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	5/4/2026-5/7/2026
	FEI NUMBER 3022592767

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Matthew J Anderson, Plant Manager

FIRM NAME	STREET ADDRESS
Steuart Custom Products, Inc.	10601 State Highway 56
CITY, STATE, ZIP CODE, COUNTRY Le Roy, MN 55951-6723	TYPE ESTABLISHMENT INSPECTED 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 I OBSERVED:
FACILITIES AND EQUIPMENT SYSTEM

OBSERVATION 1

Equipment and utensils are not cleaned and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

PRO-107 (Cleaning Validation Protocol OTC, Version 1.0, dated 12/20/2023) FRM-041 (b) (4) Removal Validation Summary Report, Version 1.0, dated 12/14/2021), and FRM-070 (b) (4) Removal Validation Summary Report – (b) (4) Blender, Version 1.0, dated 12/14/2021) do not demonstrate that the cleaning process for non-dedicated equipment used in the manufacture of (b) (4) OTC drug product prevents contamination from non-pharmaceutical products manufactured on the same shared equipment. Examples include but are not limited to:

1. Chemical residual carryover testing relies solely on (b) (4) measurement of swab (b) (4) (acceptance criterion: (b) (4) units difference from (b) (4) control). This method cannot detect the primary residues of concern, including (b) (4) and (b) (4) (the active ingredients of the (b) (4) product), residues of (b) (4) (b) (4) (b) (4) applied as the final cleaning step with no subsequent water rinse, and residues from non-pharmaceutical products manufactured on the shared (b) (4) and (b) (4) (EIN: (b) (4)), including (b) (4)

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	Elizabeth R Bloom, Investigator X Elizabeth R Bloom Investigator Signed By: ELIZABETH R. BLOOM -S Date Signed: 05-07-2026 12:48:18	5/7/2026

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2. Analytical methods and acceptance criteria do not ensure adequate (b) (4) removal and are not derived from health-based exposure limits appropriate for the (b) (4) route of administration. The (b) (4) removal validation addresses (b) (4) only and does not evaluate removal effectiveness for (b) (4) present in (b) (4) products manufactured on the same shared equipment. The (b) (4) acceptance limit of (b) (4) total (b) (4) reflects the lower limit of quantitation of the (b) (4) for Total (b) (4) test method and is not derived from a health-based (b) (4) threshold appropriate for the (b) (4) route of administration.

Since May 2024, (b) (4) lots of (b) (4), including lot (b) (4) EXP (b) (4), have been manufactured and released from the site without an adequate cleaning validation to support the safety and quality of those lots.

OBSERVATION 2

Routine inspection of automatic and electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

Installation Qualification (IQ), Operational Qualification (OQ), or Performance Qualification (PQ) of the upgraded (b) (4) and (b) (4) (EIN: (b) (4) was not performed, prior to its use in the manufacture of (b) (4) OTC drug product. As documented in proposal 1112.002-01 (b) (4), dated 5/23/2024), this upgrade included replacement of the HMI screen, redevelopment of HMI screens, addition of recipe capability, replacement of the blender motor (b) (4), and incorporation of the drive into the (b) (4) program.

Since July 2024, (b) (4) lots, including lot (b) (4) EXP (b) (4), of (b) (4) OTC drug product have been manufactured and released on unvalidated equipment.

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OBSERVATION 3

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,

The (b) (4) and (b) (4) (EIN: (b) (4)) HMI, used to manufacture (b) (4) (b) (4) OTC drug product, does not have adequate controls to ensure the accuracy and integrity of data generated during manufacturing. Examples include but are not limited to:

1. The (b) (4) and (b) (4) (EIN: (b) (4) HMI does not utilize unique user logins to identify the individuals performing operations during manufacturing, preventing attribution of data entries to a specific individual and precluding detection of unauthorized data alterations.

2. Alarms generated by the (b) (4) and (b) (4) (EIN: (b) (4) HMI are not acknowledged, reviewed, or documented as part of the batch record review process prior to lot release, preventing the firm from determining whether alarm events during manufacturing operations had any impact on product quality.

3. The current configuration of the (b) (4) and (b) (4) (EIN: (b) (4) HMI does not prevent operators from adjusting critical process parameters during manufacturing operations.

Since July 2024, (b) (4) lots, including lot (b) (4) EXP (b) (4) of (b) (4) OTC drug product have been manufactured and released without adequate controls to ensure the accuracy and integrity of data generated during manufacturing.

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PRODUCTION SYSTEM

OBSERVATION 4

Procedures designed to prevent objectionable microorganisms in drug products not required to be sterile are not.

Specifically,

The Environmental Monitoring Program (PRO-022, Version 2.1, dated 1/17/2025) does not include surface swab monitoring for Total Yeast and Mold Count (TYMC) in any zone of the manufacturing environment where bulk (b) (4) is produced. The finished product specification (PRO-122, Version 1.2, dated 10/1/2025) establishes a TYMC limit of <20 CFU/g per USP <1111>, yet the environmental monitoring trending log (FRM-091 (b) (4) Environmental Monitoring Trending) documents surface swab monitoring for Salmonella, Listeria, and E. coli only, in Zone (b) (4) areas. Airborne yeast and mold monitoring, conducted per FRM-105 (b) (4) Air Quality Monitoring Trending, do not have established numerical acceptance criteria; airborne monitoring does not substitute for surface TYMC monitoring of product contact (Zone (b) (4) and non-product contact surfaces (Zones (b) (4) and (b) (4)

Since 1/17/2025, (b) (4) lots, including lot (b) (4) EXP (b) (4), of (b) (4) OTC drug product have been manufactured and released without adequate environmental monitoring to support the prevention of objectionable microorganisms in the finished drug product.

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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."