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	3/10/2026-3/12/2026
	FEI NUMBER 3004181163

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
David P. Laschansky, Plant Manager

FIRM NAME	STREET ADDRESS
CGR Products MN, LLC.	6288 Claude Way
CITY, STATE, ZIP CODE, COUNTRY Inver Grove Heights, MN 55076-4435	TYPE ESTABLISHMENT INSPECTED 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:

OBSERVATION 1

Production controls do not include implementation of monitoring and measurement of process parameters and product characteristics.

Specifically,

When manufacturing sterile seal devices, you monitor and adjust (b) (4) (b) (4) for the lamination and slitting processes according to procedures SOP 1026-2 Rev A effective 07/28/2025 and SOP 1027 Rev F effective 05/29/2025. However, you have not adequately documented in these procedures the allowable ranges for these process parameters, nor have you adequately documented in your manufacturing records your adjustments of these process parameters during production, for example, in lots (b) (4)

OBSERVATION 2

Records of the nature of nonconforming product and any subsequent action taken, including the evaluation, and any investigation and the rationale for decisions, were not adequately maintained.

Specifically,

When manufacturing sterile seal devices, (b) (4) nonconforming product during the lamination and slitting processes according to procedures SOP 1026-2 Rev A effective 07/28/2025, SOP 1027 Rev F effective 05/29/2025, and SOP 1017 Rev G effective 12/14/2023. However, you have not adequately documented the (b) (4) nonconforming product, for example, in lots (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Albert L Nguyen, Investigator X Albert L Nguyen Investigator Signed By: Albert L. Nguyen -S Date Signed: 03-12-2026 13:51:50	3/12/2026

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(b) (4)

OBSERVATION 3

Corrective action procedures defining the requirements for reviewing the effectiveness of corrective action taken have not been adequately documented.

Specifically,

Your corrective action procedure SOP 1020 Rev D effective 03/31/2021 requires verification that the implemented corrective action is effective, and documentation to demonstrate the effectiveness. However, you have not adequately documented effectiveness checks for corrective actions, for example, 25-008, 25-009, 25-010, 25-011, 25-014, 25-019, 25-123, 25-124, and 26-204.

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

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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."