DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT OFFICE ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION Baltimore District (BLT-DO) 4/12/2021 - 4/20/2021 6000 Metro Drive, Suite 101 FEI NUMBER Baltimore, MD 21215 3015448605 (410) 779-5455 orabioinspectionalcorrespondence@fda.hhs.gov NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Dino S. Muzzin, Senior Vice President Manufacturing Operations FIRM NAME STREET ADDRESS Emergent Manufacturing Operations Baltimore, LLC. 5901 East Lombard Street CITY, STATE AND ZIP CODE TYPE OF ESTABLISHMENT INSPECTED Baltimore, MD 21224 Vaccine 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 PLANTO IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISCUSS THE OBJECTION OF 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 Failure to conduct thorough investigations into unexplained discrepancies. Specifically, a. The cross-contamination of client (b) (4) viral vaccine drug substance batch (b) (4), which was manufactured between and (b) (4), with the virus from client (b) (4) as described in deviation 3100012112 initiated on 3/17/2021 has not been thoroughly investigated. Specifically, The deviation did not include consideration of operator (b) (6) who is recorded on the batch record as weighing and dispensing the raw materials for media batch (b) (4) used in the manufacture of (b)(4) batch(b) (4) on (b) (4). This batch of media is implicated by your firm in the deviation as the most probable cause of the cross-contamination event. Operator (b) (6) also entered both manufacturing areas where client (b) (4) viral vaccine drug substance and client (b) (4) viral vaccine drug substance are respectively manufactured on (b) (4) these raw materials based upon badge access data and video surveillance. Operator (b) (6) was observed on the security camera footage dated (b) (4) wearing protective gowning and foot protection in the controlled not classified room before entering the (b) (4) hallway outside the (b) (4) through the (b) (4) The deviation investigation did not include a thorough review of personnel movements in ii. and around the facility as a potential source of contamination. The deviation did not include consideration of the potential impact of the continued use of to store raw materials used to manufacture (b) (4) used in the manufacture of client (b) (4) viral vaccine drug substance and client (b) (4) viral vaccine drug were identified in the deviation as being not designed to substance. These (b) (4) allow for proper decontamination. It is not known how long client (b) (4) virus will remain viable on a surface. There was no iv. additional cleaning performed other than the routine cleaning in response to this deviation. There is no assurance that other batches have not been subject to cross-contamination. b. Or(b) (4) 1, during the filling of batch (b) (4) bulk drug substance for client (b) (4) released on , a(b) (4) leak was observed by the operator. The fill recipe was paused and EMPLOYEE(S) SIGNATURE EMPLOYEE(S) NAME AND TITLE (Print or Type) DATE ISSUED REVERSE Debra M. Emerson, Investigator 4/20/2021 OF THIS Cody D. Rickman, Investigator PAGE

Jeremy Wally, Senior Advisor

INSPECTIONAL OBSERVATIONS

Pagel of 12

PREVIOUS EDITION OBSOLETE

FORM FDA 483 (9/08)

		IT OF HEALTH AND HUMA O AND DRUG ADMINISTRA		
DISTRICT OFFICE ADDRES Baltimore District (BLT	-DO)		DATE(S) OF IN 4/12/2021 -	
6000 Metro Drive, Suit	e 101		FEI NUMBER	
Baltimore, MD 21215 (410) 779-5455	orabioinspectionalcorresp	ondence@fda.hhs.gov	301544860	5
NAME AND TITLE OF INDIV	DUAL TO WHOM REPORT IS ISSUED			
TO: Dino S. Muzzin	Senior Vice President Manufa	acturing Operations		
FIRM NAME		STREET ADD	RESS	
Emergent Manufacti	uring Operations Baltimore, LL0	C. 5901 East	Lombard Street	
CITY, STATE AND ZIP CODI		TYPE OF EST	ABLISHMENT INSPECTED	
Baltimore, MD 2122	4	Vaccine Dr	ug Substance Manufacturer	
REPRESENT A FINAL AGENCY DI MPLEMENT, CORRECTIVE ACTIV	ATIONS MADE BY THE FDA REPRESENTATI ETERMINATION REGARDING YOUR COMPLI ON IN RESPONSE TO AN OBSERVATION, YO TO FDA AT THE ADDRESS ABOVE. IF YOU H	ANCE. IF YOU HAVE AN OBJECTION U MAY DISCUSS THE OBJECTION OF	REGARDING AN OBSERVATION, OR HAVE R ACTION WITH THE FDA REPRESENTATIV	IMPLEMENTED, OR PLAN TO E(S) DURING THE INSPECTION
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	to investigate what impact	하게 하다 그 사이 없고 있을까지 않는 아이들이 하셨다면서요. 그는 아이들이 되어 되었다면 하나요.	지 않는 기계에 되었다. 이 이 아니는 아무나를 하는 것 같아 보는 이 개를 하는 모든 것이라고 있다면 되었다.	
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DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER Baltimore District (BLT-DO) 6000 Metro Drive, Suite 101 Baltimore, MD 21215 DATE(S) OF INSPECTION 4/12/2021 - 4/20/2021

