DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Food and Drug Administration - New Jersey District, 10 Waterview Blvd, 3rd Floor, Parsippany, NJ 07054 973-331-4900 Industry Information: www.fda.gov/oc/industry	11/12/2019-11/26/2019* FEI NUMBER 3002889358

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Nellie D. Clark Eliza, VP Site Head of Manufacturing

FIRM NAME	STREET ADDRESS
ImClone Systems, L.L.C.	33 ImClone Drive
CITY, STATE, ZIP CODE, COUNTRY Branchburg, NJ 08876-3904	TYPE ESTABLISHMENT INSPECTED Biological 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 WE OBSERVED:

OBSERVATION 1

Appropriate controls are not exercised over computers or related production systems.

Specifically, electronic data obtained from manufacturing process or related equipment are not appropriately controlled. For example,

A. We observed from the audit trails of the (b) (4) identified as Calibration Study, Qualification Study and Verification Study have been deleted. These (b) (4) are used for the equipment qualifications, involving (b) (4) processes. The deleted incidents and related audit trail were not reviewed by the quality unit. For example, the following are some of the actions observed in the audit trail obtained from the (b) (4)

Validator (b) (4)	Date/Time	Actions
	(b) (4)	

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tamil Arasu, Investigator Tamil Arasu Guerlain Ulysse, Investigator Guerlain Ulysse	11/26/2019

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(b) (4)

(b) (4)

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(b) (4)

(b) (4)

(b) (4)

** Full name withheld, and only initials shown*

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B. Review of the (b) (4) audit trail also indicated users had (b) (4) followed by (b) (4) For example, the following table shows (b) (4) recorded in the audit trail:

Validator AVS Unit	Date/Time	Actions
(b) (4)	(b) (4)	

* *Full name withheld, and only initials shown*

Similar actions were observed in (b) (4) as well. The firm's quality unit did not review the (b) (4) Operators were assigned administrative privileges. In addition, the firm does not have sufficient controls to (b) (4)

C. We observed that (b) (4) (b) (4) documented or reviewed. For example, review of the run history on the (b) (4) message (b) (4) However, these events were not

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documented in the (b) (4) We were unable to ascertain why (b) (4) These (b) (4) (b) (4) that are used in the manufacturing processes of biological drug substances such as (b) (4) (b) (4) which are utilized in the production of drug products that are distributed in the U.S. market.

OBSERVATION 2

Appropriate controls are not exercised over computers or related laboratory systems.

Specifically, Quality Control (QC) laboratory data stored on (b) (4) (b) (4) We observed that QC laboratory personnel could (b) (4) For example, a QC laboratory employee demonstrated that they (b) (4) (b) (4) Other computer systems where data is not (b) (4) (b) (4) These laboratory instruments are routinely used for testing of drug substances such as (b) (4) which are utilized in the production of drug products that are distributed in the U.S. market.

***DATES OF INSPECTION**

11/12/2019(Tue), 11/13/2019(Wed), 11/14/2019(Thu), 11/15/2019(Fri), 11/18/2019(Mon), 11/19/2019(Tue), 11/20/2019(Wed), 11/21/2019(Thu), 11/25/2019(Mon) and 11/26/2019(Tue)

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."