DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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

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

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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 (b) (4) 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,

   i. 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), (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 hallway outside the (b) (4) room before entering the (b) (4) room through the (b) (4).

   ii. The deviation investigation did not include a thorough review of personnel movements in and around the facility as a potential source of contamination.

   iii. The deviation did not include consideration of the potential impact of the continued use of (b) (4) 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 substance. These (b) (4) were identified in the deviation as being not designed to allow for proper decontamination.

   iv. It is not known how long client (b) (4) virus will remain viable on a surface. There was no additional cleaning performed other than the routine cleaning in response to this deviation.

   v. There is no assurance that other batches have not been subject to cross-contamination.

b. On (b) (4) 1, during the filling of batch (b) (4) bulk drug substance for client (b) (4) released on (b) (4), a (b) (4) leak was observed by the operator. The fill recipe was paused and

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(b) (4) was (b) (4) the (b) (4) (b) (4), then the recipe was aborted, and a new recipe was initiated. The practice for aborting a fill is not described within a written procedure and is not a procedural step in the master batch record. Your firm failed to investigate how the operators were trained to perform this recipe abort and initiate a new recipe technique. Your firm also failed to investigate what impact utilizing this technique has on the product during filling operations.

c. On 1/19/2021, (b) (4) room ID# (b) (4) and (b) (4) corridor ID (b) (4) had logbook entries "fix (b) (4)" and "repair (b) (4)". The bulk drug substance batch (b) (4) for client (b) (4), released on (b) (4), was in the (b) (4) at the time of these logbook entries. Your firm failed to initiate a deviation and failed to conduct an investigation to evaluate what impact a (b) (4) (b) had on bulk drug substance batch (b) (4) or what corrective actions were initiated.

Observation 2

The building used for the manufacture of the client (b) (4) viral vaccine drug substance and client (b) (4) viral vaccine drug substance is not maintained in a clean and sanitary condition.

Specifically,

a. Waste generated during the manufacture of the client (b) (4) vaccine drug substance and client (b) (4) viral vaccine drug substance is not decontaminated using (b) (4) that have been qualified for use or a (b) (4) qualified for actual use. Such waste is transported through the warehouse before disposal and has the potential to contaminate the warehouse and adjacent areas

b. The manufacturing rooms and corridors are not cleaned with a (b) (4).

c. The painted floors in the warehouse were observed to be peeling on multiple days during the inspection. Large areas of the painted surface are missing in front of the (b) (4) and (b) (4) sampling rooms. The damaged floors and rough surfaces do not allow for adequate cleaning and sanitization.

d. On 4/14/2021, the paint on the walls of the controlled not classified corridors surrounding the manufacturing rooms for Areas (b)(4) and (b)(4) 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 (b) (4) room, during the filling of client (b) (4) viral vaccine drug substance batch (b) (4):
   i. 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 (b) (4) viral vaccine drug substance and client (b) (4) 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 (b)(4) and (b)(4) and due to an increase in waste from Areas (b) (4) and (b)(4) 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.

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b. The warehouse was observed on 1/27/2021, 2/3/2021 and 2/4/2021 through security camera footage, and on 4/12/2021 and 4/13/2021 through direct observation, to be overcrowded with materials staged for entry into manufacturing as well as material staged for QC sampling.

c. On 4/14/2021, the Area (b) (4), room (b) (4), was observed to be congested with (b) and (b) (4) containers used to hold (b) (4).

d. On 4/14/2021, the Area (b) (4), room (b) (4), was observed to be congested with carts, transport racks for (b) (4) drug substance, (b) (4) containers used to hold (b) (4) and drug substance, and various other pieces of equipment. The congestion made it difficult to move without bumping into equipment or (b).

e. The doors into and out of the (b) (4) into the (b) (4) area and into the (b) (4) area are too small as operators are unable to use a pallet jack for pallets to move material in large containers. On 4/12 and 4/13/2021, operators were observed pushing and pulling large containers along the floor to move them from (b) (4) room and (b) (4) (b) (4) room into the warehouse.

Observation 4

Written production and process control procedures to prevent cross-contamination are not followed in the execution of production and process control functions and are not documented at the time of performance.

Specifically,

a. According to security camera footage from 1/27/2021 and 2/3/2021, employees handling special medical waste from manufacturing Area (b) (4) where bulk drug substance for client (b) (4) is manufactured, failed to follow SOP041888 v 3.0 (effective 8/21/2020) regarding handling non-disinfected and non-decontaminated special medical waste.

