

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER FDA/CBER/OCBQ/Division of Manufacturing and Product Quality 10903 New Hampshire Avenue, Silver Spring, MD 20993 Attention: Carolyn Renshaw, Building 71 Rm. 4042 Telephone: (240) 402-7343 Industry Information: www.fda.gov/oc/industry		DATE(S) OF INSPECTION 02/28 - 03/04/2022
NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Christopher Savitz, Site Director		FEI NUMBER 30077266770
FIRM NAME Corixa Corporation d.b.a. GlaxoSmithKline	STREET ADDRESS 325 N. Bridge Street	
CITY, STATE AND ZIP CODE Marietta, PA. 17547	TYPE OF ESTABLISHMENT INSPECTED 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:

1. Inspection of the packaging facilities are deficient after use to assure that materials not suitable for subsequent operations have been removed.

A. Line clearance is performed by (b) (4) qualified operators after labeling and packaging operations are completed for each batch to verify absence of materials from previous packaging run, per SOP 9000006564v31, entitled "Packaging Line Clearance". However, deviations have been generated due to the findings of product labels, unlabeled syringes and vials from previous batches that were packaged on Line (b) (4) packaging line) after line clearance operations have been completed. In some instances, multiple line clearances were completed, and the materials were not detected. Specifically,

i. Notification 200885400 – A packaging operator found a rogue label from (b) (4) batch (b) (4) inside Line (b) (4) on 09/13/2021 (b) (4) shift), following production of (b) (4) batch (b) (4) and before line clearance. The (b) (4) batch (b) (4) was labeled on 09/07/2021. Five (5) line clearances were performed on line (b) (4) between before the label was discovered.

ii. Notification 200887572 – On 09/25/2021, a rogue syringe from (b) (4) batch (b) (4) was found on the bottom of a piece of equipment on line (b) (4) zone (b) (4) while packing batch (b) (4). The syringe was discovered during the (b) (4) shift on 09/25/2021 and the line clearance for (b) (4) batch (b) (4) was completed on 09/24/2021.

iii. Notification 200890975 – On 10/12/2021, an unlabeled vial was discovered in zone (b) (4) of line (b) (4) during line clearance following the completion of (b) (4) batch (b) (4). The unlabeled vial was discovered on the floor under the control panel for the (b) (4) used for the (b) (4) Labeler. Per the investigation, this is a recurrent deviation.

iiii. Notification 200996322 – On 11/09/2021, after production of (b) (4) batch (b) (4), a rogue labeled syringe

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE /S/	EMPLOYEE(S) NAME AND TITLE (Print or Type) (Pete) Pankaj Amin, CSO Viviana Matta, CSO Burnell M. Henry, CSO	DATE ISSUED 03/04/2022
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10903 New Hampshire Avenue, Silver Spring, MD 20993
Attention: Carolyn Renshaw, Building 71 Rm. 4042
Telephone: (240) 402-7343

Industry Information: www.fda.gov/oc/industry

DATE(S) OF INSPECTION

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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Christopher Savitz, Site Director

FIRM NAME

Corixa Corporation d.b.a. GlaxoSmithKline

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Marietta, PA. 17547

TYPE OF ESTABLISHMENT INSPECTED

Drug manufacturer

from (b) (4) batch (b) (4) was found on the upper (b) (4) guard of the packaging equipment during the first ancillary line clearance of (b) (4) in zone (b) (4). The line clearance for (b) (4) batch (b) (4) was completed on 11/03/2021. Three (3) line clearances were performed on line (b) (4) before the label was discovered.

2. Written records of investigations into the failure of a batch or any of its components to meet specifications do not always include the conclusions and follow-up. Specifically,

A. Notification 200893385 – On 10/26/2021, the packaging line (b) (4) Vision System failed the end of run challenge for a missing (b) (4) during production of (b) (4) batch (b) (4). The Line (b) (4) Vision System is designed to detect the absence of (b) (4) in the (b) (4). The root cause was attributed to a malfunctioning (b) (4) in the vision system camera that needed to be replaced. A total of (b) (4) shippers (each containing (b) (4)) were packaged for this batch and shippers (b) (4) were potentially compromised. The investigation did not assess the impacted shippers to ensure the presence of missing (b) (4) (b) (4).

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3/4/22

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OF THIS
PAGE

EMPLOYEE(S) SIGNATURE

/S/

EMPLOYEE(S) NAME AND TITLE (Print or Type)

(Pete) Pankaj Amin, CSO
Viviana Matta, CSO
Burnell M. Henry, CSO

DATE ISSUED

03/04/2022

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."