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	2/2/2026-2/13/2026*
	FEI NUMBER 3010166945

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Jo-Ann Schobel, Director Quality Systems

FIRM NAME	STREET ADDRESS
Accupac, Llc	1700 Oak St
CITY, STATE, ZIP CODE, COUNTRY Lakewood, NJ 08701-5926	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.

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

Processes for production and service provision where the resulting output cannot be, or is not, verified by subsequent monitoring or measurement were not adequately validated.

Specifically, the Summary Report, #788-24-PKV-045-SR, Summary Report for the Packaging Process Validation (b) (4) (b) (4) (Formula # (b) (4) for (b) (4) does not indicate the induction seal settings used in the validation.

The batch record for the validation lot number (b) (4) VAL, Section 3.1.3 lists the Induction Seal Parameters as power Range (b) (4) %, Height of Induction Seal: (b) (4) ", and Conveyor Belt Speed (b) (4) The actual settings used were not recorded for the validation run.

The Accupac Packaging Process Validation Protocol, (b) (4) (b) (4) Protocol No. 788-24-PKV-045-Rev 0, Bulk packaging, Table 3, Internal Process Controls, lists the proposed (b) (4) Induction Seal Parameters as Power: (b) (4) %, Height (b) (4) ", Conveyor Belt Speed: (b) (4)

The Manufacturing and Packaging Validations procedure, SOP-VD-000013, Section 8.3.4 states all protocols are developed to challenge (b) (4) Section 8.3.5 states internal process controls are required to be validated.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Frank J Marciniak, Investigator X Frank J Marciniak Investigator Signed By: Frank J. Marciniak -S Date Signed: 02-13-2026 10:39:24	2/13/2026

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OBSERVATION 2

The correct unique device identifier (UDI) information regarding device identifier portion of the UDI assigned to the version or model was not provided to the FDA via the Global Unique Device Identification Database (GUDID).

Specifically, the following UDI numbers were not provided to the FDA via the Global Unique Device Identification Database (GUDID):

A (b) (4) for the (b) (4)

B. (b) (4) for the (b) (4)

C. (b) (4) for the (b) (4)

D. (b) (4) for the (b) (4) (b) (4).

OBSERVATION 3

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

The Packaging Failure Modes and Effects Analysis (FMEA) for the (b) (4) did not identify the process controls necessary to control the risk associated with each unit operation or process step in the packaging operation.

The SOP-QS-000050, Risk Management Program, Section 7.2.11, Risk Control, requires the measures which are appropriate for reducing the risks to an acceptable level to be determined.

OBSERVATION 4

Supplier performance in meeting requirements for the purchased product was not adequately monitored.

Specifically,

A. The Supplier Oversight Procedure, SOP-QS-000059, section 7.8, Scorecards, states the quality performance

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monitoring score card is the main tool to assess the continued performance of suppliers/ service providers over an established timeframe and ranking is performed (b) (4) for Tier 1 suppliers and (b) (4) for Tier 2 and Tier 3 suppliers.

The ranking was not performed on a (b) (4) basis for Tier 1 Suppliers. Examples include (b) (4) (supplies phosphoric acid (b) (4)% food grade), (b) (4) (supplies xanthan gum), (b) (4) (supplies Glycerin USP (b) (4)%), and (b) (4) (supplies Carbomer 980 NF).

B. The approved supplier list was not reviewed and updated for 2025. The Supplier Oversight Procedure, SOP-QS-000059, section 7.6.1, Maintenance of the Approved Supplier List and Approved External Service Provider List, states the approved supplier list and approved external service provider list will be reviewed and updated (b) (4) at a minimum.

***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), 2/13/2026(Fri)

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Annotations to Observations

Observation 1: Promised to correct

Observation 2: Promised to correct

Observation 3: Promised to correct

Observation 4: Promised to correct

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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."