DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781)587-7500 Fax:(781)587-7556 ORAPHARM1_RESPONSES@fda.hhs.gov	9/18/2023-10/20/2023*
	FEI NUMBER 3013736415

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Scott P. Luce, Chief Executive Officer

FIRM NAME	STREET ADDRESS
SCA Pharmaceuticals, LLC	755 Rainbow Rd Ste B
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Windsor, CT 06095-1024	Outsourcing Facility

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

There is no quality control unit.

Specifically,

A. The firm's investigation process is deficient in that the firm does not require identification of particulates found during the visual inspection process.

B. The firm's visual inspection process governed by SOP ILP-001-W "Product Inspection and Defect Classification" effective 2/22/2023 is deficient in that the SOP does not require the opening of an investigation after a failure of the 100% visual inspection.

For example, in the last 6 months your firm has performed 100% visual inspection on approximately 3663 batches and approximately 783 failed 100% visual inspection. These batches were released without an investigation because the firm's visual inspectional AQL passed.

Furthermore, your SOP does not require an investigation after an AQL failure, unless a critical defect is found, or an investigation after a second 100% inspection failure. In the last 6 months you have had approximately 55 instances where you had a 100% visual inspection failure, AQL failure, a second 100% visual inspection failure, and a passing tightened AQL and an investigation is not always opened. Examples of products released by Quality are included in the following chart.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Jonah S Ufferfilge, Investigator John P Mistler, Investigator		10/20/2023

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Lot	Product Name	Compound Date	# of Units	Qty Distributed	100% Inspection	Reason for 100% Inspection Failure	AQL	Reason for AQL Failure	2nd 100%	Reason for 2nd 100% Inspection Failure	TAQL	Reason for TAQL Failure	Deviation #
1223048045	Hydromorphone HCl 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe (30 mg/3	7/20/23	243	204	Fail	Foreign material between stopper and syringe wall Non-integral or Non- functional container, e.g. leaking	Fail	Non-integral or Non- functional container, e.g. leaking	Fail	Gross Cosmetic flaw (manufacturer defect) on exterior of container	Pass		DEV-2023-0343 AQL Failure for Critical Defect for lot
1223048117	Hydromorphone HCl 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe (30 mg/3	7/24/23	269	264	Fail	Foreign material between stopper and syringe wall	Fail	Non-integral or Non- functional container, e.g. leaking Foreign material between stopper and syringe wall	Fail	Foreign material between stopper and syringe wall Gross Cosmetic flaw (manufacturer defect) on exterior of container Non-integral or Non-	Pass		DEV-2023-0350 AQL Failure for Critical Defect for lot
1223048170	Labetalol 5 mg/mL 4 mL fill Syringe (20 mg/4 mL)	7/26/23	1,295	1,231	Fail	Non-integral or Non- functional container, e.g. leaking	Fail	Non-integral or Non- functional container, e.g. leaking	Fail	stopper and the syringe wall Non-integral or Non-	Pass		DEV-2023-0353 AQL Failure for Critical Defect for lot
1223048351	Fentanyl 50 mcg/mL 50 mL Fill Bag (2,500 mcg/50 mL)	8/2/23	279	243	Fail	Particulate/Material in solution	Fail	Particulate/Material in solution	Fail	Particulate/Material in solution	Pass		No Deviation
1223048461	Hydromorphone HCl 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe (30 mg/3	8/7/23	284	235	Fail	Foreign material between stopper and syringe wall Non-integral or Non- functional container, e.g. leaking	Fail	Non-integral or Non- functional container, e.g. leaking	Fail	Non-integral or Non- functional container, e.g. leaking	Pass		DEV-2023-0404 AQL Failure for Critical Defect for lot
1223048694	Hydromorphone HCl 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe (30 mg/3	8/18/23	306	263	Fail	Foreign material between stopper and syringe wall Particulate/Material in solution Non-integral or Non- functional container, e.g. leaking	Fail	Foreign material between stopper and syringe wall Particulate/Material in solution	Fail	Foreign material between stopper and syringe wall Non-integral or Non- functional container, e.g. leaking	Pass		No Deviation
1223048807	Midazolam HCl 1 mg/mL in 0.9%	8/21/23	247	243	Fail	Particulate/Material in solution	Fail	Particulate/Material in	Fail	Particulate/Material in	Pass		No Deviation

