DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	3/16/2026-3/23/2026* FEI NUMBER 2243057

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Justin N. Tice, President

FIRM NAME	STREET ADDRESS
Pausch LLC	808 Shrewsbury Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Tinton Falls, NJ 07724-3002	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

A risk-based approach to the control of the appropriate processes needed for the quality management system has not been applied.

Specifically, your firm has not documented risk analysis studies and their results as specified in your procedure Doc ID QSPI7117011101, rev A, titled "Process Risk Management" which states in section 2.4 that "Risk analysis studies and their results, as well as any actions taken to reduce risk factors, are documented in process risk management files." Risk analysis provides a systematic evaluation of potential hazards and their likelihood of occurrence. None of your firm's products which include the Mobile Patient Fixed Table, Mobile Patient Fixed Table Heavy duty, Cirrus Overhead Tube Stand, Elevator Max, Combimax Table Base, Paxis 100 Tube Stand Column, Paxis 200 Tube Stand Column and FS 100 Wall Stand have documented risk analysis studies.

OBSERVATION 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	William R Chang, Investigator	X William R Chang Investigator Signed By: WILLIAM R. CHANG - S Date Signed: 03-23-2026 09:38:58	3/23/2026

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Corrective action was not adequately taken to eliminate the cause of nonconformities in order to prevent recurrence.

Specifically, your firm recorded three consecutive complaint incidents of "battery charger not working" on the Innocare V14 Battery Charger from June 2024 to December 2024 in which an evaluation for a corrective/preventative action was not documented. Your procedure QSPI8531011101, rev A titled "Corrective and Preventative Action Procedure" states in section 2.3 that "Preventative actions are initiated when quality performance data indicates that there are trends of decreasing quality capability and/or effectiveness of the quality system."

OBSERVATION 3

Procedures to ensure that purchased product conforms to specified purchasing information have not been adequately documented.

Specifically, your firm has not documented any quality specifications for purchased components of your products which include the Mobile Patient Fixed Table, Mobile Patient Fixed Table Heavy duty, Cirrus Overhead Tube Stand, Elevator Max, Combimax Table Base, Paxis 100 Tube Stand Column, Paxis 200 Tube Stand Column and FS 100 Wall Stand as per your procedure QSFDC424212221, rev A titled "Product Specification Form". The SOP states in part II that "This applies to products purchased by the organization that are needing a specification to control and monitor them and assure the quality system is functioning properly."

OBSERVATION 4

Records of the results of monitoring of supplier capability or performance were not maintained.

Specifically, procedures specified in your firm's QSPI7413011101, rev A titled "Supplier Information

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and Monitoring" to evaluate the monitoring and approval of suppliers was not performed for any of your suppliers that provide critical components for your firm's products that include the Mobile Patient Fixed Table, Mobile Patient Fixed Table Heavy duty, Cirrus Overhead Tube Stand, Elevator Max, Combimax Table Base, Paxis 100 Tube Stand Column, Paxis 200 Tube Stand Column and FS 100 Wall Stand. Your procedure states in section 1.3 that "a supplier control record is established for every supplier in the (b) (4) module. All documents supporting the initial evaluation and qualification of the supplier are saved in the supplier's record as attachments. The (b) (4) module is also used for keeping records of the supplier's ongoing quality performance."

OBSERVATION 5

Top management did not review the quality management system at documented planned intervals to ensure its continued suitability, adequacy, and effectiveness.

Specifically, your firm has not performed a management review as per your procedure QSPI5611011101, rev A titled "Management Review Procedures" in which Part III states that "Management reviews must be conducted at least (b) (4) " This procedure was effective since Aug 30, 2011 and there has not been any reviews conducted.

***DATES OF INSPECTION**

3/16/2026(Mon), 3/17/2026(Tue), 3/23/2026(Mon)

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Annotations to Observations

Observation 1: Not annotated

Observation 2: Not annotated

Observation 3: Not annotated

Observation 4: Not annotated

Observation 5: 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."