FEI NUMBER 3015448605

(410) 779-5455 orabioinspectionalcorrespondence@fda.hhs.gov

TO: Dino S. Muzzin, Senior Vice President Manufacturing Operations

FIRM NAME
Emergent Manufacturing Operations Baltimore, LLC.

STREET ADDRESS

5901 East Lombard Street

TYPE OF ESTABLISHMENT INSPECTED

Vaccine 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:

- d. On 4/14/2021, the paint on the walls of the controlled not classified corridors surrounding the manufacturing rooms for Areas and were observed to be peeling in multiple areas. Paint flecks were observed on the floor all along the sides of these walls. Damage to the wall boards was also observed approximately 6 inches above the floor and approximately 3 feet above the floor. This peeling paint and wall damage impacts the firms' ability to adequately clean and disinfect the area.
- e. On 4/14/2021, the following items were observed inside room (b) (4), a Grade (1) room, during the filling of client (b) (4) viral vaccine drug substance batch (b) (4)
 - Paint flecks, loose particles/debris, and a washer were observed on the floor along the sides
 of the wall
 - ii. Brown residue was observed on the wall
 - iii. Black residue from a (b) (4) was observed on the floor
 - iv. Blue peeling paint was observed along the door jam into room (b) (4)

Observation 3

The building used for the manufacture of the client viral vaccine drug substance and client viral vaccine drug substance is not of suitable size, design, and location to facilitate cleaning, maintenance, and proper operations.

Specifically,

a. The number and size of decontamination (b) (4) used to decontaminate waste generated during the manufacture of client (b) (4) viral vaccine drug substance or client (b) (4) viral vaccine drug substance are inadequate to ensure that such waste is decontaminated in a timely manner. In addition, an assessment of the building's capacity to decontaminate waste was not performed as part of the incoming process gap assessment prior to introduction of the manufacturing of client (b) (4) viral vaccine drug substance into the facility.

The inadequacy of waste handling is underscored by planned deviation 3100012410 that was opened on 4/9/2021 to change the path of waste out of the building for Areas and and due to an increase in waste from Areas(b) (4) and big this waste will not be(b) (4) but it will be (b) (4) bagged and the exterior of the bag will be (b) (4) with (b) (4) prior to transport through the warehouse and out of the building for a limited number of days.

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE	INSPECTIONAL OBSERVATIONS	Page of 12
REVERSE OF THIS PAGE	EMPLOYEE(S) NAME AND TITLE (Print or Type) Debra M. Emerson, Investigator Cody D. Rickman, Investigator Jeremy Wally, Senior Advisor	4/20/2021

