DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	3/23/2026-3/26/2026 FEI NUMBER 2410271

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Carlos J. Ufret, Director of MS&T

FIRM NAME	STREET ADDRESS
Fougera Pharmaceuticals, LLC.	55 Cantiague Rock Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Hicksville, NY 11801-1126	Non-Sterile 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 WE OBSERVED:

OBSERVATION 1

Equipment and utensils are not maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

Your firm failed to have adequate data and procedures to support the use of hoses that are not product dedicated or used in multi-day campaign during manufacturing and filling operations of your drug products:

- ☐ (b) (4) **hoses** used during manufacturing are not product-dedicated and are used interchangeably across multiple products. (b) (4) hoses used during filling operations are product-dedicated but are used during campaign runs lasting up to (b) (4) .
- ☐ (b) (4) **hoses** used during filling operations are (b) (4) use but are used throughout campaign runs lasting up to (b) (4) .

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Syeda N Mahazabin, Investigator
Divek R Jumani, Investigator

X Syeda N Mahazabin Investigator Signed By: Syeda N. Mahazabin - S Date Signed: 03-26-2026 14:45:17

DATE ISSUED
3/26/2026

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X Divek R Jumani
Investigator
Signed By: Divek R. Jumani -S
Date Signed: 03-26-2026 14:49:50

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Syeda N Mahazabin, Investigator
Divek R Jumani, Investigator

X Syeda N Mahazabin
Investigator
Signed By: Syeda N. Mahazabin -S
Date Signed: 03-26-2026 14:49:17

DATE ISSUED
3/26/2026

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."