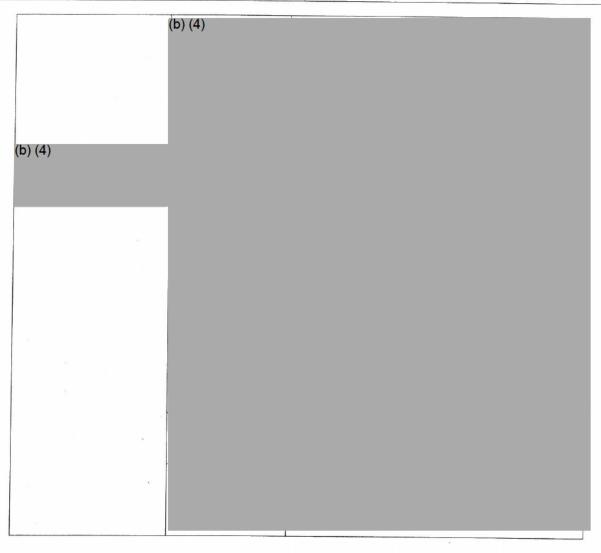
	DEPARTMENT OF HEALT FOOD AND DRUG	TH AND HUMA	N SERVICES	
DISTRICT ADDRESS AND P		ALDINIO TRATTO	DATE(S) OF INSPECTION	
Food and Dr	Drug Administration - New Jersey		11/12/2019-11/26/2019*	
	0 Waterview Blvd, 3rd Floor,	(3002889358	
Parsippany,				
973-331-490	0			
Industry Informati	on: www.fda.gov/oc/industry			
	DUALTO WHOM REPORTISSUED lark Eliza, VP Site Head of Ma			
FIRM NAME	Tark Eliza, VP Site Head Of Ma	STREET ADDRESS	ng	
ImClone Sys	tems, L.L.C.	11		
CITY, STATE, ZIP CODE, CO	700000	TYPE ESTABLISHMENT INSPECTED		
Branchburg	, NJ 08876-3904	Biological Drug Substance Man		nufacturer
implemented, or plan representative(s) dur	observations made by the FDA representative(s) due to final Agency determination regarding your conto implement, corrective action in response to a ring the inspection or submit this information to implement and address above.	mpliance. If you	u have an objection regarding ar	observation, or have
DURING AN INSPEC OBSERVATION	OTION OF YOUR FIRM WE OBSERVED:			
Ammanuista	strole ore not assessed assessed		1	
Appropriate cor	ntrols are not exercised over compute	rs or related	production systems.	
Ø				
Specifically, el	ectronic data obtained from manu	ifacturing r	process or related equi	inment are not
	ontrolled. For example,		or related equi	pinent are not
	,			
A. We obse	rved from the audit trails of the (b) (4)		identified
as Calib	ration Study, Qualification Study and	l Verificatio	on Study have been delet	ed. These (b) (4)
(b) (4)			cations, involving(b) (4)	
processe	s. The deleted incidents and related a			mality unit For
	the following are some of the action			
(b) (4)		is coserved	in the addit trail obtained	i from the cover
Validat	tor (b) (4) Date/Time A	ctions		
	Colombia Service Service Colombia Colom	CHOMS		
	(b) (4)			
8	*.			
	a .			
		1		
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	Guerlain Ulysse, Investigator	(kulur	Arasie. Ulyse	
			0	
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSPE	CTIONAL OBS	ERVATIONS	PAGE 1 OF 5 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 11/12/2019-11/26/2019* FEI NUMBER Food and Drug Administration - New Jersey 3002889358 District, 10 Waterview Blvd, 3rd Floor, Parsippany, NJ 07054 973-331-4900 Industry Information: www.fda.gov/oc/industry NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED Nellie D. Clark Eliza, VP Site Head of Manufacturing ImClone Systems, L.L.C. 33 ImClone Drive CITY, STATE, ZIP CODE, COUNTRY TYPE ESTABLISHMENT INSPECTED Branchburg, NJ 08876-3904 Biological Drug Substance Manufacturer



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Tamil Arasu, Investigator

Guerlain Ulysse, Investigator

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DATE ISSUED 11/26/2019

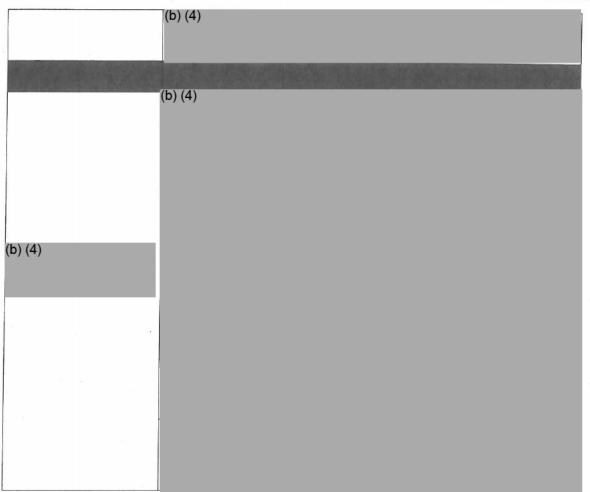
FORM FDA 483 (09/08)

