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	5/21/2026-5/29/2026* FEI NUMBER 3012991344

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Daniel Linder, General Manager

FIRM NAME	STREET ADDRESS
Janssen Vaccines, Zweigniederlassung der Cilag GmbH International	Rehhagstrasse 79
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bern, Bern, 3018 Switzerland	Biological Drug Substance 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 OBSERVED:

Observation 1

Discrepancy and failure investigations related to (b)(4) were not complete and expanded as necessary to assess product impact. For example:

Between January 2025 and October 2025, you confirmed OOS results for (b)(4) (b)(4) in - batches of (b)(4) expiry). Your firm's investigation (CAPA-006675) did not include an impact assessment of all (b)(4) (b)(4) batches manufactured during the subject timeframe. In addition to the - rejected batches, - batches – - released to the U.S. market (b)(4), and --- awaiting disposition, were not assessed for impact. No root cause for the OOSs has been determined and your interim investigation report ((b)(4) -361161 v1.0, effective 13 May 2026) documented a statistically significant (b)(4) across all --- batches compared to --- (mean --- vs. --- Donor 1; (b)(4)).

Additionally, it was observed that your --- stability batches for (b)(4) were reported OOS on April 28 2026 (investigation ongoing), under NC-070606 as follows:

a. The (b)(4) Stability batch --- was OOS for --- results of -- (Donor 1) and - (Donor 2) at the (b)(4) stability timepoint (specification ---).

b. The (b)(4) Stability batch --- was OOS --- results of - (Donor 1) and --

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Travis S Bradley, Investigator X Travis S Bradley Investigator Signed By: TRAVIS S. BRADLEY .S Date Signed: 05-29-2026 03:27:27	5/29/2026

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10903 New Hampshire Ave, Bldg71, Rm 5054 Silver Spring, MD 20993-0002 (240)402-9160	5/21/2026-5/29/2026* FEI NUMBER 3012991344

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Daniel Linder, General Manager	
FIRM NAME Janssen Vaccines, Zweigniederlassung der Cilag GmbH International	STREET ADDRESS Rehhagstrasse 79
CITY, STATE, ZIP CODE, COUNTRY Bern, Bern, 3018 Switzerland	TYPE ESTABLISHMENT INSPECTED Biological Drug Substance Manufacturer

(Donor 2) at the [redacted] stability timepoint (specification [redacted]).

Your [redacted] Stability batch [redacted] was manufactured and released within the [redacted] OOS timeline assessed by CAPA investigation-006675. It was observed that by the batch release date of [redacted] batches within the timeline had been reported OOS. [redacted] batches were manufactured and distributed to the U.S. market in [redacted] covering [redacted] Stability batch [redacted] and [redacted] batches have been manufactured and distributed to the U.S. market covering Annual Stability batch [redacted]. All batches were distributed in support for manufacture of [redacted] drug product.

All [redacted] OOS (confirmed and ongoing investigations) covering batches manufactured from [redacted] through the [redacted] are as follows:

Batch #	Date of Mfg.	Disposition	Disposition Date	Specification	[redacted] Donor 1	[redacted] Donor 2	Released to US
(b)(4)							

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Travis S Bradley, Investigator	DATE ISSUED 5/29/2026

Travis S Bradley
Investigator
Signed By: TRAVIS S. BRADLEY
-S
Date Signed: 05-29-2026
03:27:27

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	5/21/2026-5/29/2026* FEI NUMBER 3012991344

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Daniel Linder, General Manager

FIRM NAME	STREET ADDRESS
Janssen Vaccines, Zweigniederlassung der Cilag GmbH International	Rehhagstrasse 79
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bern, Bern, 3018 Switzerland	Biological Drug Substance Manufacturer

(b)(4)

***DATES OF INSPECTION**
5/21/2026(Thu), 5/22/2026(Fri), 5/26/2026(Tue), 5/27/2026(Wed), 5/28/2026(Thu), 5/29/2026(Fri)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Travis S Bradley, Investigator X Travis S Bradley Investigator Signed By: TRAVIS S. BRADLEY -S Date Signed: 05-29-2026 03:27:27	5/29/2026

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE **INSPECTIONAL OBSERVATIONS** PAGE 3 of 3 PAGES

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."