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	4/3/2025-4/11/2025* FEI NUMBER 3002808087

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Donal Kelleher, Site Lead

FIRM NAME	STREET ADDRESS
MSD International GmbH	Brinny, Innishannon
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Co. Cork, Cork, T12 RD82 Ireland	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 WE OBSERVED:

You did not adequately validate your (b) (4) (b) (4) to support your V116 (Capvaxive) monovalent bulk conjugate (MBC) drug substance manufacturing operations.

Since validating and implementing your (b) (4) utilized for documenting V116 serotype production, quality review, and release on 07DEC2023, multiple deviations have been initiated pertaining to (b) (4) design limitations resulting in potential impact to product quality. For example:

a) Deviation QN201223715 was initiated on 18OCT2024 for the following (not all inclusive):

- MBC time out of (b) (4) C stored at 2-8˚C controlled storage (TOC) calculated but not verified within the (b) (4) to be within the allowed limit ((b) (4) . Since (b) (4) implementation, (b) (4) V116 serotype batches were released without MBC (b) (4) C stored at 2-8˚C TOC verification.
- MBC time out of 2-8˚C TOC not calculated nor verified within the (b) (4) to be within the allowed limit ((b) (4). Since (b) (4) implementation, (b) (4) V116 serotype batches were released without MBC 2-8˚C TOC verification.
- (b) (4) hold time not calculated and verified within the (b) (4) to be within the allowed Hold Time limit (b) (4) . Since (b) (4) implementation, (b) (4) V116 serotype batches were released without (b) (4) hold time verification.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Laurel A Beer, Investigator Travis S Bradley, Investigator	X Laurel A Beer Investigator Signed By: 0014345915 Date Signed: 04-11-2025 05:50:27	4/11/2025

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- No tolerance check and verification within the (b) (4) for weight ((b) (4) of NaCl buffer charged to (b) (4) . Since (b) (4) implementation, (b) (4) V116 serotype batches were released without weight of NaCl buffer tolerance check and verification.

b) Deviation QN2012278663 was initiated on (b) (4) for the following:

- The (b) (4) did not detect that number of (b) (4) passes (b) (4) passes) was outside the allowable operating parameter range of (b) (4) passes to (b) (4) passes (as defined within U.S. license 0002) for V116 Serotype 23A (Batch Number (b) (4) . This deviation was observed during quality review, assessed for product impact, and released with the batch placed on stability.

In response to the deviations listed above, six CAPAs were opened to assess and remediate (b) (4) design errors that were not identified during (b) (4) validation. The status for the six CAPAs are as follows:

- CAPA QN201232350 – Complete, waiting for effectiveness verification
- CAPA QN201232351 – Open (Due Date: 27APR2025)
- CAPA QN201232353 – Complete, waiting for effectiveness verification
- CAPA QN201232354 – Complete, waiting for effectiveness verification
- CAPA QN201216353 – Complete, waiting for effectiveness verification
- CAPA QN201239889 – Complete, waiting for effectiveness verification

***DATES OF INSPECTION**

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4/03/2025(Thu), 4/04/2025(Fri), 4/07/2025(Mon), 4/08/2025(Tue), 4/09/2025(Wed), 4/10/2025(Thu), 4/11/2025(Fri)

X Travis S Bradley
Investigator
Signed By: TRAVIS S. BRADLEY -S
Date Signed: 04-11-2025 05:51:21

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Laurel A Beer, Investigator
Travis S Bradley, Investigator

X Laurel A Beer
Investigator
Signed By: 0014345915
Date Signed: 04-11-2025
05:50:27

DATE ISSUED
4/11/2025

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."