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	Sodium Chloride 100 mL Bag (100 mg/100 mL)							solution		solution			
1223048801	Hydromorphone HCl 0.2 mg/mL in 0.9% Sodium Chloride 50 mL fill Syringe (10 mg/50 mL)	8/21/23	188	183	Fail	Non-integral or Non- functional container, e.g. leaking Particulate/Material in solution	Fail	Non-integral or Non- functional container, e.g. leaking	Fail	Non-integral or Non- functional container, e.g. leaking	Pass		DEV-2023-0449 AQL Failure for Critical Defect for lot
1223048865	Hydromorphone HCl 1 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syringe (30 mg/3	8/23/23	252	246	Fail	Non-integral or Non- functional container, e.g. leaking Foreign material between stopper and syringe wall Particulate/Material in solution	Fail	Foreign material between stopper and syringe wall Particulate/Material in solution	Fail	Foreign material between stopper and syringe wall	Pass		No Deviation
1223048963	Hydromorphone HCl 0.2 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syr (6 mg/30 m	8/25/23	239	187	Fail	Foreign material between stopper and syringe wall Non-integral or Non- functional container, e.g. leaking	Fail	Non-integral or Non- functional container, e.g. leaking	Fail	between stopper and syringe wall Particulate/Material in solution	Pass		DEV-2023-0431 AQL Failure for Critical Defect for lot
1223048959	Fentanyl 10 mcg/mL in 0.9% Sodium Chloride 50 mL fill Syringe (500 mcg/50 mL)	8/28/23	363	357	Fail	Non-integral or Non- functional container, e.g. leaking	Fail	Non-integral or Non- functional container, e.g. leaking	Fail	Non-integral or Non- functional container, e.g. leaking	Pass		DEV-2023-0446 AQL Failure for Critical Defect for lot
1223049009	Fentanyl 10 mcg/mL in 0.9% Sodium Chloride 50 mL fill Syringe (500 mcg/50 mL)	8/29/23	360	20	Fail	Non-integral or Non- functional container, e.g. leaking	Fail	Non-integral or Non- functional container, e.g., broken cap (Primary seal cap) Non-integral or Non-functional container, e.g. leaking	Fail	Non-integral or Non- functional container, e.g. leaking	Pass		No Deviation
1223049559	Hydromorphone HCl 0.2 mg/mL in 0.9% Sodium Chloride 30 mL fill 35 mL Plungerless Syr (6 mg/30 m	9/21/23	234	223	Fail	Particulate/Material in solution Foreign material between stopper and syringe wall	Fail	Particulate/Material in solution Foreign material between stopper and syringe wall	Fail	Particulate/Material in solution	Pass		No Deviation

C.In addition, your visual inspection process is deficient. For example:

a.The visual inspection SOP ILP-001-W “Product Inspection and Defect Classification”

is deficient in that an AQL failure after a passing of 100% visual inspection does not trigger a retraining your Visual Inspector employees.

b.Production employees perform the AQL and tightened AQL, Quality does not perform the AQL Visual inspection.

OBSERVATION 2

Actual yield and percentages of theoretical yield are not determined at the conclusion of each appropriate phase of manufacturing of the drug product.

Specifically,

The visual inspection % yield is not calculated or established in the batch record or is an established quality parameter. For example, the following batches were compounded and released.

A.Batch record for Hydromorphone HCL 1mg/mL in 0.9% Sodium Chloride 30mL fill 35mL Plungerless Syringe, Lot number 1223048865, shows 372 compounded units released to visual inspection and after the visual inspection rejection the amount of product released to labeling was 249 units, which had an approximate yield of 70%.

B.Batch record for Fentanyl 50mcg/mL 50mL bag, Lot number 1223048351, shows 286 compounded units released to visual inspection and after visual inspection rejection the amount of product released to labeling was 246 units, which had an approximate yield of 86%.

C.Batch record for Hydromorphone HCL 0.2 mg/mL in 0.9% Sodium Chloride 30mL fill 35mL Plungerless Syringe, Lot number 1223049559, shows 306 compounded units released to visual inspection and after visual inspection rejection the amount of product released to labeling was 226 units, which had an approximate yield of 74%.

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OBSERVATION 3

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A)Your SOP TM 008 "USP <788> Particulate Matter" is deficient in that after a failure of Test Method 1 (Light Obscuration Particle Count Test) than Test Method 2 (Microscopic Particle Count Test) is performed.

a.Your SOP states that If after a failure of Test Method 1 and a passing of Test Method 2, the product can be released and distributed without opening an investigation.

