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	2/2/2026-2/6/2026
	FEI NUMBER 1025483

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Consuelo Orozco, Quality Assurance Manager

FIRM NAME	STREET ADDRESS
Tarmac Products, Inc.	16311 Nw 52nd Ave
CITY, STATE, ZIP CODE, COUNTRY Miami Gardens, FL 33014-6209	TYPE ESTABLISHMENT INSPECTED Contract 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 I OBSERVED:

OBSERVATION 1

Specific identification tests are not conducted on components that have been accepted based on the supplier's report of analysis.

Specifically,

1. Your firm does not perform specific identity testing on each container of each shipment of each lot of (b) (4) used in the manufacture of OTC drug products, such as (b) (4) suppositories.

   The following lots were released without appropriate identification testing

   - (b) (4) lots of various count sizes of (b) (4) suppositories in 2025, totaling approximately (b) (4) doses distributed

2. Your firm does not perform all required identification and compendial tests for (b) (4) . Testing for these components has been reduced despite their classification as high-risk materials. Full compendial testing is not conducted to ensure the quality, purity, strength, and suitability of these components prior to use in drug product manufacturing.

   The following lots were released without appropriate identification testing

   - (b) (4) lots of various count sizes of (b) (4) suppositories in 2025, totaling approximately (b) (4) doses distributed

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Mickell Smith, Investigator X Mickell Smith Investigator Signed By: 2004525368 Date Signed: 02-06-2026 13:00:44	2/6/2026

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OBSERVATION 2

Equipment for adequate control over humidity and temperature is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically,

During the inspection, a walkthrough of the (b) (4) stability chamber set to operate at (b) (4) °C ± (b) (4) °C / (b) (4) % RH ± (b) (4) % RH revealed the use of an (b) (4) , unqualified device to assist with temperature control while OTC drug products were on stability. The (b) (4) device had not been qualified, validated, or approved for use in maintaining required stability conditions.

OBSERVATION 3

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically,

Your firm's written procedure titled "Annual Product Review" requires the preparation and maintenance of APRs for all OTC drug products. During the inspection, APRs for calendar years 2024 and 2025 were requested for all OTC drug products manufactured at this facility. Your Quality Unit was only able to provide one (1) APR for (b) (4) for 2024.

Your firm currently manufactures over (b) (4) different OTC drug products; however, APRs have not been completed for the majority of these products, indicating that APRs were not conducted in accordance with your established procedure.

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For example, in 2024, your firm manufactured (b)(4) batches (b) (4) (b)(4) batches of (b) (4) Cream, (b)(4) batches of (b) (4), (b)(4) batches of (b) (4) Ointment, (b)(4) batches of (b) (4) Ointment, (b)(4) batches of (b) (4), (b)(4) batches of (b) (4), and (b)(4) batches of (b) (4), without documented annual reviews evaluating adverse trends, customer complaints, deviations, or other product quality concerns.

OBSERVATION 4

Time limits are not established when appropriate for the completion of each production phase to assure the quality of the drug product.

Specifically,

During the inspection, the manufacturing process for (b) (4) suppositories was observed. Your firm compounded (b) (4) in a designated compounding tank, and the compounded material was held in the tank for multiple days without proceeding to the next step of production. Your Quality personnel confirmed that your firm does not have data or studies to support this hold time for compounded material in the compounding tank.

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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."