DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
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	11/11/2022 to 11/16/2022
	FEI NUMBER 3013498720

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Suma Krishnan, President of Krystal

FIRM NAME	STREET ADDRESS
Krystal Biotech, Inc.	2100 Wharton Street, Suite 701
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Pittsburgh, PA 15203	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), (WE) OBSERVED:

1. Drug product production and control records are not reviewed and approved by the quality control unit to determine compliance with all established written procedures before a batch is released or distributed. Specifically, Supplier reports from the (b) (4) conducted in the (b) (4) Suite are not approved by the Quality Unit. The report is reviewed and archived by the Facilities Department and is not attached to the batch record, (b) (4) "B-VEC DP Vial (b) (4) Vials (b) (4) Revision (b) (4) Effective 11/10/2022.

2. Procedures designed to prevent objectionable microorganisms in drug substance (b) (4) are not followed. Specifically,
During the observation of (b) (4) for KB103 drug substance batch (b) (4) on 11/11/2022, the PLI team noticed the (b) (4) from the (b) (4) Suite (Grade (b) (4) during (b) (4) process. This (b) (4) is used for the (b) (4) according to Section (b) (4) in Manufacturing Batch Record (b) (4) Process: KB103 (b) (4) Revision (b) (4) Approved 10/24/2022.

/S/ 11/16/2022

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	/S/ /S/	Wei Wang, Microbiologist; Anna Kwilas, Lead Biologist; Carl Perez, CSO; Priscilla M. Pastrana , CSO, Bo Liang, Staff Fellow, Jianyang Wang, Biologist	11/16/2022

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3. Building used in the manufacture of KB103 drug substance and drug product is not maintained free of insects. Specifically,
Deviations DEV-(b) (4) DEV-(b) (4) and DEV-(b) (4) pertain to insects found in KB103 drug substance and drug product manufacturing area on 09/08/2022 and 09/15/2022. These insects were detected during the cleaning of Grade(b) (4) personnel airlocks (b) (4) and (b) (4) and (b) (4) Suite (Grade(b) (4) (b) (4) Suite and (b) (4) Suite (Grade(b) (4) (b) (4) Suite is used for (b) (4) processes. (b) (4) Suite is used for (b) (4) . (b) (4) Suite is used for (b) (4) (b) (4) of KB103 drug product (DP), and (b) (4) Investigations INV-(b) (4) and INV-(b) (4) and CAPA-(b) (4) were initiated to address these deviations. The root cause of INV-(b) (4) and INV-(b) (4) were pest intrusion through gaps in the perimeter of the manufacturing area. The corrective actions described in CAPA-(b) (4) are the repair of gaps in the perimeter of the manufacturing area. Pest control reports from 09/20/2022 and 10/25/2022 reported insects in pest control traps located in (b) (4) (b) (4) in the manufacturing area. Per discussion with quality manager on 11/13/2022, the actions described in CAPA-(b) (4) were not implemented.

4. There is no (b) (4) on incoming starting materials, including the (b) (4) (b) (4)

5. (b) (4) drug product vials (DP bulk) are (b) (4) (b) (4) without control of DP (b) (4)

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