For example, since 2019 there were approximately 38 instances where there was a failure of Test Method 1 and a Passing of Test Method 2 without opening an investigation. For example, see the chart below

X											
Lot Number	**Product Code**	**Product Name**	**Method 1 Result**	**Method 2 Results ≥ 10 µm, ≥ 25 µm**	**Method 2 results - ≤3000 particles/cont, ≤300 particles/cont**	**Method 2 Result**	**Compound Date**	**BUD**	**Route of Administration**	**# of Units compounded**	**Disposition of Lot**
1223048899	F078140	Norepinephrine 4 mg contains sulfites in 0.9% Sodium Chloride 250 mL Bag (16 mcg/mL)	Fail	0,0	-	Pass	08/24/23	11/22/23	Intravenous	389	Released
1223048904	F078540	Norepinephrine 16 mg contains sulfites in 0.9% Sodium Chloride 250 mL Bag (64 mcg/mL)	Fail	0,1	-	Pass	08/24/23	03/01/24	Intravenous	199	Released
1223043932	F078140	Norepinephrine 4 mg contains sulfites in 0.9% Sodium Chloride 250 mL Bag (16 mcg/mL)	Fail	0,2	-	Pass	01/20/23	04/20/23	Intravenous	400	Released

These products have been released and distributed.

B)Since December 2019, the firm has documented twenty-nine (29) Out of Specifications (OOS)

results for in-house sterility testing of finished drug products intended to be sterile using a rapid scan method (BioMérieux ScanRDI). All batches were rejected; however, the firm failed to adequately investigate and remediate all potential sources of microbial contamination including spore-forming microbes.

For example: Out of Specification (OOS-2023-0069) initiated on or about 29-Aug-2023 identified circular spore like structures in lot# 1223048877 (Phenylephrine HCl 40 mcg/mL in 0.9per Sodium Chloride 10 mL fill 12 mL Syringe 400 mcg 10 mL). The firm's accompanying manufacturing deviation (DEV-2023-0435) identified inadequate material sanitization and poor aseptic technique demonstrated by the Compounder as identified causes; however, the firm failed to identify Sanitization Technicians also wiped totes with IPA wipes prior to meeting the firm's established sporicidal disinfectant contact time of 5 minutes. On 26-SEP-2023 via the firm's Avigilon video recordings, sporicidal disinfectant contact times for the 10 totes associated with lot 1223048877 were observed to be as low as 63 seconds before Sanitization Technicians wiped the totes with IPA. The firm's investigation remains open.

In addition, there is no assurance the firm's remediation actions for all sterility OOSs and accompanying manufacturing deviations are adequate, specifically for spore-forming microbes. For example: the firm's corrective and preventative actions included retraining of individual Compounders, Aseptic Assistants, and Sanitization Technicians associated with specific sterility OOSs, and the firm opened CAPA-2023-0017 in response to a lack of standardized material sanitization by firm personnel, which was associated with five (5) sterility OOSs that occurred in April of 2023; however, the CAPA due date for training of all staff is not until 31-JAN-2024 and six (6) of the firm's last 10 sterility OOSs identified spores or spore-forming microbe morphologies. For additional example, on 11-OCT-2023, the firm opened DEV-2023-0525 as a result of a failed media fill. The firm identified the microbe from the failed media fill as genius Bacillus, a spore-forming bacterial microbe.

C)The firm failed to adequately assess and remediate numerous findings of foreign materials, described as cardboard and hair, found in sterile starting material syringe tray packs from the

firm's three (3) syringe suppliers. Since January 2022, the firm documented numerous incidences of foreign materials found in syringe tray packs during production within ISO-5 environments via Form QA-01401, Foreign Material Documentation forms. The firm trends starting material lots found with foreign materials and rejects in-process product found to be associated with tray packs in which foreign material was identified; however, there is no assurance all foreign material is found and removed as the firm does not qualify operators to identified foreign materials, the firm does not track or trend operators who identifying foreign materials, and the firm continues to use the same suppliers.

D)The firm failed to adequately address 100% visual inspection and AQL failures. The firm opened CAPA-2022-0034 (Corrective Action and Preventive Action) on 23 Sep 2022 with a CAPA due date of 23 JUN 2024. A CAPA action plan was signed by Quality on 23 Jun 23, The action plan includes opening an investigation after 100% Visual Inspection failure. Since 23 Jun 23, the firm has had approximately 480 lots that failed 100% inspection, without an investigation being opened.

OBSERVATION 4

Written procedures are not established and followed for the cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically,

A)There are no established procedures for preparing Spor-Klenz wipes used to sanitize all starting compounding materials, totes, and cleanroom equipment such as the firm's ISO-5 Horizontal Laminar Flow Hoods, to ensure consistency and adequacy of cleaning. The firm prepares Spor-Klenz wipes used to sanitize starting materials and totes by adding an undefined amount of Spor-Klenz from a gallon container into a Contec non-sterile and low linting Sanotex Environmental Surface Wipes container. The firm prepares Spor-

Klenz wipes used to perform nightly cleaning of the ISO-5 hoods by adding and an undefined amount of Spor-Klenz from a gallon container into a mop bucket containing an undefined amount of Berkshire Corporation sterile Gamma Wipes.