	EALTH AND HUMAN SERVICES DRUG ADMINISTRATION	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER Baltimore District (BLT-DO) 6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 orabioinspectionalcorrespondence NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	ee@fda.hhs.gov	DATE(S) OF INSPECTION 4/12/2021 – 4/20/2021 FEI NUMBER 3015448605
TO: Dino S. Muzzin, Senior Vice President Manufacturing	Operations	
FIRM NAME	STREET ADDRESS	
Emergent Manufacturing Operations Baltimore, LLC.	5901 East Lombard Stree	et
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INS	PECTED
Baltimore, MD 21224	Vaccine Drug Substance	Manufacturer
THIS DOCUMENT LISTS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DUR REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF IMPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DIS OR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY DURING AN INSPECTION OF YOUR FIRM WE OBSERVED: b. The warehouse was observed on 1/27/202 footage, and on 4/12/2021 and 4/13/2021 materials staged for entry into manufacture. c. On 4/14/2021, the Area (b) (4) and (b) (4) containers used to hold (b) (4)	you have an objection regarding an obscuss the objection or action with the polestions, please contact for at the phase of the phase contact for at the phase contact for a	DAREPRESENTATIVE(S) DURING THE INSPECTION OF NUMBER AND ADDRESS ABOVE. Through security camera to be overcrowded with ed for QC sampling. The deduction of the inspection of
d. On 4/14/2021, the Area (b) (4), ro transport racks for (b) (4) drug substance, drug substance, and various other pieces of without bumping into equipment or (b).	(b) (4) containers used to f equipment. The congestion	hold (b) (4) and on made it difficult to move
e. The doors into and out of the (b) (4) (b) (4) area are too small a move material in large containers. On 4/1 pulling large containers along the floor to (b) (4) room into the warehouse.		
Observation 4		
Written production and process control procedure execution of production and process control functions. Specifically, a. According to security camera footage from medical waste from manufacturing Area manufactured, failed to follow SOP04188	m 1/27/2021 and 2/3/2021, end where bulk drug substance	ed at the time of performance. employees handling special e for client (b)(4) is
disinfected and non-decontaminated speci		of regarding nandling non-

OF THIS PAGE FORM FDA 483	Coly D. Will Joseph 3 (9/08) PREVIOUS EDITION OBSOLETE	Debra M. Emerson, Investigator Cody D. Rickman, Investigator Jeremy Wally, Senior Advisor INSPECTIONAL OBSERVATIONS	Page#of 12
SEE REVERSE	EMPLOYEE(S) SIGNATURE	Debra M. Emerson, Investigator	4/20/2021

		EALTH AND HUMAN SERVICE RUG ADMINISTRATION	ES
Baltimore Distriction of the Baltimore, MD 2 (410) 779-5455	re, Suite 101 1215 orabioinspectionalcorrespondence	e@fda.hhs.gov	DATE(S) OF INSPECTION 4/12/2021 - 4/20/2021 FEI NUMBER 3015448605
NAME AND TITLE	OF INDIVIDUAL TO WHOM REPORT IS ISSUED		
	Muzzin, Senior Vice President Manufacturing		
IRM NAME	E C W SE OF BUILD WAS	STREET ADDRESS	ZwZ V
	nufacturing Operations Baltimore, LLC.	5901 East Lombard	
Baltimore, MD		Vaccine Drug Subst	
HIS DOCUMENT LIST: REPRESENT A FINAL A MPLEMENT, CORRECT	S OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURI GENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF Y TIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISI RMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY O	NG THE INSPECTION OF YOUR FACILITY OU HAVE AN OBJECTION REGARDING CUSS THE OBJECTION OR ACTION WITH	TY, THEY ARE INSPECTIONAL OBSERVATIONS, AND DO NO AN OBSERVATION, OR HAVE IMPLEMENTED, OR PLAN TO THITHE FOA REPRESENTATIVE(S) DURING THE INSPECTION
OURING AN INSPECTION i.	On 1/27/2021 and 2/3/2021, emplo		
	for client (b) (4) is manufactured, wer	in a significant of the first and the second of the second	
	waste into the service elevator acce		
ii.	On 1/27/2021 and 2/3/2021, emplo for client (b) (4) is manufactured, fail (b) (4)		
iii.	On 1/27/2021 and 2/3/2021, emplo medical waste from manufacturing	Area The unsealed	bags were observed contacting
	(b) (4) corridor of the warehouse On 1/27/2021 and 2/3/2021, emplo		
iv.	and unsealed bags of special medic		
V.	On 2/3/2021, employees were obse bags of special medical waste from materials were staged for manufact	erved compacting, using manufacturing Area	in the warehouse where raw
	On 2/3/2021, employees were obse		And the second s
vi.	warehouse floor where raw materia and placing the garments in open g	als were staged for ma	
empl	ording to direct observation and securion oyees handling raw materials intended ance for client (b) (4) failed to follow So (effective 9/3/2020) regarding the har	ity camera footage from d for the use in manufo OP001518 v 15.0 (effe	acturing Area where bulk drug ctive 4/9/2021) and SOP001518 v
the(b		dr. v	
i.	On 2/4/2021, employees were obse floor of the (b) (4) wa bottom of the container.	erved dragging contain rehouse corridor failir	
ii.	On 4/12/2021, employees were obs	served dragging contain	ners of raw materials across the
11.	floor of the (b) (4) wa		failing to apply (b) (4) to the
	bottom of the container.	1-7-7-7	
REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE TO THE TOTAL OF THE PROPERTY OF THE PROP	Debra M. Emerson, In Cody D. Rickman, In	nvestigator 4/20/2021 vestigator

