

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION			
<small>DISTRICT ADDRESS AND PHONE NUMBER</small> 11155 Dolfield Boulevard, Suite 117 Owings Mills, MD 21117 (410) 779-5455 Fax: (410) 779-5707		<small>DATE(S) OF INSPECTION</small> 6/9/2025-6/20/2025* <small>FEI NUMBER</small> 3004760616	
<small>NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED</small> Kenneth C. Carter, Ph.D., Executive Chairman, Testing Facility Management			
<small>FIRM NAME</small> Noble Life Sciences, Inc		<small>STREET ADDRESS</small> 1500 Fannie Dorsey Rd	
<small>CITY, STATE, ZIP CODE, COUNTRY</small> Sykesville, MD 21784-8213		<small>TYPE ESTABLISHMENT INSPECTED</small> Nonclinical Laboratory	
<p>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.</p>			
<p>DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:</p> <p>OBSERVATION 1</p> <p>Testing facility management failed to assure that all personnel clearly understood the functions they were to perform.</p> <p>Specifically,</p> <p>Facility personnel have not adequately maintained the testing facility as evidenced by:</p> <p>A. Significant accumulations of potential pest harborage including cage racks designated for (b) (4) (b) (4) as well as leaves and plant overgrowth were observed (b) (4) Buildings (b) (4) and (b) (4)</p> <p>B. In Building (b) (4) Large Animal Holding area (b) (4), Barn), holes have been chewed in the (b) (4) with evidence of animal nesting material in the chewed holes.</p> <p>C. In Building (b) (4) Room (b) (4) the (b) (4) contained significant accumulations of dirt and hair.</p> <p>D. In Building (b) (4) on the clean side of the cage wash area, clean/sanitized cage racks were observed being stored with significant accumulations of dirt and hair under them.</p> <p>E. In Building (b) (4) Lab (b) (4) a (b) (4) (b) (4) of the building was observed with a (b) (4) of the (b) (4)</p>			
SEE REVERSE OF THIS PAGE		<small>EMPLOYEE(S) SIGNATURE</small> Hugh M McClure, Investigator Christine M Smith, Investigator Amanda M Szucsik, FDA Center Employee	
		<div style="text-align: right;"> <small>DATE ISSUED</small> 6/20/2025 </div> <div style="text-align: right; margin-top: 10px;"> <small>Hugh M McClure Investigator Signed By: Hugh M. McClure II -6 Date Signed: 06-20-2025 024431</small> _____ X </div>	

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F. In Building (b) (4) hot water tank room (b) (4) a significant accumulation of trash including used exam gloves and apparent (b) (4) material was observed.

OBSERVATION 2

Not all animal cages, racks and accessory equipment were cleaned and sanitized at appropriate intervals.

Specifically,

A. In Building (b) (4) on the clean side of the cage washer, at least (b) (4) clean/sanitized rodent feeders were observed with significant accumulations of encrusted feed residue inside of the feeders.

B. In Room (b) (4) Radiographic Development Room, clean rodent cage boxes were observed being stored in (b) (4)

OBSERVATION 3

The quality assurance unit failed to determine whether any deviations from approved protocols or standard operating procedures had been made without proper authorization and documentation.

Specifically,

A. SOP (b) (4)-008/2, (b) (4), Section 6.6.8 states that (b) (4) may be (b) (4) only at the time of dispensing. On 6/10/2025, (b) (4) labeled as (b) (4) with no expiration date or date of preparation were found in the (b) (4) in the necropsy room (b) (4).

B. In Building (b) (4) Room (b) (4) (Immunocompromised Animal Room), rodent feed Lot # (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Hugh M McClure, Investigator Christine M Smith, Investigator Amanda M Szucsik, FDA Center Employee	Hugh M McClure Investigator Signed By: Hugh M. McClure II -G Date Signed: 06-20-2025 024431 X _____	DATE ISSUED 6/20/2025

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6/9/2025-6/20/2025*

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FIRM NAME

Noble Life Sciences, Inc

STREET ADDRESS

1500 Fannie Dorsey Rd

CITY, STATE, ZIP CODE, COUNTRY

Sykesville, MD 21784-8213

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with an expiration date of 25May25 was found to be available for use with no other feed present in the room. According to SOP (b) (4)-001, Animal Husbandry, feed is assigned an expiration date of (b) (4) (b) (4) the manufacturer's (b) (4). A study utilizing mice was ongoing in the room.

C. In Building (b) (4) racks of ferret cages were observed being (b) (4) with no label indicating the date of sanitization. SOP (b) (4)-007, Handling Clean Caging and Equipment, requires placement of a label indicating the date of sanitization.

D. On at least (b) (4) occasions when the cage wash was in use from (b) (4) (b) (4) for verification of cage washer performance in Building (b) (4) was not performed as per SOP (b) (4)-004/2 Cage and General Equipment Cleaning, section 6.6.

***DATES OF INSPECTION**

6/09/2025(Mon), 6/10/2025(Tue), 6/11/2025(Wed), 6/12/2025(Thu), 6/13/2025(Fri), 6/16/2025(Mon), 6/17/2025(Tue), 6/20/2025(Fri)

Christine M Smith
Investigator
Signed By: Christine M. Smith -S
Date Signed: 06-20-2025 09:45:08

X

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Hugh M McClure, Investigator
Christine M Smith, Investigator
Amanda M Szucsik, FDA Center Employee

Hugh M McClure
Investigator
Signed By: Hugh M. McClure II -G
Date Signed: 06-20-2025
09:44:31

X

DATE ISSUED

6/20/2025

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

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OF THIS PAGE**

EMPLOYEE(S) SIGNATURE

Hugh M McClure, Investigator
Christine M Smith, Investigator
Amanda M Szucsik, FDA Center Employee

Hugh M McClure
Investigator
Signed By: Hugh M. McClure II -6
Date Signed: 06-20-2025
024431

X

DATE ISSUED

6/20/2025

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."