DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Lead Insp: Email: CBERDMPQ483Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	May 18-22, 2026
	FEI NUMBER 3038376013

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Arjen Schippers, Site Operations Director

FIRM NAME	STREET ADDRESS
Janssen Biologics B.V.	Warmonderweg 11
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Sassenheim, The Netherlands, 2171 AH	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 firm's procedure (b) (4)-SOP-21679, Version14, The Non-Conformance Process at Leiden JBV requires that investigations into nonconformances be initiated within (b) (4) of detection/identification. However, a review of nonconformance records during the period July 2024 to May 2026 revealed that your firm met this requirement in only approximately 73% of cases, indicating a systemic failure to comply with your own established procedure.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Sharmila Shrestha Kevin Matthews Jessica Chery	Sharmila Shrestha, Biologist Kevin Matthews, CSO Jessica Chery, Lead Biologist Stephanie Val, Staff Fellow	05/22/2026

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."