of product vials in the Grade - area. For example,

A. The operator was observed to not perform frequent glove (hand) sanitization.

B. The operator was observed to repeatedly perform rapid movements and to not move slowly and deliberately.

C. The operator was observed placing their hands, including while holding the (b)(4) used to manipulate (b)(4) vials, (b)(4) and did not keep their hands at (b)(4) times, and did not sanitize their hands (b)(4) them (b)(4) when making an adjustment (b)(4).

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lizaida Perez, Investigator	X Lizaida Perez Investigator Signed By: 2004213019 Date Signed: 04-09-2025 11:59:10	4/9/2025

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Buildings used in the manufacturing of a drug product are not maintained in a good state of repair.

Specifically, on APR-03-2025, while observing filling operations for delandistrogene moxeparvovec-rokl (ELEVIDYS) drug product batch number [(b)(4)] was observed on the floor of room [redacted], a personnel [redacted], where operators perform [redacted] and [redacted] the Grade [redacted] filling area. On APR-08-2025, you clarified that you had determined that the [redacted] on the floor was due to the floor [redacted] the floor of the personnel [redacted] during [redacted] of the [redacted]. On the same day, you provided a work order (#MNT-63353-2025) opened on APR-07-2025, to remove the [redacted] and adjust the floor [redacted] to prevent future [redacted] from occurring.

***DATES OF INSPECTION**
4/01/2025(Tue), 4/02/2025(Wed), 4/03/2025(Thu), 4/04/2025(Fri), 4/07/2025(Mon), 4/08/2025(Tue), 4/09/2025(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Lizaida Perez, Investigator	X Lizaida Perez Investigator Signed By: 2904213019 Date Signed: 04-09-2025 11:59:10	4/9/2025

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."