DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1777 Hardee Ave SW Atlanta, GA 30310 (404)253-1284 Fax:(404)669-4443	5/26/2026-6/2/2026* FEI NUMBER 3044182936

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
George A. Marquez, EVP Global Operations

FIRM NAME	STREET ADDRESS
THERAPAK LLC	4000 Chamblee Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Oakwood, GA 30566	Repacker/Relabeler

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

The inspection or other activities necessary for ensuring that purchased product meets specified purchasing requirements were not established and implemented.

Specifically, supplier evaluation procedures have not been fully implemented. Your firm's SOP-QA009-01, Purchasing Controls | Rev 5 | dated 01/09/2026 requires that (b) (4) supplier, (b) (4) , be audited every (b) (4) ; however, your firm has never conducted an audit of this supplier. During the inspection conducted on 5/26/2026, your firm's VP, Quality and Regulatory confirmed that no audit has ever been performed for (b) (4) .

*DATES OF INSPECTION

5/26/2026(Tue), 5/27/2026(Wed), 5/28/2026(Thu), 5/29/2026(Fri), 6/02/2026(Tue)

AMENDMENT 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lorraine N Williams, Investigator X Lorraine N Williams Investigator Signed By: LORRAINE N. WILLIAMS -S Date Signed: 06-02-2026 16:02:11	6/2/2026

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George A. Marquez, EVP Global Operations

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THERAPAK LLC	4000 Chamblee Rd
CITY, STATE, ZIP CODE, COUNTRY Oakwood, GA 30566	TYPE ESTABLISHMENT INSPECTED Repacker/Relabeler

Annotations to Observations

Observation 1: Promised to correct

AMENDMENT 2

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Lorraine N Williams, Investigator X Lorraine N Williams Investigator Signed By: LORRAINE N. WILLIAMS -S Date Signed: 06-02-2026 16:02:11	6/2/2026

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."