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	1/23/2025-1/31/2025* FEI NUMBER 3008322822

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Ibolya Tarjani, Site Director

FIRM NAME	STREET ADDRESS
GlaxoSmithKline Biologicals Kft.	Homoki Nagy Istvan Utca 1
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Godollo, Pest, 2100 Hungary	Licensed Biological Drug 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:

1. **Discrepancy and failure investigations related to manufacturing were not expanded to assess worst case conditions. Specifically,**

   a) Deviation 201042740 initiated on 09JAN2024, pertaining to particulate contamination of (b) (4) was not adequately investigated. Your (b) (4) identified an (b) (4) within a (b) (4) sent for analysis during the deviation investigation. However, you failed to perform an adequate risk analysis that included worst case conditions to support the utilization of (b) (4) during manufacturing of (b) (4) batch (b) (4). This batch was released and distributed for further manufacture of final drug products INFANRIX (lots (b) (4)) and BOOSTRIX (lot (b) (4)).

   b) Deviation 201079963 was initiated on 25JUL2024 pertaining to a (b) (4) (17 total (b) (4)) storage temperature excursion. This batch was identified as out of controlled temperature for (b) (4) hrs with the warmest temperature reaching (b) (4)). You failed to evaluate product impact for all 17 (b) (4) and failed to adequately investigate and justify your viability testing sample was representative of worst-case conditions. This (b) (4) was released for further manufacture of (b) (4) and (b) (4) batches (b) (4) and (b) (4).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Thai D Truong, Investigator Travis S Bradley, Investigator	X Thai D Truong Investigator Signed By: 0014274389 Date Signed: 01-31-2025 03:21:22	1/31/2025

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2. Procedures for the acceptance and rejection of components and materials utilized within drug substance manufacturing are not adequate.

Procedure LSOP 9000087267 (ver. 01 – approved 20MAR2024), titled "FILT.UF (b) (4) " was implemented as a corrective action in response to deviation 201042740 and requires visual inspection of the (b) (4) prior to use within (b) (4) manufacturing. The procedure allows for the acceptance and use of (b) (4) containing (b) (4) ," however, no risk assessment or study was conducted to assess the impact of utilizing (b) (4) with (b) (4) " within your (b) (4) process.

***DATES OF INSPECTION**

1/23/2025(Thu), 1/24/2025(Fri), 1/27/2025(Mon), 1/28/2025(Tue), 1/29/2025(Wed), 1/30/2025(Thu), 1/31/2025(Fri)

X Travis S Bradley
Investigator
Signed By: TRAVIS S. BRADLEY -S
Date Signed: 01-31-2025 03:22:15

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
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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."