DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875	4/29/2026-5/5/2026* FEI NUMBER 1000136461

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Amanda J Rennig, Quality Assurance/Regulatory Affairs Director

FIRM NAME	STREET ADDRESS
Digestive Care Inc	1120 Win Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bethlehem, PA 18017-7059	Manufacture

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

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

Specifically,

a) Your firm has failed to demonstrate that manufacturing equipment is free of residual agents following cleaning. Your firm has not identified worst-case sampling locations for swab recovery studies, nor has your firm established a cleaning verification or cleaning validation for your manufacturing equipment of (b) (4) capsule). As a result, your firm cannot ensure that cleaning procedures are effective at removing residual contamination from equipment surfaces.

b) On May 01, 2026, during an inspectional walkthrough of production room #(b) (4) white residue was observed on the surface of the (b) (4) of a dedicated (b) (4), equipment ID DCI ~~#1290~~ **1292**. The equipment was identified as clean. This (b) (4) is used in the manufacturing process of commercial drug product (b) (4) capsule). ~~Cleaning protocol EQP-020, entitled, "Equipment #1290, Cleaning and Maintenance of the (b) (4) ", for (b) (4) equipment ID DCI #1290~~ **Cleaning protocol EQP-014, entitled, "Cleaning and Maintenance of the (b) (4) (b) (4) ", for (b) (4) equipment ID DCI #1292**, provides limited instructions for manually cleaning the (b) (4) ((b) (4) using a vacuum. From 2023 until 2025, your firm manufactured (b) (4) lots of (b) (4)

AMENDMENT 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Ruben C Quintana, Investigator	X Ruben C Quintana Investigator Signed By: RUBEN C. QUINTANA -S Date Signed: 05-05-2026 13:58:51	5/5/2026

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capsule) resulting in (b) (4) bottles being commercially distributed.

***DATES OF INSPECTION**

4/29/2026(Wed), 4/30/2026(Thu), 5/01/2026(Fri), 5/04/2026(Mon), 5/05/2026(Tue)

AMENDMENT 2

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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."