DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160	11/14/2024-11/22/2024* FEI NUMBER 3005932318

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Bernard E. Jacques, General Manager

FIRM NAME	STREET ADDRESS
Henogen SRL	Rue De La Marlette 14
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Seneffe, Hainaut, 7180 Belgium	Viral Vector 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:

There is a lack of adequate control data with regard to manufacturing of viral vector (b)(4) (b)(4).

Specifically, the batch records (master record [redacted]-000150367 v6.0) or other control records for downstream processing which includes (b)(4) (b)(4) do not include a reconciliation of production yield to account for viral (b)(4).

Additionally, (b)(4) operations are documented with a batch record (master record [redacted]-000184189 v5.0) which includes calculation of [redacted] yield by volume. However, there is no criteria for which an investigation would occur for excessively high or low yield calculated with the [redacted]. Since (b)(4), five batches of the viral vector (b)(4) have been manufactured and [redacted] without exception criteria.

*DATES OF INSPECTION

11/14/2024(Thu), 11/15/2024(Fri), 11/18/2024(Mon), 11/19/2024(Tue), 11/20/2024(Wed), 11/21/2024(Thu), 11/22/2024(Fri)

X Scott T Ballard
National Expert
Signed By: Scott T. Ballard -S
Date Signed: 11-22-2024 05:03:23

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Priscilla M Pastrana, Investigator Scott T Ballard, National Expert	X Priscilla M Pastrana Investigator Signed By: Priscilla M. Pastrana -S Date Signed: 11-22-2024 05:02:46	11/22/2024

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."