PREVIOUS EDITION OBSOLETE

INSPECTIONAL OBSERVATIONS

PAGE 2 OF 5 PAGES

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION 11/12/2019-11/26/2019* FEI NUMBER Food and Drug Administration - New Jersey 3002889358 District, 10 Waterview Blvd, 3rd Floor, Parsippany, NJ 07054 973-331-4900 Industry Information: www.fda.gov/oc/industry Nellie D. Clark Eliza, VP Site Head of Manufacturing FIRM NAME ImClone Systems, L.L.C. 33 ImClone Drive CITY, STATE, ZIP CODE, COUNTRY TYPE ESTABLISHMENT INSPECTED Branchburg, NJ 08876-3904 Biological Drug Substance Manufacturer



^{*} Full name withheld, and only initials shown

FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	PAGE 3 OF 5 PAGES
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	EMPLOYEE(S) SIGNATURE Tamil Arasu, Investi	gator (TA)	DATE ISSUED 11/26/2019

		TH AND HUMAN SERVICES ADMINISTRATION	S	
DISTRICT ADDRESS AND PI		DATE(S) OF INS	PECTION	
			11/12/2019-11/26/2019*	
	ood and Drug Administration - New Jersey		FEI NUMBER	
	0 Waterview Blvd, 3rd Floor,	300288	9358	
Parsippany,				
973-331-490	0			
To do store To Comment	C1			
NAME AND TITLE OF INDIVID	on: www.fda.gov/oc/industry			
Nellie D. C	lark Eliza, VP Site Head of Ma	mufacturing		
FIRM NAME		STREET ADDRESS		
ImClone Syst	tems, L.L.C.	33 ImClone Drive		
The state of the s	CITY, STATE, ZIP CODE, COUNTRY TYPE ESTABLISHI			
Branchburg	, NJ 08876-3904	Biological Drug	Substance Manufacturer	
(b) (4)	For example, and only initials shown	the following table s	audit trail also indicated users followed by shows (b) (4)	
	actions were observed in (b) (4)		as well. The	
	ality unit did not review the(b) (4)		Operators	
were assi	igned administrative privileges. In ac	ldition, the firm does	not have sufficient controls to	
(b) (4)				
C. We obser (b) (4)	rved that (b) (4)	ented or reviewed. F	or example, review of the run	
history o	n the (b) (4)	or reviewed, 1	or example, review of the full	
1113101 y 0.	b) (4)			
message(-, ()	H	owever, these events were not	
	EMPLOYEE(S) SIGNATURE		DATE ISSUED	
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OF THIS PAGE			11/20/2019	
	Guerlain Ulysse, Investigato:	r Goll		
FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSPE	CTIONAL OBSERVATIONS	PAGE 4 OF 5 PAGES	

	DEPARTMENT OF HEALT	H AND HUMA	N SERVICES	
DISTRICT ADDRESS AND PR	FOOD AND DRUG	ADMINISTRATIO	N DATE(S) OF INSPECTION	
			11/12/2019-11/26/20	19*
	Drug Administration - New Jersey		FEINUMBER	
	, 10 Waterview Blvd, 3rd Floor,		3002889358	
Parsippany, 973-331-490				
9/3-331-490	0			
Industry Information	on: www.fda.gov/oc/industry			
	DD: www.fda.gov/oc/industry DUAL TO WHOM REPORT ISSUED			<u> </u>
	lark Eliza, VP Site Head of Ma	nufacturi	ng	
FIRM NAME		STREET ADDRESS		
ImClone Syst		33 ImClone Drive		
	, NJ 08876-3904	TYPE ESTABLISHMENT INSPECTED Biological Drug Substance Manufacture:		
Branchburg	, NO 08876-3904	B101091C	al Drug Substance Mai	nufacturer
docume	nted in the (b) (4)		We were unable to	o oposatsia suluu
(b) (4)	These (b)	(4)	we were unable to	ascertain why
	These	()	_	
(b) (4)		(1.) (4)	that are used in the	manufacturing
processe	s of biological drug substances such	h as (b) (4)		
(b) (4)	which are utilized in the pro	duction of	drug products that are di	stributed in the
U.S. ma			mag products that the th	stirouted in the
0.5. 110	TACC.			
OBSERVATION	N 2			
34				
Appropriate con	trols are not exercised over computer	s or related	laboratory systems	
	1		incorniory by breing.	
Specifically, Ou	ality Control (QC) laboratory data s	stored or (b)	(4)	
(b) (4)	, , , , , , , , , , , , , , , , , , ,		rved that OC laboratory r	serconnel could
(b) (4)		*** © 0000	TVCC that C/C/ miximin V	ici some: Cimio
(b) (4)			For evample a	OC laboratory
l employee demoi	nstrated that they (b) (4)	Other computer systems where data is not		
(b) (4)	istiated that they (/ (/			
(b) (4)			other computer systems w	nere data is not
(b) (4)				
b) (4)		7711	1	
	a substances such as (b) (4)	These la	aboratory instruments are	
	g substances such as (b) (4)	11 1 11	1'-4-110	which
are utilized in the	e production of drug products that are	e distributed	in the U.S. market.	
*DATES OF IN				
11/12/2019(Tue), 11	//13/2019(Wed), 11/14/2019(Thu), 11/15/20	19(Fri), 11/18	8/2019(Mon), 11/19/2019(Tue)),
11/20/2019(Wed), 1	1/21/2019(Thu), 11/25/2019(Mon) and 11/2	6/2019(Tue)		
				1
			5	
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FORM FDA 483 (09/08)	PREVIOUS EDITION OBSOLETE INSPE	CTIONAL OBS	ERVATIONS	PAGE 5 OF 5 PAGES

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
- 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."