DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314	5/19/2026-5/20/2026
	FEI NUMBER 3010822231

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Joseph H. Hakim, President

FIRM NAME	STREET ADDRESS
Talbot's Pharmaceuticals Family Products, LLC	3030 Aurora Ave Fl 2
CITY, STATE, ZIP CODE, COUNTRY Monroe, LA 71201-7295	TYPE ESTABLISHMENT INSPECTED Wholesale Distributor

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

The quality control unit lacks responsibility for approving or rejecting drug products manufactured, processed and packed under contract by another company.

Your firm has failed to establish adequate oversight of contract facilities responsible for the manufacturing, testing, and/or packaging of your drug products.

Contract agreements with (b) (4), responsible for manufacturing bulk for OTC liquids (e.g., (b) (4) (b) (4)), and with (b) (4), responsible for the manufacturing, testing, and packaging of OTC liquid and ointment (e.g., (b) (4)), do not clearly define responsibilities for critical quality and compliance functions, including, but not limited to:

1. Stability Studies: Agreements do not specify responsible party, requirements, storage conditions, or acceptance criteria to support product shelf-life determinations.
2. Changes in Operations: Agreements do not require contractors to notify your firm of changes to processes, equipment, or facilities that could affect product quality.
3. Right to Audit and Inspect: Agreements do not include provisions granting your firm the right to conduct periodic audits to verify CGMP compliance.

In addition, your firm's quality unit has failed to ensure that established policies and procedures are implemented and followed. During the inspection, no training records were provided to demonstrate that warehouse personnel, who have been performing receiving, storage, and distribution of OTC drug products for more than 10 years, have received GMP or training on warehouse operations, in accordance with TALBOTS-013-P002 (Employee Training Procedure), last revised on March 11, 2014.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Milton J De Jesus Tavarez, Investigator X Milton J. De Jesus Digitally signed by Milton J. De Jesus Date: 2026.05.20 14:48:04 -05'00'	5/20/2026

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Milton J De Jesus Tavarez, Investigator

X Milton J. De Jesus Digitally signed by Milton J. De Jesus Date: 2026.05.20 14:48:04 -05'00'

DATE ISSUED

5/20/2026

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."