INSPECTIONAL OBSERVATIONS

Page Sof 12

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER
Baltimore District (BLT-DO)
6000 Metro Drive, Suite 101
Baltimore, MD 21215
(410) 779-5455 orabioinspectiona

DATE(S) OF INSPECTION 4/12/2021 - 4/20/2021

FEI NUMBER 3015448605

(410) 779-5455 orabioinspectionalcorrespondence@fda.hhs.gov NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dino S. Muzzin, Senior Vice President Manufacturing Operations

FIRM NAME

Emergent Manufacturing Operations Baltimore, LLC.

CITY, STATE AND ZIP CODE

Baltimore, MD 21224

STREET ADDRESS

5901 East Lombard Street

TYPE OF ESTABLISHMENT INSPECTED

Vaccine 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 COMPLANCE. 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.

- iii. On 4/12/2021, employees were observed dragging containers of raw materials across the floor of the (b) (4) corridor failing to apply (b) (4) to the bottom of the container.
- c. According to security badge access logs, shower logs, and security camera footage from 1/19/2021 to 2/21/2021, employees were observed entering manufacturing Area where bulk drug substance for client and Area where bulk drug substance for client de-gowning, showering, and gowning activities according to SOP001516 v 23.0 (effective 2/5/2021) and SOP001516 v 22.0 (effective 9/2/2019).
 - i. According to the security badge access log, security camera footage, and batch record (b) (4) on (b) (4), a manufacturing associate (Operator upstream MFG) was observed entering manufacturing Area when manufacturing for client (b) (4) was taking place, then (b) (4) for raw materials for client (b) (4), and then loading of materials into the (b) (4) in manufacturing Area for client (b) (a) without documenting de-gowning and showering.
 - ii. According to security badge access logs between 1/19/21 2/21/21, one MFG Bioprocess Associate entered manufacturing Area and manufacturing Area from the same day, during 19 different days, only documenting once in shower logbook on 2/21/21.
 - iii. According to security badge access logs between 1/19/21 2/21/21, one engineer entered manufacturing Area and Area on the same day, during 4 different days, not documenting in shower logbook for any of the days.
 - iv. According to firm management between 1/19/21 1/31/21, approximately 14 different personnel entered manufacturing Area and manufacturing Area on the same day, there was no documentation of a shower.
 - v. According to firm management between 2/1/21 2/11/21, approximately 13 different personnel entered manufacturing Area and manufacturing Area on the same day, there was only one documented in the shower logbook.
 - vi. According to firm management between 2/12/21 2/21/21, approximately 13 different personnel entered manufacturing Area and manufacturing Area on the same day, there were only two documented in the shower logbook.

SEE
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OF THIS
PAGE

EMPLOYEE(S) SIGNATURE
Debra M. Emerson, Investigator
Cody D. Rickman, Investigator
Jeremy Wally, Senior Advisor

