DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768	2/2/2026-2/10/2026* FEI NUMBER 3006559549

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
George E. Wilson, Jr. , President

FIRM NAME	STREET ADDRESS
PACKAGE SOLUTIONS LLC	2131 Blount Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Pompano Beach, FL 33069-5112	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 WE OBSERVED:

OBSERVATION 1

Procedures for timely complaint handling do not adequately include requirements and responsibilities for receiving and recording information, evaluating information to determine if the feedback constitutes a complaint, investigating complaints, determining the need to report the information to FDA, handling of complaint-related product and determining the need to initiate corrections or corrective actions.

Specifically,

Your organization has not established and maintained an effective process for customer feedback.

a)Physical Returns: 186 records of physically returned products (January 2024-January 2026) were not processed according to your established procedure for complaint handling, documentation, and investigation (Product Complaints SOP MDSPS-B-011 Rev 9 dated 07/18/2025).

b)Customer Refunds: 282 refund records (July 2024-January 2026) were not evaluated as potential quality issues or complaints requiring formal documentation and trending analysis.

c)Distribution Issues: 111 shipment-related issues (July 2024-January 2026) were not systematically reviewed to determine if they constitute customer complaints requiring investigation.

d)Direct Customer Complaints: 25 complaints received through your website and phone system (January 2024-December 2025) were not properly documented, investigated, or trended per your

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	Ebony D Sanon, Investigator Lorraine N Williams, Investigator	X Ebony D Sanon Investigator Signed By: 2001003788 Date Signed: 02-10-2026 14:16:26	2/10/2026

procedure.

The majority of issues involved Swiss Navy brand personal lubricant devices and included:

- Physical/visual defects: damage, leakage, broken seals, broken caps, broken pumps, incorrect fill volumes, missing labels, cloudy appearance, product yellowing
- Labeling issues: illegible or missing lot numbers, expired products
- Adverse skin reactions: pain, burns, rash, itchiness, irritation

Additionally, your procedure does not include provisions for electronic submission of Medical Device Reports (MDRs) within required timeframes, which may impact regulatory compliance obligations.

OBSERVATION 2

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

Specifically,
You have not implemented your documented risk management procedure, Quality Risk Assessment Process SOP MDSPS-B-186 Rev 1 dated 10/21/2024, in the following areas:
A. Regulatory Compliance Risk Assessment: The firm failed to conduct risk assessments prior to product distribution to ensure regulatory compliance requirements are met. Products continue to be distributed without appropriate premarket authorization, indicating inadequate risk evaluation of regulatory compliance impacts.

B. Product Risk Management Documentation: Risk management documentation is inadequate for individual device types, with a single FMEA table applied across all lubricant devices rather than device-specific risk analyses. Risk identification is incomplete, failing to systematically address environmental, biological, functional, and mechanical hazards as required for comprehensive risk

management.

C. Post-Market Surveillance Risk Assessment: The complaint handling system lacks risk-based prioritization, treating all complaints with equal severity regardless of potential safety impact. Data aggregation and trend analysis are not performed to identify emerging risks from post-market feedback.

D. Supplier and Material Change Risk Assessment: Changes to preservative raw material specifications and suppliers (b) (4) were implemented without conducting risk assessments to evaluate potential impacts on device safety and performance. The change control process does not incorporate systematic risk evaluation as required

E. Design Change Risk Assessment: Modifications to package size and cap configuration were implemented without risk assessment to determine potential impacts on product safety and effectiveness. Design change controls lack integration with risk management processes.

F. Manufacturing Process Change Risk Assessment: Changes to manufacturing batch sizes were implemented without risk-based evaluation of potential impacts on product quality and safety. Process validation gaps in packaging and sealing operations were not identified through risk assessment, resulting in quality issues including leakage and potential contamination risks.

This systemic failure to apply risk-based thinking throughout the quality management system demonstrates non-conformance.

OBSERVATION 3
Medical device files have not been established and maintained.

Specifically,
You have not established a Medical Device File (MDF) for your Swiss Navy Silicone Lubricant device.

