DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
FDA/CBER/OCBQ/DMPQ 10903 New Hampshire Avenue, Silver Spring, MD 20993 Attention: Carolyn Renshaw, Building 71 Room 4042 Telephone: 240.402.7343 Industry Information: www.fda.gov/oc/industry	03/06/23-03/10/23
	FEI NUMBER 3015434301

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Joe Torres, VP Operations, Cell Gene & Therapy and Biologics Drug

FIRM NAME	STREET ADDRESS
Catalent Maryland, Inc.	7555 Harmans Road
CITY, STATE AND ZIP CODE Harmans, MD 20177	TYPE OF ESTABLISHMENT INSPECTED Drug Substance Manufacture

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) (WE) OBSERVED:

1. Your Quality Unit failed to ensure the integrity and effectiveness of the Quality Management system.

Specifically,

Change controls are not scientifically justified and do not include a sufficient analysis of the impact of the change by the Quality Unit as delineated in standard operating procedure (b) (4) Change Control Management (b) (4) (b) (4) effective 01/28/2022. In 03/23/2022, SRP-9001 Lot # (b) (4) was prepared utilizing (b) (4) rather than (b) (4) (b) (4) and (b) (4) drug substance batch record was signed off for release by the quality unit on 03/06/2023. Change control (b) (4) covering the change, was not approved by the Quality Unit prior to release of the lot.

2. The Quality Unit failed to address issues that have the potential to impact the quality of the product.

Specifically,

The Quality Unit did not follow the SOP (b) (4) Deviations, which requires (b) (4) (b) (4) as agreed upon the Quality Unit and subject matter experts. The most recent Deviation (b) (4) Report Harmans (BWI) Facility (b) (4) approved 03/01/2023, does not include (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
/s/	/s/	3/10/23

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 judgement, 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."