EMPLOYEE(S) SIGNATURE

DATE ISSUED
4/20/2021

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE

INSPECTIONAL OBSERVATIONS

Page of 12

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION DISTRICT OFFICE ADDRESS AND PHONE NUMBER DATE(S) OF INSPECTION Baltimore District (BLT-DO) 4/12/2021 - 4/20/2021 6000 Metro Drive, Suite 101 FEI NUMBER Baltimore, MD 21215 3015448605 (410) 779-5455 orabioinspectionalcorrespondence@fda.hhs.gov NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED Dino S. Muzzin, Senior Vice President Manufacturing Operations FIRM NAME STREET ADDRESS Emergent Manufacturing Operations Baltimore, LLC. 5901 East Lombard Street CITY, STATE AND ZIP CODE TYPE OF ESTABLISHMENT INSPECTED Baltimore, MD 21224 Vaccine 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: d. According to direct observation and security camera footage from 1/27/2021 to 4/12/2021, employees were observed entering the materials airlock for manufacturing Area where bulk drug substance for client (b) (4) is manufactured, warehouse, (b) (4) room, and (b) (4) room failing to adhere designated gowning zones according to SOP001516 v 23.0 (effective 2/5/2021) and SOP001516 v 22.0 (effective 9/2/2019). According to security camera footage on 1/27/2021, employees were observed removing gloves and booties into waste containers located in the warehouse with staged raw materials present after handling special medical waste from manufacturing Area According to security camera footage on 2/3/2021, employees were observed removing ii. protective gowns onto the floor of the warehouse and into waste containers located in the warehouse with staged raw materials present after handling special medical waste from manufacturing Area Per direct observation on 4/12/21, employees were observed wearing protective gowns and iii. booties into the warehouse and warehouse corridor while conducting activities in the Area materials airlock, (b) (4) room, and (b) (4) Observation 5 The components, product containers and/or closures were not handled and/or stored in a manner to prevent contamination. Specifically, Product components, containers, and closures involved in manufacturing operations, quality control sampling, weigh and dispense operations are not handled and stored to prevent cross contamination of viral bulk drug substances created for client (b) (4) and client (b) (4) a. On 3/16/2021, the firm was notified by clien(b) (4) that bulk drug substance batch (b) (4) manufactured between (b) (4) and (b) (4) , was contaminated with a(b) (4) manufacture of bulk drug substance for client (b) (4) Review of security camera footage found: EMPLOYEE(S) SIGNATURE EMPLOYEE(S) NAME AND TITLE (Print or Type) DATE ISSUED SEE REVERSE Debra M. Emerson, Investigator 4/20/2021

Cody D. Rickman, Investigator

Jeremy Wally, Senior Advisor

INSPECTIONAL OBSERVATIONS

Page 7 of 12

PAGE

FORM FDA 483 (9/08)

PREVIOUS EDITION OBSOLETE

		ALTH AND HUMAN SERVICES RUG ADMINISTRATION		
Baltimore Distr 000 Metro Dri	ve, Suite 101		DATE(S) OF INSI 4/12/2021 - 4	
Baltimore, MD		@(d- bb	FEI NUMBER 3015448605	
410) 779-5455 AME AND TITLE	orabioinspectionalcorrespondence of Individual to whom report is issued	@fda.nns.gov	3013448003	
o: Dino S.	Muzzin, Senior Vice President Manufacturing (Operations		
RM NAME		STREET ADDRESS		
Charles and the same of the sa	anufacturing Operations Baltimore, LLC.	5901 East Lombard Stre		
TY, STATE AND		TYPE OF ESTABLISHMENT IN	ZPUT-BUILDEN	
Baltimore, M		Vaccine Drug Substance		DOCTO ATIONS AND DO NO
EPRESENT A FINAL IPLEMENT, CORREC	IS OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURIN AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF YO STIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DISC DRMATION TO FDA AT THE ADDRESS ABOVE, IF YOU HAVE ANY QU	OU HAVE AN OBJECTION REGARDING AN OB- SUSS THE OBJECTION OR ACTION WITH THE	SERVATION, OR HAVE IN FOA REPRESENTATIVE(PLEMENTED, OR PLAN TO S) DURING THE INSPECTION
	ON OF YOUR FIRM WE OBSERVED:	107 2 2	101 2/3	
i.	On 1/27/2021 and 2/3/2021, employ			
	medical waste from manufacturing	가장 하기 있다. 그는 이 시간 보기가 되는 것 같아요 하는 것 같아 그리지 않는 것 같아.	Charles and the second	
	staged manufacturing materials, wa	lls, and fence barriers in the	he (b) (4)	corrido
	of the warehouse.			And a second particle of the second
ii.				
	and unsealed bags of special medica		ng Area	oss the floor of
		the warehouse.		
iii.	On 2/3/2021, employees were observed		the state of the s	
	from manufacturing Area in the w		rials were stag	ged for
	manufacturing in Area for client			
iv.	On 2/3/2021, employees were observed			
	warehouse floor and placing them i			
	staged for manufacturing in Area on 2/3/2021, an employee was obse	for client (b) (4).		
v.				
	table in the service elevator accessing		Section of the section of the section of	
	medical waste from manufacturing			iterial bucket
	containers into the(b) (4)	room without deconta	minating or di	sinfecting the
	(b) (4) materials bucket contain			
vi.	On 2/4/2021, employees were observed			s across the
	The state of the s	rehouse corridor failing to	apply (b) (4)	to the
	bottom of the container.			
	4/12/2021, employees were observed di			
the ((b) (4) and (b) (4)	warehouse cor	ridor floor fail	ing to apply
(b) (to the bottom of the container.			
			909 & W.	
		terial bucket containers w		
	e raw materials staging area of the war	ehouse staged for manufa	cturing in Are	a for client
(b) (4)				
	4/14/2021, we observed employees lifti	The state of the s	onto a	platform,
oper	ning the container, and then using a sco	op to add the(b) (4)	into the(b) (4) of a
REVERSE	EMPLOYEE(S) SIGNATURE	Debra M. Emerson, Investi		DATE ISSUED 4/20/2021
OF THIS PAGE	Cody D. de	Cody D. Rickman, Investig	ator	TO AN EN CO.
		Jeremy Wally, Senior Advi	SOF	

