DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
New Jersey District Office 10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973) 331-4900 Industry Information: www.fda.gov/oc/industry	07/26-29/2022, 08/02-05/2022, 08/22-25/2022
	FEI NUMBER 3002889358

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Nellie D. Clark, VP, Site Head of Manufacturing

FIRM NAME	STREET ADDRESS
ImClone Systems, LLC	33 ImClone Drive
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Branchburg, NJ 08876	Drug Substance 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:

Observation 1

There is a failure to control the disposition and availability of drug substances determined to be within the scope of deviation investigations before the satisfactory completion of evaluation by the quality unit.

Specifically:

1. The disposition and availability of drug substance lots manufactured in your Branchburg, NJ facility and implicated in Deviation Investigation TR# (b) (6), (b) (7)(C), initiated on 06/25/2022, for unknown debris observed in the building (b) (4) production CIP (b) (4) (b) (4) Tank T-4992 were not adequately controlled pending satisfactory completion of evaluation by the quality unit and closure of the investigation on 07/25/2022. Deviation Investigation TR# (b) (6), (b) (7)(C) initially listed numerous drug substance lots within the scope of the investigation including but not limited to: Material Number: (b) (4), Dulaglutide Drug Substance, Batch: (b) (4) Material Number: (b) (4) Galcanezumab Drug Substance, Batch: (b) (4) Material Number: (b) (4), Ramucirumab (b) (4) drug substance, Batch: (b) (4); and Material Number: (b) (4), Cetuximab drug substance, Batch: (b) (4) You removed all drug substance batch references from the Deviation Record "(b) (4) (b) (4) " on 06/30/2022 before having approval of the "Initial Product Quality Impact Assessment" (approved on 07/01/2022).

2. You did not include all implicated drug substance lots for assessment in the TR# (b) (6), (b) (7)(C) Deviation Record "(b) (4) " when the (b) (4) was populated on 06/28-29/2022. For example: Material Number: (b) (4) Dulaglutide ((b) (4) Drug Substance, Batch: (b) (4), Manufactured: 03/30/2022 was omitted from the "(b) (4) ".

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	E K. [illegible] 08/25/2022 Kath M Jor 08/25/2022	Edmund F. Mrak Jr., Investigator Kathleen M. Jordan, Investigator	08/25/2022

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3. The Deviation Record for investigation TR#(b) (6), (b) (7)(C), closed on 07/25/2022, does not include all implicated drug substance material numbers and material descriptions in the "(b) (4) ". Review of your production history revealed that implicated drug substances: Material Number: (b) (4) Olaratumab (IMC-3G3) Drug Substance Process (b) (4) Material Number: (b) (4) Olaratumab (IMC-3G3) Drug Substance Process (b) (4); Material Number (b) (4), Ramucirumab (b) (4); and Material Number: (b) (4), Necitumumab Drug Substance Process (b) (4) were omitted from the "(b) (4) ".

Observation 2
There is a failure to adequately document, explain, and investigate all deviations from established laboratory procedures.

Specifically:

You did not document an investigation to determine the impact, root cause, and appropriate corrective and preventive actions when an Analyst in the (b) (4) Quality Control Laboratories failed to follow procedure QCA-OP-0019, Qualification and Maintenance of (b) (4) HPLC Systems to remove the column from the HPLC system before starting system flow during cleaning. Review of the LIMS column usage log for column 03_SEC_1492_0010 revealed that the column was discarded after being exposed to a cleaning cycle in HPLC Equipment ID # HPL (b) (4) using (b) (4) and (b) (4) on 12/14/2021.

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	E. Mrak Jr. 08/25/2022 Kath M Jor 08/25/2022	Edmund F. Mrak Jr., Investigator Kathleen M. Jordan, Investigator	08/25/2022