**DEPARTMENT OF HEALTH AND HUMAN SERVICES**
FOOD AND DRUG ADMINISTRATION

| DISTRICT ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| 10 Waterview Blvd., 3rd Floor<br>Parsippany, NJ 07054<br>(973)331-4900 | 3/3/2025-3/7/2025 |
| | FEI NUMBER<br>1000151295 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Glenn D. Graves, Managing Director

| FIRM NAME | STREET ADDRESS |
|---|---|
| Intertek USA Inc. | 291 Route 22 East |
| CITY, STATE, ZIP CODE, COUNTRY | TYPE ESTABLISHMENT INSPECTED |
| Whitehouse, NJ 08888 | Control Laboratory |

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:**

## OBSERVATION 1

Electronic records are used, but they do not meet audit trail requirements to ensure that they are trustworthy, reliable and generally equivalent to paper records.

Specifically,

A. Procedure SOP-000012 (Version 13, Effective Date: JAN-14-2025), titled "*Review and Release of Analytical Reports*", includes *Attachment 1*, titled "*Analytical Data Packages (ADP) Review Form*", which lists items to be reviewed during the peer and QA reviews. The list of items includes the review of audit trails. Section 3.2.1 of the cited procedure states that the review performance is documented in the ADP Review Form and stored with the Analytical Data Packages (ADP) generated for regulated analyses. However, *Analytical Data Packages* for testing of LUXTURNA "Lot (b) (4) ", "Lot (b) (4) ", and "Lot (b) (4) did not include *Attachment 1*.

B. In addition, evaluation of audit trail records in the software of analytical equipment HPLC-CAD (Equipment Number (b) (4)) and ICP-MS Equipment Number (b) (4) for LUXTURNA Drug Substance Lot Number (b) (4) did not show access into the system by the personnel that signed for the responsibilities of QA Review, which includes audit trail review. Audit trail review is not done on the analytical equipment but reviewed using a non-validated software (b) (4) that pulls information from the audit trails log of analytical equipment. However, the information captured by the (b) (4) is not complete as it does not retrieve who accessed the system and there is no evidence that review of the audit trail was completed.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | | DATE ISSUED |
|---|---|---|---|
| | Lizaida Perez, Investigator<br>Christian Lynch, Investigator | X Lizaida Perez Investigator Signed By: 2004213019 Date Signed: 03-07-2025 11:52:14 | 3/7/2025 |

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**OBSERVATION 2**

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

A. Procedure SOP-000031(Version 16, Effective Date: JUN-02-2023), titled "*Analytical Result Investigation*", requires that (b) (4) of "*Analytical Result Investigation Reports*" (ARIR) be completed within (b) (4) business days of the discovery of the ARIR. During the inspection, three ARIR records (ARIR-0000062, ARIR-0000096, and ARIR-0000100) were reviewed and found to exceed the (b) (4) business days requirement by 23 days, 18 days and 11 days, respectively. Each of these ARIRs was associated with testing of LUXTURNA drug substance/product.

B. Procedure SOP-000242 (Version 10, Effective Date: MAY-24-2023), titled "*Cleaning Laboratory and Administrative Units*" defines requirements for a (b) (4) cleaning that includes instructions for the disposal of expired reagents, solutions and solutions no longer required in the laboratory refrigerators and freezers. On March 03, 2025 during a walkthrough of laboratory areas, four expired solutions were identified in refrigerator (b) (4). Each of these solutions expired on DEC-8-2024. The logbook for (b) (4) cleaning, including the section of disposal of expired solution, had been initialed and dated for executed cleaning schedules for the period after the expiry date until the inspection, however, these solutions have yet to be discarded.

C. Procedure SOP-000163 (Version 13, Effective Date: May 9, 2022), titled "*Operation, Maintenance and Calibration of Laboratory Balances*" includes Attachment 1 with the templates for the balance Instrument Logbooks. Inspection identified logbooks for balance calibrations with the incorrect form and (b) (4) balance logbooks (b) (4) and (b) (4) were found to include forms with incorrect tolerances for (b) (4) weight checks. Additionally, the discrepancies associated with the incorrect forms and tolerances were not identified during peer review of the completed forms.

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X Christian Lynch
Investigator
Signed By: Christian D. Lynch -S
Date Signed: 03-07-2025 11:52:50

**SEE REVERSE OF THIS PAGE**

EMPLOYEE(S) SIGNATURE
Lizaida Perez, Investigator
Christian Lynch, Investigator

X Lizaida Perez
Investigator
Signed By: 2004213019
Date Signed: 03-07-2025 11:52:14

DATE ISSUED
3/7/2025

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."