	EALTH AND HUMAN SERVICES PRUG ADMINISTRATION	
DISTRICT OFFICE ADDRESS AND PHONE NUMBER Baltimore District (BLT-DO) 5000 Metro Drive, Suite 101		ATE(S) OF INSPECTION /12/2021 — 4/20/2021
Baltimore, MD 21215 (410) 779-5455 orabioinspectionalcorrespondenc	1 0	EI NUMBER 015448605
AME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED TO: Dino S. Muzzin, Senior Vice President Manufacturing	Operations	
IRM NAME	STREET ADDRESS	
Emergent Manufacturing Operations Baltimore, LLC.	5901 East Lombard Street	
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECT	ED
Baltimore, MD 21224	Vaccine Drug Substance Manu	ıfacturer
REPRESENT A FINAL AGENCY DETERMINATION REGARDING YOUR COMPLIANCE. IF Y MPLEMENT, CORRECTIVE ACTION IN RESPONSE TO AN OBSERVATION, YOU MAY DIS DR SUBMIT THIS INFORMATION TO FDA AT THE ADDRESS ABOVE. IF YOU HAVE ANY OUTLING AN INSPECTION OF YOUR FIRM WE OBSERVED: (b) (4) for (b) (4) (b) (4) batto the employees failing to remove or sanitize	CUSS THE OBJECTION OR ACTION WITH THE FDA REQUESTIONS, PLEASE CONTACT FDA AT THE PHONE N	PRESENTATIVE(S) DURING THE INSPECTION SUMBER AND ADDRESS ABOVE in Area We observed
Observation 6 Written procedures designed to assure that the druidentity, strength, quality, and purity they purport Specifically,		
does not include a description of how the land (b) (4) to ensure that there is a decontaminate the waste. Such waste is trare received and staged, prior to disposal. b. The procedure used for the periodic monit	adequate(b) (4) in an apported through the warehout	nto these bags to se, where raw materials
described in BOP040102 and documented placement of the (b) (4) or (b	on FRM042531 does not inclu	de a requirement for location inside the
through the warehouse, where raw materia		[14] [14] [14] [14] [14] [14] [14] [14]
c. The procedure for cleaning and decontaminaterials described in SOP001518 does not remove residual (b) (4) store the raw materials inside the (b) (4). 3100012112 as being able to introduce ma (b) (4) used to manufacture the client (b) (4).	onto the (b) (4) prior to ple Such(b) (4) (b) were identifuterial on the outside of the (b)	aning the (b) (4) or to acing(b) (4) (b) used to ied in deviation into a (b) (4) in which
d. The procedure "Material and Waste Flow	for Arag Me SODO41888 vargic	on 2.0 offention 21 Ave
2020 does not reflect current operations fo states (b) (4) all potentially contamina	r the movement of contaminate ted waste", however staff in An	ed waste. The procedure
2020 does not reflect current operations fo states (b) (4) all potentially contamina dispose of potentially contaminated waste	or the movement of contaminate ted waste", however staff in An without first using the (b) (4)	ed waste. The procedure rea were allowed to
2020 does not reflect current operations fo states (b) (4) all potentially contamina	r the movement of contaminate ted waste", however staff in An	ed waste. The procedure rea vere allowed to ntor Type) DATE ISSUED

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER
Baltimore District (BLT-DO)
6000 Metro Drive, Suite 101
Baltimore, MD 21215
(410) 779-5455 orabioinspectionalcorrespondence@fda.hhs.gov

DATE(S) OF INSPECTION 4/12/2021 - 4/20/2021

FEI NUMBER 3015448605

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Dino S. Muzzin, Senior Vice President Manufacturing Operations

Emergent Manufacturing Operations Baltimore, LLC.

