DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	2/17/2026-2/23/2026* FEI NUMBER 3016439754

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Cindy C. Pruitt, Chief Operating Officer

FIRM NAME	STREET ADDRESS
Misemer Pharmaceutical, Inc.	203 N Main St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Ripley, MS 38663-2027	Own Label 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

Not all quarterly periodic adverse drug experience reports have been submitted within 30 days of the close of the quarter.

Specifically, quarterly Periodic Adverse Drug Experience Reports (PADERS) for Fenoprofen (ANDA 215548) were not submitted. These PADERS should have been reported on a quarterly basis since the ANDA approval date on 5/16/2023. This resulted in 10 quarterly reports that were not submitted.

OBSERVATION 2

Not all annual periodic adverse drug experience reports have been submitted within 60 days of the anniversary date of the approval of the application.

Specifically,
Ketoprofen (ANDA 074014) Periodic Adverse Drug Experience Report (PADER)

- 2023: PADER was due on 3/30/2023 and was submitted on 6/20/2023.

OBSERVATION 3

An annual report was not submitted within 60 days of the anniversary date of U.S. approval of the application to the FDA division responsible for reviewing the application.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kellie R Riggs, Investigator	X Kellie R Riggs Investigator Signed By: KELLIE R. RIGGS -S Date Signed: 02-23-2026 09:14:19	2/23/2026

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FIRM NAME Misemer Pharmaceutical, Inc.	STREET ADDRESS 203 N Main St
CITY, STATE, ZIP CODE, COUNTRY Ripley, MS 38663-2027	TYPE ESTABLISHMENT INSPECTED Own Label Distributor

Specifically,

a. Your firm did not file two required Annual Reports for Fenoprofen (ANDA 215548), that was approved on 5/16/2023.

b. Your firm submitted the following annual reports late for Ketoprofen (ANDA 074014)

- 2023: Annual report was due on 3/30/2023 and was submitted on 6/20/2023
- 2024: Annual report was due on 3/29/2024 and was submitted on 6/19/2024
- 2025: Annual report was due on 3/30/2025 and was submitted on 5/13/2025

c. Your firm submitted the following annual reports late for Chlordiazepoxide (ANDA 210579)

- 2023: Annual report was due on 9/27/2023 and was submitted on 2/23/2024
- 2024: Annual report was due on 9/27/2024 and was submitted on 12/10/2024

OBSERVATION 4

Written procedures have not been developed for the reporting to FDA of post marketing adverse drug experiences.

Specifically, your firm has not developed written procedures for the reporting of postmarketing adverse drug experiences to FDA. For example, standard operating procedure, 'SOP No. QLT-001-0, Handling Customer Complaints and Inquiries,' Section 4.0, describes how it is the responsibility of the Chief Scientific Officer or regulatory agent designee to file 15-Day Alert and Periodic ADE Reports. However, the SOP does not describe the procedure for filing the Postmarketing Adverse Drug Experience Reports or Annual Reports with the FDA.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Kellie R Riggs, Investigator X Kellie R Riggs Investigator Signed By: KELLIE R. RIGGS -S Date Signed: 02-23-2026 09:14:19	2/23/2026

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***DATES OF INSPECTION**
2/17/2026(Tue), 2/18/2026(Wed), 2/19/2026(Thu), 2/20/2026(Fri), 2/23/2026(Mon)

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Kellie R Riggs, Investigator

X Kellie R Riggs
Investigator
Signed By: KELLIE R. RIGGS -S
Date Signed: 02-23-2026
09:14:19

DATE ISSUED
2/23/2026

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."