DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	12/11/2024-12/13/2024 FEI NUMBER 3023068533

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Hyeon Gyu Park, Operations Manager

FIRM NAME	STREET ADDRESS
MRT BIO Inc	6 Centerpointe Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
La Palma, CA 90623-2503	HCT/P Establishment

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

Storage temperatures of HCT/Ps were not recorded and maintained.

Specifically,

From August 23, 2022-current date, storage temperatures of HCT/Ps were never monitored, documented, and maintained in accordance with your firm's Standard Operating Procedures entitled "(b)(4).

OBSERVATION 2

Procedures including release criteria for activities relating to the receipt, shipment and distribution of HCT/Ps were not documented, implemented and followed.

Specifically,

Your firm's Standard Operating Procedure "(b)(4) (b)(4) indicates that you must complete document (b)(4) (b)(4) of HCT/P products and complete (b)(4) of HCT/P products. Your firm has not completed the required documentation in accordance with your SOPs during the receipt and release of HCT/P from August 23, 2022 to current date.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Melsomar R Ramos, Investigator X Melsomar R Ramos Investigator Signed By: Melsomar R. Ramos -S Date Signed: 12-13-2024 07:30:52	12/13/2024

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EMPLOYEE(S) SIGNATURE
Melsomar R Ramos, Investigator

X Melsomar R Ramos
Investigator
Signed By: Melsomar R. Ramos - S
Date Signed: 12-13-2024
07:30:52

DATE ISSUED
12/13/2024

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."