CITY, STATE AND ZIP CODE

STREET ADDRESS
5901 East Lombard Street

TYPE OF ESTABLISHMENT INSPECTED

Vaccine 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 7

Baltimore, MD 21224

Employees were not trained in the particular operation that they performed and/or in CGMPs related to their job function.

Specifically,

The firm has failed to adequately train personnel involved in manufacturing operations, quality control sampling, weigh and dispense, and engineering operations to prevent cross contamination of bulk drug substances created for client (b) (4) and client (b) (4).

Review of security camera footage found:

- a. Personnel involved in manufacturing operations entered manufacturing Area while processing of client bulk drug substance was taking place, then entered (b) (4) rooms where operations for client bulk drug substance was taking place without properly adhering to gowning procedures.
- b. Personnel involved in manufacturing operations and engineering entered manufacturing Area while processing of client (b) (4) bulk drug substance was taking place, then entered manufacturing Area while processing for client (b) (4) bulk drug substance was taking place without properly adhering to gowning procedures.
- c. Personnel involved in manufacturing operations dragged non-disinfected and non-decontaminated special medical waste from manufacturing Area across the warehouse corridor, (b) (4)

 (b) (4) corridor, and (b) (4) corridor floors, failing to adhere to materials and waste handling procedures.
- d. Personnel involved in manufacturing operations collided with walls, warehouse barriers, (b) (4)
 (b) (4) doors, (b) (4) doors, and staged raw material containers with non-disinfected and non-decontaminated special medical waste from manufacturing Area failing to adhere to materials and waste handling procedures.

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EMPLOYEE(S) SIGNATURE
Debra M. Emerson, Investigator
Cody D. Rickman, Investigator
Jeremy Wally, Senior Advisor

FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE

EMPLOYEE(S) NAME AND TITLE (Print or Type)
A4/20/2021

DATE ISSUED
Debra M. Emerson, Investigator
Jeremy Wally, Senior Advisor

INSPECTIONAL OBSERVATIONS

Page of 12

DISTRICT OFFICE	ADDRESS AND PHONE NUMBER	RUG ADMINISTRATION DATE(S) OF	INSPECTION
Baltimore Distri	ct (BLT-DO)		- 4/20/2021
3000 Metro Driv Baltimore, MD 2		FEI NUMBE	R
410) 779-5455		@fda.hhs.gov 30154486	605
	OF INDIVIDUAL TO WHOM REPORT IS ISSUED		
*****************	Muzzin, Senior Vice President Manufacturing	· · · · · · · · · · · · · · · · · · ·	
IRM NAME		STREET ADDRESS	
ITY, STATE AND	anufacturing Operations Baltimore, LLC.	5901 East Lombard Street	
Baltimore, MD	No. 10 Company of the	TYPE OF ESTABLISHMENT INSPECTED	
	S OBSERVATIONS MADE BY THE FDA REPRESENTATIVE(S) DURIN	Vaccine Drug Substance Manufacture	
e. Persimani from gowi	on of your firm we observed: onnel involved in manufacturing operation and the address above. If you have any of the address above, if you have any of the address above, if you have any of the address above. If you have any of the address above, if you have any of the address and the	ations removed protective gowns and sinfected and non-decontaminated space with staged raw materials, failing	foot covers worn in secial medical wast to adhere to
(b) (c) processing (b) (c) (c) (c) (d) (d) (d) (d) (d) (d) (d) (d) (d) (d	n 8 used is not of adequate size to facilitat	idor, failing to adhere to materials and	d waste handling
(b) (comprosed to procedular proc	and (b) (4) corredures. n 8 used is not of adequate size to facilitate. 4/13/2021, (b) dating back to 2/22/2 b) (4) inside the microbiology lab	e operations for its intended use or for	r cleaning and plastic container in the
Observatio Equipment maintenance Specifically a. On 4 the subs	and (b) (4) correduces. n 8 used is not of adequate size to facilitate. 4/13/2021, (b) dating back to 2/22/2 b) (4) inside the microbiology labitance. These (b) included environment of the control o	e operations for its intended use or for a coratory that is used for testing of clience to be sent for microbial identifications.	r cleaning and plastic container in tent (b) (4) viral drug (b) (4)
Observatio Equipment maintenance Specifically a. On 4 the subs	and (b) (4) correduces. n 8 used is not of adequate size to facilitate. 4/13/2021, (b) dating back to 2/22/2 b) (4) inside the microbiology labitance. These (b) included environment of the control o	e operations for its intended use or for the control of a poratory that is used for testing of clience that is used for the control of the contr	r cleaning and plastic container in tent (b) (4) viral drug (b) (4)
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Observation Equipment of maintenance Specifically a. On 4 the limits and of the limi	and (b) (4) corredures. n 8 used is not of adequate size to facilitate. 4/13/2021, (b) dating back to 2/22/2 b) (4) inside the microbiology lab tance. These (b) included environmicrobial limit testing for client (b) (4) was overcrowded, and a cleaned (4/14/2021, the (b) (4) inside the (a) the analysts store (b)	e operations for its intended use or for a coratory that is used for testing of cliental monitoring (b), raw materia at are to be sent for microbial identificant had occurred on 4/12/2021.	r cleaning and plastic container in the plast
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Observation Equipment of maintenance Specifically a. On 4 the limits and of the limi	and (b) (4) corrections. n 8 used is not of adequate size to facilitate. 4/13/2021, (b) dating back to 2/22/2 b) (4) inside the microbiology label trance. These (b) included environment of the correction of	e operations for its intended use or for a poratory that is used for testing of clientental monitoring (b), raw materia and are to be sent for microbial identificant had occurred on 4/12/2021. (b) (a) lab (b) (4) room (b) (4), was observed to a waiting send out for identification client (b) (4) (b) (4), (b) (4)	r cleaning and plastic container in the plast
(b) (c) process of pro	and (b) (4) corrections. n 8 used is not of adequate size to facilitate. 4/13/2021, (b) dating back to 2/22/2 b) (4) inside the microbiology label trance. These (b) included environment of the correction of	e operations for its intended use or for a poratory that is used for testing of clientental monitoring (b), raw materia and are to be sent for microbial identificant had occurred on 4/12/2021. (b) (a) lab (b) (4) room (b) (4), was observed to a waiting send out for identification client (b) (4) (b) (4), (b) (4)	r cleaning and plastic container in the plast
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	EALTH AND HUMAN SERV RUG ADMINISTRATION	ICES
DISTRICT OFFICE ADDRESS AND PHONE NUMBER Baltimore District (BLT-DO)		DATE(S) OF INSPECTION 4/12/2021 - 4/20/2021
6000 Metro Drive, Suite 101 Baltimore, MD 21215 410) 779-5455 orabioinspectionalcorrespondence HAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED	e@fda.hhs.gov	FEI NUMBER 3015448605
O: Dino S. Muzzin, Senior Vice President Manufacturing	Operations	
IRM NAME	STREET ADDRESS	
Emergent Manufacturing Operations Baltimore, LLC.	5901 East Lomba	rd Street
ITY, STATE AND ZIP CODE	TYPE OF ESTABLISHI	MENT INSPECTED
Baltimore, MD 21224	Vaccine Drug Sub	stance Manufacturer
		to the state of the
Equipment and/or utensils are not cleaned and mathat would alter the safety, identity, strength, qual Specifically, a. The non-dedicated (b) (4) (b) (4) used to written procedure to be cleaned after each 14) requires that they are (b) (4) (5) (4) airlock.	hold (b) (4) use. The procedure	raw materials are not required by

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE FORM FDA 483 (9/08) PREVIOUS EDITION OBSOLETE

EMPLOYEE(S) NAME AND TITLE (Print or Type) Debra M. Emerson, Investigator Cody D. Rickman, Investigator Jeremy Wally, Senior Advisor INSPECTIONAL OBSERVATIONS

DATE ISSUED 4/20/2021

Pagel of 12

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 judgement, 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."