DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900	4/13/2026-4/17/2026
	FEI NUMBER 3006271438

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
James Valenzuela, Vice President & Site Head

FIRM NAME	STREET ADDRESS
Novel Laboratories, Inc. d.b.a Lupin Somerset	400 Campus Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Somerset, NJ 08873-1145	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:

OBSERVATION 1

Investigations of an unexplained discrepancy and a failure of a batch or any of its components to meet any of its specifications did not extend to other batches of the same drug product.

Specifically,

During the investigation (LAB-00433) initiated on February 6, 2026, for an out-of-specification (OOS) (b) (4) result obtained for (b) (4), USP, Receiving Lot # (b) (4) (Retest Date: (b) (4)), you determined that the root cause was the aging of the (b) (4) material, which decreases (b) (4) over time. (b) (4) Lot # (b) (4) was subsequently rejected. However, this same (b) (4) lot had previously been used while meeting in-house (b) (4) limits at the time of use to manufacture the following finished product batches that were released to the market:

- Bulk Batch (b) (4) → Filling Batch (b) (4) → (b) (4) Batch (b) (4) ((b) (4); Manufacture Date: (b) (4); Expiry Date: (b) (4))
- Bulk Batch (b) (4) → Filling Batch (b) (4) → (b) (4) Batch (b) (4) ((b) (4); Manufacture Date: (b) (4); Expiry Date: (b) (4))

The investigation concluded that the associated drug product batches were not impacted because the (b) (4) material met in-house (b) (4) limits at the time of use and the finished product batches passed drug product specifications at release. However, the investigation was not extended to evaluate

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Anthony J Donato, Investigator Daniel T Lee, Investigator X Anthony J Donato Investigator Signed By: 2003042872 Date Signed: 04-17-2026 16:35:43	4/17/2026

the potential impact on the stability of finished product batches (b) (4) and (b) (4) Specifically, you did not place these batches on a stability program or conduct additional stability testing to assess whether the known aging behavior of (b) (4) Lot # (b) (4), which you had identified as causing a progressive and measurable decrease in (b) (4) over time could affect the (b) (4) of the finished product over its shelf life.

Your own investigation data (LAB-00380, Phase II) established that (b) (4) has a positive correlation with (b) (4) bulk (b) (4), and that (b) (4) continues to decrease with aging. Despite this knowledge, no additional stability monitoring was initiated for (b) (4) Batches (b) (4) and (b) (4) to ensure that the finished product would remain within specification throughout its shelf life.

OBSERVATION 2

The number of containers to be sampled and amount of material taken from each container is not based upon appropriate criteria.

Specifically,

The number of containers to be sampled and the amount of material to be taken from each container for (b) (4) and (b) (4) testing of high-risk components is not based upon appropriate criteria.

Specifically, your sampling procedure (SOP No. NL-QA-017.12) does not include a written scientific or statistical rationale for the amount of sample collected from each container for (b) (4) testing of high-risk drug components. You collect approximately (b) (4) per container; however, there is no documented justification establishing that this quantity is appropriate relative to container size or sufficient to perform all required testing, including repeat testing. Additionally, your written procedure does not establish criteria requiring that each individual container of each lot of high-risk drug

components be sampled and tested individually for (b) (4) and (b) (4); rather, the SOP describes preparation of a composite sample from selected containers.

OBSERVATION 3

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

Specifically,

Excel spreadsheets used to perform GMP calculations, including system suitability assessments and analytical result calculations for HPLC analyses, were observed to be unvalidated and executed outside of your validated (b) (4) system. Specifically, the following spreadsheets were observed in use:

- (b) (4) SysSuit.xlsx — HPLC system suitability for (b) (4)
- (b) (4) SysSuit.xlsx — HPLC system suitability for (b) (4) analysis
- (b) (4) _BU_Calc.xlsx — (b) (4) bulk calculation
- (b) (4) _ASCU_Calculation.xlsx — Assay/content uniformity calculation
- (b) (4) _AS_Calc.xlsx — (b) (4) assay calculation
- (b) (4) _ASCU_Calculation.xlsx — Content uniformity calculation
- (b) (4) Disso calc.xlsx — Dissolution calculation
- (b) (4) CU By(b) (4).xlsx — Content uniformity calculation
- (b) (4) BU Calc.xlsx — Bulk calculation
- (b) (4) As Calc.xlsx — Assay calculation
- (b) (4) Calculation.xlsx — Assay calculation
- (b) (4) _Calc.xlsx — (b) (4) calculation
- (b) (4) _Calc.xlsx — (b) (4) calculation
- (b) (4) _DS_Calculation.xlsx — Dissolution calculation
- (b) (4) _Calc.xlsx — Content uniformity calculation

- (b) (4) _DS_Calculation.xlsx — Dissolution calculation
- (b) (4) _calculation.xlsx — Assay calculation
- (b) (4) _Calcn.xlsx — (b) (4) calculation
- (b) (4) _BU_Calculation.xlsx — Bulk uniformity calculation
- (b) (4) _Calc.xlsx — Impurity calculation
- (b) (4) Calculation.xlsx — (b) (4) impurity calculation
- (b) (4) _DV.xlsx — Deliverable volume calculation
- (b) (4) .xlsx — (b) (4) calculation

These spreadsheets were observed to lack the identification numbering convention ((b) (4)), version control, cell protection, audit trail functionality, and electronic signature controls required by your own procedures. No evidence was observed that these spreadsheets were imported into or executed within the (b) (4) validated environment. No evidence of a second-person review or QA data reviewer sign-off was observed for the data contained within these spreadsheets.

Applicable Firm Procedures:

- **SOP NL-VA-007.3**, *Preparation, Protection, and Qualification of Excel Calculation Sheets*, Section 6.4.2: "Users must use validated excel templates from (b) (4) only. System will not record audit trails if they are executed outside (b) (4)."
- **SOP NL-VA-007.3**, Section 6.1.2: Requires assignment of a unique identification number ((b) (4) -) to all GMP Excel calculation sheets.
- **SOP NL-IT-011.0**, *Data Integrity*, Section 7.10: "All the electronic recording documents including excel spread sheets along with the formulas shall be validated and any changes thereafter shall follow change management process."
- **SOP NL-QA-075.0**, *Review of Laboratory Documentation*, Section 6.3.1.7: "When using Microsoft Excel spreadsheets for calculations, data reviewers must verify all the entries and calculations manually if Excel spreadsheet validation is not performed. If the Excel spreadsheet is validated, all the input entries and one model calculation must be verified."

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X Daniel T Lee
Investigator
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EMPLOYEE(S) SIGNATURE

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Daniel T Lee, Investigator

X Anthony J Donato
Investigator
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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."