DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
250 Marquette Ave, Ste. 600 Minneapolis, MN 55401 (612)334-4100 Fax:(612)334-4134	2/9/2026-2/13/2026
	FEI NUMBER 2182825

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Michael F. Shelton, President & CEO

FIRM NAME	STREET ADDRESS
Birchwood Laboratories, LLC	7900 Fuller Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Eden Prairie, MN 55344-2138	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 I OBSERVED:

Facilities & Equipment System

OBSERVATION 1

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

1. During the facility walk-through of the QA laboratory, the date and time settings on the desktop computer connected to your firm's only HPLC system, which utilizes (b) (4) software to perform ingredient assay and impurity testing for all OTC drug products, were observed to be user-accessible and capable of being modified by laboratory personnel. No adequate controls were in place to restrict or prevent unauthorized changes to the system clock. The ability to alter system date and time settings creates a risk to the integrity, accuracy, and reliability of electronic data, including analytical test results and audit trail information generated by the chromatographic data system.

2. Your data acquisition software and workstations, the systems used for your chromatography instruments, have not been suitably qualified to ensure that the data generated for routine release of incoming and final drug products are maintained and free of manual manipulation or deletion. For example, your QA Supervisor demonstrated within your computer system the deletion of an unknown conditioning run acquired by the chromatography software, (b) (4) . **(REPEAT OBSERVATION)**

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Beatrix D Hippe, Investigator	X Beatrix D Hippe Investigator Signed By: BEATRIX D. HIPPE-S Date Signed: 02-13-2026 11:19:51	2/13/2026

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Laboratory System

OBSERVATION 2

The written stability program for drug products does not include specific test methods.

Specifically,

Your firm's written stability procedure, SOP 2-0102, Revision 17, effective December 11, 2025, titled "Stability Program," identifies required stability parameters, including bioburden, (b) (4) , and concentration. However, the procedure fails to reference, specify, or link to the validated analytical test methods to be used for testing these attributes. The absence of defined and validated test methods within, or cross-referenced by, the stability program does not ensure that stability testing is performed using appropriate, validated procedures, and therefore does not provide adequate assurance of the reliability and accuracy of stability data generated to support product quality and expiry dating.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Beatrix D Hippe, Investigator	X Beatrix D Hippe Investigator Signed By: BEATRIX D. HIPPE-S Date Signed: 02-13-2026 11:19:51	2/13/2026

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."