DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

Use this check box to generate the required 483 statement on page 1 for medical device observations. ☐

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
US Custom House Rm 900 200 Chestnut St. Philadelphia, PA 19106 Phone: (216)597-4390 ext. 4200 Fax: (215) 597-0875 ORAPHARMI_Responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	08/04/2021-08/16/2021* FEI NUMBER 3012124170

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Francis H. Ranier, Owner

FIRM NAME	STREET ADDRESS
Ranier's Rx Laboratory, Inc.	1107 Lowry Ave.
CITY, STATE AND ZIP CODE Jeannette, PA 15644-3030	TYPE OF ESTABLISHMENT INSPECTED Non-sterile Drug 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

Vermin was observed in your production area.

Specifically, on 08/06/2021, I observed six ceiling lights in your general compounding lab area and one ceiling light in the hallway to your hazardous compounding room to contain two to 12 apparent dead insects. Furthermore, I observed a cracked ceiling light that sits approximately 24 inches directly above hood (b) (4) in your general compounding lab and approximately an 0.25-inch gap in the ceiling light within your hazardous compounding room. Examples of non-sterile product being made during the inspection on 08/06/2021 includes the following:

Drug Name, form	Expiration Date	Lot Number
Aluminum Hydroxide 135mg/ml, suspension	08/20/2021	080621-7
ABH 0.5/20/0.5 mg/1ml, gel	02/02/2022	080621-6
Biest (80:20)/ Testosterone 0.5/1mg/ml, cream	02/02/2022	080621-8
BMX Mouthwash 1:1:1, suspension	02/02/2022	080621-2
Guanfacine 1mg/ml, suspension	08/20/2021	080621-5
Progesterone (veg capsules) 100mg, capsules	02/02/2022	080621-1
Vancomycin 250mg/5ml, solution	08/20/2021	080621-3
Gabapentin 10mg/ml (VET), suspension	10/01/2021	080621-4

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
	Jazmine Still -S Digitally signed by Jazmine Still -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Jazmine Still -S, 0.9.2342.19200300.100.1.1=2001954135 Date: 2021.08.16 14:09:39 -04'00'	Jazmine N. Still Consumer Safety Officer	08/16/2021

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 judgement, 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."