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

i. On 1/27/2021 and 2/3/2021, employees in manufacturing Area (b)(4) where bulk drug substance for client (b)(4) is manufactured, were observed throwing unsealed bags of special medical waste into the service elevator accessing the warehouse corridor.

ii. On 1/27/2021 and 2/3/2021, employees in manufacturing Area (b)(4) where bulk drug substance for client (b)(4) is manufactured, failed to (b)(4) all special medical waste with (b)(4).

iii. On 1/27/2021 and 2/3/2021, employees were observed carrying unsealed bags of special medical waste from manufacturing Area (b)(4). The unsealed bags were observed contacting containers of staged manufacturing materials, walls, and fence barriers in the (b)(4) (b)(4) corridor of the warehouse.

iv. On 1/27/2021 and 2/3/2021, employees were observed dragging used materials containers and unsealed bags of special medical waste from manufacturing Area (b) across the floor of the (b)(4) corridor of the warehouse.

v. On 2/3/2021, employees were observed compacting, using their gloved hands, unsealed bags of special medical waste from manufacturing Area (b)(4) in the warehouse where raw materials were staged for manufacturing in Area (b)(4) for client (b)(4).

vi. On 2/3/2021, employees were observed removing their outer protective garments onto the warehouse floor where raw materials were staged for manufacturing in Area (b)(4) for client (b)(4) and placing the garments in open garbage containers.

b. According to direct observation and security camera footage from 2/4/2021 and 4/12/2021, employees handling raw materials intended for the use in manufacturing Area (b) where bulk drug substance for client (b)(4) failed to follow SOP001518 v 15.0 (effective 4/9/2021) and SOP001518 v 14.0 (effective 9/3/2020) regarding the handling of materials into the (b)(4) room and the (b)(4) sampling room.

i. On 2/4/2021, employees were observed dragging containers of raw materials across the floor of the (b)(4) warehouse corridor failing to apply (b)(4) to the bottom of the container.

ii. On 4/12/2021, employees were observed dragging containers of raw materials across the floor of the (b)(4) warehouse corridor floor failing to apply (b)(4) to the bottom of the container.

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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 (b) (4) where bulk drug substance for client (b) (4) and Area (b) (4) where bulk drug substance for client (b) (4) in the same day failing to document 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 (b) (4) 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 (b) (4) for client (b) (4) 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 (b) and manufacturing Area (b) (4) on 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 (b) (4) and Area (b) (4) 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 (b) (4) and manufacturing Area (b) 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 (b) (4) and manufacturing Area (b) (4) 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 (b) (4) and manufacturing Area (b) (4) on the same day, there were only two documented in the shower logbook.

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 (b) (4) where bulk drug substance for client (b) (4) is manufactured, warehouse, (b) (4) room, and (b) (4) (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).

i. 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 (b) (4)

ii. According to security camera footage on 2/3/2021, employees were observed removing 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 (b) (4)

iii. Per direct observation on 4/12/21, employees were observed wearing protective gowns and booties into the warehouse and warehouse corridor while conducting activities in the Area (b) materials airlock, (b) (4) room, and (b) (4) room.

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 client (b) (4) that bulk drug substance batch (b) (4) manufactured between (b) (4) and (b) (4), was contaminated with a (b) (4) used in the manufacture of bulk drug substance for client (b) (4) Review of security camera footage found:

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i. On 1/27/2021 and 2/3/2021, employees were observed carrying unsealed bags of special medical waste from manufacturing Area (b)(4). The unsealed bags contacted containers of staged manufacturing materials, walls, and fence barriers in the (b) (4) corridor of the warehouse.

ii. On 1/27/2021 and 2/3/2021, employees were observed dragging used materials containers and unsealed bags of special medical waste from manufacturing Area (b)(4) across the floor of the (b) (4) corridor of the warehouse.

iii. On 2/3/2021, employees were observed compacting unsealed bags of special medical waste from manufacturing Area (b)(4) in the warehouse where raw materials were staged for manufacturing in Area (b)(4) for client (b) (4).

iv. On 2/3/2021, employees were observed removing outer protective garments onto the warehouse floor and placing them in open garbage containers where raw materials were staged for manufacturing in Area (b) for client (b) (4).

v. On ~~2/3/2021~~ 1/27/2021 CDR 4/20/2021, an employee was observed putting (b) (4) material bucket containers on a table in the service elevator accessing manufacturing Area (b)(4) amongst unsealed special medical waste from manufacturing Area (b)(4) then bringing the (b) (4) material bucket containers into the (b) (4) room without decontaminating or disinfecting the (b) (4) materials bucket containers.

vi. On 2/4/2021, employees were observed dragging containers of raw materials across the floor of the (b) (4) warehouse corridor failing to apply (b) (4) to the bottom of the container.

b. On 4/12/2021, employees were observed dragging containers of raw materials across the floor of the (b) (4) and (b) (4) warehouse corridor floor failing to apply (b) (4) to the bottom of the container.

c. On 4/12/2021, we observed (b) (4) material bucket containers with cracked or opened closures in the raw materials staging area of the warehouse staged for manufacturing in Area (b) (4) for client (b) (4).

d. On 4/14/2021, we observed employees lifting containers of (b) (4) onto a platform, opening the container, and then using a scoop to add the (b) (4) into the (b) (4) of a

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(b) (4) for (b) (4) (b) (4) batch (b) (4) in manufacturing in Area (b) (4) We observed the employees failing to remove or sanitize their gloves after grabbing the bottom of the container.

