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	3/4/2026-3/12/2026* FEI NUMBER 3007726770

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Troy D. Webb, VP MAPS Operations Value Stream/Marietta Site Head

FIRM NAME	STREET ADDRESS
Corixa Corporation	325 N Bridge St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Marietta, PA 17547-1134	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 WE OBSERVED:

OBSERVATION 1

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Specifically, LSOP-9000004973, *Environmental Monitoring*, version 34, effective 08Dec2025, and previous versions 30, 31, 32, and 33, effective 31Jan2024, 03Jul2024, 06Nov2024, and 27Oct2025, respectively, requires that environmental monitoring samples are to be incubated at 20-25°C and 30-35°C for the recovery of viable microorganisms. These samples are collected in (b) (4) (b) (4) settle plates and (b) (4) contact plates. The (b) (4) plates have not been properly qualified for their intended use at 20-25°C.

*DATES OF INSPECTION

3/04/2026(Wed), 3/05/2026(Thu), 3/06/2026(Fri), 3/09/2026(Mon), 3/10/2026(Tue), 3/11/2026(Wed), 3/12/2026(Thu)

X Laurel A Beer
Investigator
Signed By: 0014345915
Date Signed: 03-12-2026 15:38:36

X Annette Melendez
Investigator
Signed By: Annette Melendez -S
Date Signed: 03-12-2026 15:39:18

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE
Priscilla M Pastrana, Investigator
Laurel A Beer, Investigator
Annette Melendez, Investigator

X Priscilla M Pastrana
Investigator
Signed By: PRISCILLA M. PASTRANA -S
Date Signed: 03-12-2026 15:37:54

DATE ISSUED
3/12/2026

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."