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 Lead Insp.: Carl Perez Telephone: 301-796-9102 Industry Information: www.fda.gov/oc/industry	July 8-12, 2024
	FEI NUMBER 3014382532

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Maria Meuwissen, Site Head

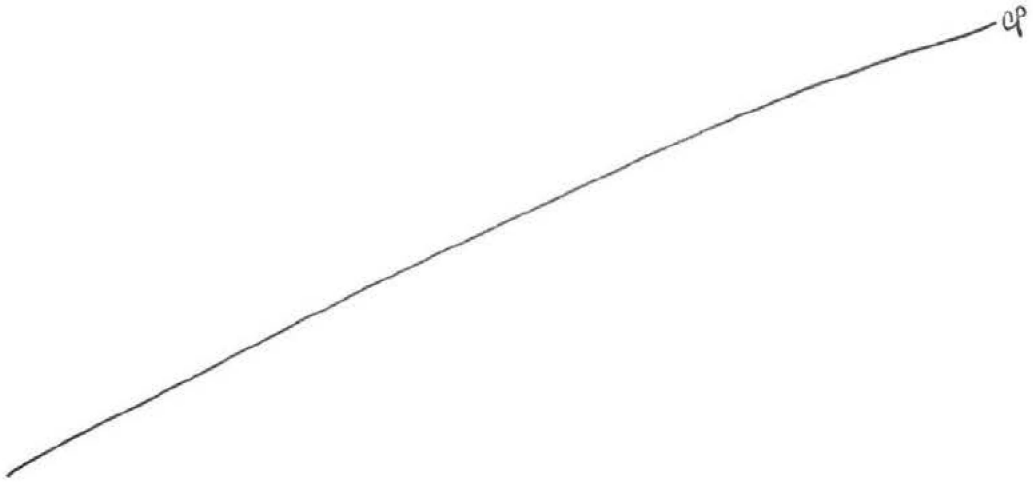
FIRM NAME	STREET ADDRESS
Lonza Netherlands B.V.	Urmonderbaan 20-B
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
6167 RD Geleen, Netherlands	Drug product manufacturer

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) (WE) OBSERVED:

1. Inadequate procedures to document decisions following an out-of-specification (OOS) (b) (4) test result. Specifically, SOP NLGE-922, Deviation Management (v 7.0), does not contain instructions to document decisions with justification to continue or abort manufacturing. Deviation 1144213 (OOS for (b) (4) on (b) (4) of batch (b) (4)) was initiated following an OOS for the (b) (4) result ((b) (4) vs. spec. of (b) (4)). Manufacturing using this (b) (4) material was continued after the OOS (b) (4) result, with no documentation, either in the deviation report or the batch record, of the justification to proceed with batch manufacture.

2. The process (equipment and procedures) for the storage and shipment of commercial drug product (DP) has not been validated. Specifically, the proposed (b) (4) dedicated to the released (b) (4) DP have not been installed and validated, the (b) (4) study for DP pack out has not been conducted, and the proposed commercial DP shipping validation study has not been performed.



SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	/S/	Carl Perez, Lead Inspector, CSO Jie He, Lead CSO Graeme Price, Supervisory Biologist Timothy Kamaldinov, Staff Fellow	07/12/2024

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 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."