DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
550 Main Street, Ste 4-930 Cincinnati, OH 45202 (513)322-0700 Fax:(513)679-2772	2/17/2026-2/25/2026* FEI NUMBER 3004082002

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Troy D. Howton, Plant Manager

FIRM NAME	STREET ADDRESS
Rogers Foam Corporation	310 Flint Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Mount Sterling, KY 40353-7200	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.

The observations noted in this Form FDA-483 are not an exhaustive listing of objectionable conditions. Under the law, your firm is responsible for conducting internal self-audits to identify and correct any and all violations of the quality system requirements.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Processes for production and service provision where the resulting output cannot be, or is not, verified by subsequent monitoring or measurement were not adequately validated.

Specifically, validation of the (b) (4) application process used in production of (b) (4) has not been adequately documented.

Additionally, an initial validation of the foam cutting process performed by the automated (b) (4) (b) (4) and used in production of the (b) (4) line of products, has not been performed.

OBSERVATION 2

Procedures for validation of processes did not adequately include statistical techniques with rationale for sample sizes.

Specifically, rationale for sample sizes used for in-process, quality assurance inspections has not been adequately documented.

*DATES OF INSPECTION

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Shannon A Gregory, Investigator X Shannon A Gregory Investigator Signed By: Shannon A. Gregory - S Date Signed: 02-25-2026 14:42:00	2/25/2026

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2/17/2026(Tue), 2/18/2026(Wed), 2/19/2026(Thu), 2/20/2026(Fri), 2/25/2026(Wed)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Shannon A Gregory, Investigator

X Shannon A Gregory
Investigator
Signed By: Shannon A. Gregory - S
Date Signed: 02-25-2026 14:42:00

DATE ISSUED
2/25/2026

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

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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."