Observation 6

Written procedures designed to assure that the drug substances manufactured in the facility have the identity, strength, quality, and purity they purport or are represented to possess are inadequate. Specifically,

a. The procedure for decontamination of waste generated during the manufacture of the client (b) (4) viral vaccine drug substance and client (b) (4) viral vaccine drug substance described in SOP040195 does not include a description of how the bags containing the waste are to be placed into the (b) (4) to ensure that there is adequate (b) (4) into these bags to decontaminate the waste. Such waste is transported through the warehouse, where raw materials are received and staged, prior to disposal.

b. The procedure used for the periodic monitoring of decontamination (b) (4) effectiveness described in BOP040102 and documented on FRM042531 does not include a requirement for placement of the (b) (4) or (b) (4) in a (b) (4) location inside the (b) (4) to support that all of the waste is decontaminated. Such waste is transported through the warehouse, where raw materials are received and staged, prior to disposal.

c. The procedure for cleaning and decontamination of (b) (4) used to store and transport raw materials described in SOP001518 does not include a requirement for cleaning the (b) (4) or to remove residual (b) (4) onto the (b) (4) prior to placing (b) (4) (b) used to store the raw materials inside the (b) (4). Such (b) (4) (b) were identified in deviation 3100012112 as being able to introduce material on the outside of the (b) into a (b) (4) in which (b) (4) used to manufacture the client (b) (4) viral vaccine drug substance are formulated.

d. The procedure "Material and Waste Flow for Area (b) (4) SOP041888, version 3.0, effective 21 Aug 2020 does not reflect current operations for the movement of contaminated waste. The procedure states (b) (4) all potentially contaminated waste", however staff in Area (b) (4) were allowed to dispose of potentially contaminated waste without first using the (b) (4)

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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

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 (b) (4) while processing of client (b) (4) bulk drug substance was taking place, then entered (b) (4) rooms where operations for client (b) (4) bulk drug substance was taking place without properly adhering to gowning procedures.

b. Personnel involved in manufacturing operations and engineering entered manufacturing Area (b) while processing of client (b) (4) bulk drug substance was taking place, then entered manufacturing Area (b) (4) 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 (b) (4) 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 (b) (4) failing to adhere to materials and waste handling procedures.

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

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

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

e. Personnel involved in manufacturing operations removed protective gowns and foot covers worn in manufacturing Area (b)(4) and handling non-disinfected and non-decontaminated special medical waste from manufacturing Area (b)(4) in the warehouse with staged raw materials, failing to adhere to gowning procedures.

The following was directly observed during the inspection:

f. Personnel involved with (b) (4), and (b) (4) sampling operations were observed dragging raw material containers used in manufacturing Area (b)(4) across the (b) (4) (b) (4) and (b) (4) corridor, failing to adhere to materials and waste handling procedures.

Observation 8

Equipment used is not of adequate size to facilitate operations for its intended use or for cleaning and maintenance.

Specifically,

a. On 4/13/2021, (b) dating back to 2/22/2021 were observed in and on top of a plastic container in the (b) (4) inside the microbiology laboratory that is used for testing of client (b) (4) viral drug substance. These (b) included environmental monitoring (b), raw material (b) (4) (b), and microbial limit testing for client (b) (4) that are to be sent for microbial identification. This (b) (4) was overcrowded, and a cleanout had occurred on 4/12/2021.

b. On 4/14/2021, the (b) (4) inside the (b) (4) lab (b) (4) room (b) (4), was observed to be overcrowded. Inside this (b) (4) the analysts store (b) awaiting send out for identification, (b) (4) (b) (4), retains for client (b) (4) (b) (4), (b) (4) (b) of in-process and final drug substance samples, and laboratory supplies and (b) (4) needing storage under (b) (4)

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

Observation 9

Equipment and/or utensils are not cleaned and maintained at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug substance.

Specifically,

a. The non-dedicated (b) (4) (b) (4) used to hold (b) (4) raw materials are not required by written procedure to be cleaned after each use. The procedure as described in SOP001518 (version 14) requires that they are (b) (4) (b) (4) with (b) (4) when travelling through the material airlock.

b. I observed residue on the bottom of a (b) (4) inside the Area (b) (4) suite. Rouging was observed on the metal screws that attach the (b) (4) to the (b) (4) below in many of the (b) (4) seen in the hallway. These (b) (4) are used to transport material in Area (b) (4)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Debra M. Emerson, Investigator Cody D. Rickman, Investigator Jeremy Wally, Senior Advisor	4/20/2021

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 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."