DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Detroit District Office 300 River Place. Suite 5900 Detroit, MI 48207 (313) 393-8100	04/14/2026 - 04/20/2026* FEI NUMBER 1822410

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Mr. Kurtis K. Searcy, Quality Assurance Manager

FIRM NAME	STREET ADDRESS
Nice-Pak Products, LLC	One Nice-Pak Rd.
CITY, STATE, ZIP CODE, COUNTRY Mooresville, IN 46158	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, WE OBSERVED:

OBSERVATION 1

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

You manufacture multiple non-sterile OTC drug products and cosmetic products on non-dedicated equipment, including manufacturing Lines (b) (4) and (b) (4) However, cleaning validation studies have not been performed for this shared equipment to demonstrate your cleaning procedures are effective in removing residues and preventing cross-contamination.

OBSERVATION 2

Written procedures, designed to prevent objectionable microorganisms in drug products not required to be sterile, are deficient.

Specifically,

Your environmental monitoring program, governed by SOP QAS-094, "Microbial Environmental Monitoring," Rev. 6, is inadequate as it omits sampling of critical product-contact surfaces. Your firm does not perform microbial sampling of the internal surfaces of drug product mixing and storage tanks. These product-contact surfaces, where the drug product is held for extended periods, represent a potential source for microbial contamination of the finished product. The exclusion of this equipment from your environmental monitoring program means you have no data to demonstrate that your processing equipment is maintained in a state of microbial control.

SEE REVERSE OF THIS PAGE	Muna Algharibeh, Investigator	Muna Algharibeh	04/20/2026

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OBSERVATION 3

Buildings used in the manufacturing of a drug product are not maintained in a good state of repair.

Specifically,

Ceiling tiles located directly above active manufacturing equipment and the production line were observed to be damaged, missing, and visibly contaminated. Numerous tiles exhibited water stains, dirt, and large, dark patches consistent in appearance with mold, creating a direct risk of contamination to exposed drug products and product-contact surfaces.

***DATES OF INSPECTION:**

04/14/2026 (Tue), 04/15/2026 (Wed), 04/17/2026 (Fri), and 04/20/2026 (Mon).

SEE REVERSE OF THIS PAGE	Muna Algharibeh, Investigator	Muna Algharibeh	04/20/2026

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."