DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Customhouse Rm900 200 Chestnut St Philadelphia, PA 19106 (215)597-4390 Ext:4200 Fax:(215)597-0875 ORAPHARM1_RESPONSES@fda.hhs.gov	2/5/2024-2/13/2024* FEI NUMBER 3012124170

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Francis H. Ranier, President

FIRM NAME	STREET ADDRESS
Ranier's Compounding Laboratory	1107 Lowry Ave
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Jeannette, PA 15644-3030	Producer of Non-Sterile Drug Products

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

Vermin or other animals or evidence of their presence was observed in the production area.

Specifically, on 02/05/2024, I observed three ceiling lights in your general compounding lab area that contained one to two apparent dead insects. Examples of non-sterile products being made during the inspection on 02/05/2024 includes the following:

Drug Name, form	Expiration Date	Lot Number
Enalapril 1MG/0.25 ML, Suspension	08/03/2024	020524-4
Pimobendan 0.5MG/0.25 ML, Suspension	04/03/2024	020524-3
Furosemide VET CMPD 10MG/ML, Suspension	08/03/2024	020524-6
Guanfacine 1MG/ML, Suspension	02/19/2024	020524-2

Repeat Observation from 2021 FDA 483.

OBSERVATION 2

Use of ingredients not intended for pharmaceutical use in non-sterile drug production.

Specifically, you failed to purchase and use the appropriate compendial grade components when preparing and producing human and veterinary drug products. A store brand ingredient, (b)(4) was used in the preparation of Lidocaine/ Prilocaine/ Tetracaine/ Phenylephrine 12.5/2/12.5/3% Dental Paste, Lot 113023-1, Beyond Use Date: 01/30/2024, and Lot 091823-1, Beyond Use Date: 10/18/2023. Both products were distributed to the patients for use.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jazmine N Brown, Investigator	X Jazmine N Brown Investigator Signed By: Jazmine N. Brown -S Date Signed: 02-13-2024 15:48:50	2/13/2024

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Ranier's Compounding Laboratory	1107 Lowry Ave
CITY, STATE, ZIP CODE, COUNTRY Jeannette, PA 15644-3030	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drug Products

*DATES OF INSPECTION

2/05/2024(Mon), 2/06/2024(Tue), 2/07/2024(Wed), 2/08/2024(Thu), 2/12/2024(Mon), 2/13/2024(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Jazmine N Brown, Investigator X Jazmine N Brown Investigator Signed By: Jazmine N. Brown -S Date Signed: 02-13-2024 15:48:50	2/13/2024

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."