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Your firm has distributed at least (b) (4) units of Swiss Navy Silicone Lubricant devices in various sizes to customers since July 2024 and continues to distribute. It was noted in the previous inspection that your firm distributed approximately (b) (4) units of these same devices during January 2022-June 2024.

OBSERVATION 4

Procedures were not adequately documented for preserving the conformity of product to requirements during processing, storage, handling, and distribution.

Specifically,

Your firm is not following procedure SOP MDSPS-C-019, Rev 1, dated 12/20/2018, Finished Product Customer Returns and Product Salvage. Between July 1, 2024 and December 30, 2025, your firm received 60,116 returned finished goods from customers. Review of customer return records revealed the following deficiencies:

A. Your firm failed to take photographs of returned items received from Amazon and their package inserts, as required by Section 6.2.8 of SOP MDSPS-C-019.

B. Form MDSPS-C-20 does not include documentation of the reason for return. Section 6.5.5 of SOP MDSPS-C-019 defines specific return reasons that must be documented (expired products, defective items, damaged items, cap induction seal, pouch seal, tube seal, label/film, shrink band/sleeve, cap/pump, fill level/count, defective/damaged bottles, problems with bulk product, display or retail boxes damaged and other defects); however, this required information is not captured on Form MDSPS-C-20.

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OBSERVATION 5

The output from management review did not adequately include the input reviewed and any decisions and actions related to improvement needed to maintain the suitability, adequacy, and effectiveness of the quality management system and its processes.

Specifically,

Your firm failed to follow procedure MDSPS-B-135, Management Review Procedure, issued 6/25/2025, Revision No. 1. The Management Review Meeting Minutes attached to Form MDSPS-B-136, Management Review Form, issued 2/26/2019, Revision No. 0, for the meeting dated 03/21/2025 (covering Q1 2024 to Q4 2024) failed to document:

A. Decisions and actions related to known product quality issues despite evidence of product leaking issues were not documented in the meeting minutes.

B. Assignments and deadlines for corrective and preventive actions for 10 CAPAs were referenced as inputs in the Management Review Meeting Minutes, the minutes did not include the resulting assignments for these CAPA, and action deadlines for completion.

C. The meeting minutes did not capture improvement actions related to the effectiveness of the quality management system, per your procedure the purpose for conducting management reviews of the QMS is to ensure its continuing suitability, adequacy, effectiveness, and alignment with the strategic direction of your organization.

OBSERVATION 6

Internal audits have not been conducted at planned intervals to determine whether the QMS is effectively implemented and maintained.

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Specifically,

Your firm failed to follow procedure SOP MDSPS-B-022, Internal Audits, Revision No. 2, effective date 08/15/2025. Your procedure requires (b) (4) internal audits to ensure the effectiveness of the quality management system and identify areas for continual improvement. However, you failed to conduct (b) (4) internal audits for calendar years 2024 and 2025.

OBSERVATION 7

The labels of the medical device(s) do not bear a unique device identifier (UDI) that meet the requirements of 801 Subpart B and 21 CFR 830.

Specifically,
None of your Class II lubricant devices bear a unique device identifier (UDI). Your President stated the firm has yet to acquire or implement UDIs.

This is a repeat observation from the previous inspection in 2024.

OBSERVATION 8

The information required by the Global Unique Device Identification Database for each medical device version or model required to bear a unique device identifier (UDI) was not provided.

Specifically,
None of your Class II lubricant devices are listed in the Global Unique Device Identification Database because they do not bear a unique device identifier (UDI). Your President stated the firm has yet to acquire or implement UDIs.

This is a repeat observation from the previous inspection in 2024.

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*DATES OF INSPECTION

2/02/2026(Mon), 2/03/2026(Tue), 2/04/2026(Wed), 2/05/2026(Thu), 2/06/2026(Fri), 2/09/2026(Mon), 2/10/2026(Tue)

X Lorraine N Williams
Investigator
Signed By: LORRAINE N. WILLIAMS -S
Date Signed: 02-10-2026 14:17:23

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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

Observation 6: Not annotated

Observation 7: Not annotated

Observation 8: 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."