B)Polypropylene totes used to transfer all compounding materials from an unclassified staging area (room 252) to the ISO-7 compounding suite (rooms 1102, 1104, 1107, & 1110) and placed immediately adjacent to ISO-5 Horizontal Laminar Flow Hoods are not adequately sanitized. Sanitization technicians were observed to wipe totes with IPA wipes prior to meeting the firm's established Spor-Klenz contact time of 5 minutes. For example, Spor-Klenz contact times for 10 totes associated with lot 1223048877 (Phenylephrine HCl 40mcg/ml in Sodium Chloride 10mL fill in 12 mL Syringes) were observed to be as low as 63 seconds before being wiped with IPA. The firm currently has an open sterility OOS for lot 1223048877.

C)The firm uses Spor-Klenz wipes to perform nightly sporicidal cleanings of top, side walls, and deck of the firm's 15 ISO-5 Horizontal Laminar Flow Hoods used to produce product purported to be sterile; however, the firm does not perform periodic sporicidal cleanings of the grate covering the HEPA filter for any of the hoods. The firm has not performed a risk assessment for this practice.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not written.

Specifically,

A)Operators failed to follow techniques intended to maintain sterility of items and surfaces

during aseptic operations. For example, on 18-SEP-2023, during production of lot 1223049390 Fentanyl 20mcg/mL in 0.9% Sodium Chloride 100mL Bags in bay CT0120, hood #7/2, Aseptic Assistant (PJ) was observed to touch items including totes, a chair, repeater pumps, gowning, and subsequently reached into the ISO-5 hood to provide additional starting materials and retrieve finished product without sanitizing hands or changing gloves. In addition, upon review of the firm's Avigilon video recordings, Aseptic Assistant (PJ) touched the surface of a table were non-sterile paper and label items were located, as well as the paper batch record, and subsequently reached into the ISO-5 hood to provide additional starting materials and retrieve finished product without sanitizing hands or changing gloves. The firm's SOP (COM-001-W) requires operators to don new sterile gloves or sanitize gloves with 70% IPA prior to staging material into and collecting material out of ISO-5 hoods. Lot 1223049390 was approved by Quality on 26-SEP-2023.

B)The firm failed to ensure adequate cleanroom airflow to not potentially compromise aseptic operations. For example, on 18-SEP-2023, during production of lot 1223049390 Fentanyl 20mcg/mL in in 0.9% per Sodium Chloride 100mL Bags in bay CT0120, hood #7/2, air return vents for the firm's HVAC system, located in half walls separating the firm's ISO-5 hoods, were observed to be obstructed. The firm's SOP (SAN-002-W) requires materials or totes on carts to be stored in a manner that does not block airflow for air return vents.

OBSERVATION 6

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

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The firm's environmental monitoring practices of classified and aseptic processing areas do not ensure appropriate levels of environmental cleanliness. For example:

A)Personnel monitoring of gloved fingertips for Aseptic Assistants never occurs as part of the firm's routine personnel monitoring program; however, Aseptic Assistants were observed reaching into ISO-5 hoods to stage starting materials and collect finished products during production.

B)The firm's personnel monitoring action limit for the sleeves of Aseptic Assistants is > 10 colony forming units (CFUs); however, Aseptic Assistants were observed to reach into hoods during production. Since January 2020 there were 30 spore-forming microbial recoveries of < 10 CFUs on the sleeves of Aseptic Assistants. The firm failed to investigate and assess product impact for any of these spore-forming microbial recoveries.

C)The firm does not consider spore-forming bacteria recovered from classified environments as objectionable unless action levels are reached. Since January 2020, the firm documented 404 media plates which identified spore-forming microbial recoveries from ISO-7 environments; however, only recoveries with 10 CFUs or more are investigated.

D)The firm performs viable active air monitoring during compounding via SAS Super 180 Portable Microbial Air Monitors; however, the monitor is placed to the far right of the ISO-5 hood with the probe approximately six inches and directly facing the HEPA filter. The firm did not perform or provided directionality studies or scientific justification for this practice.

E)Cleanroom items such totes, chair, and repeater pumps, observed to be touched by Aseptic

Assistants, are never sampled as part of the firm's routine environmental monitoring program.

OBSERVATION 7

Equipment used in the manufacture, processing, packing or holding of drug products is not of appropriate design to facilitate operations for its intended use and cleaning and maintenance.

Specifically,

The firm uses polypropylene totes to transfer all compound materials from non-classified environments into the ISO-7 compounding suite, which are further staged immediately adjacent to ISO-5 hoods. The totes appeared to have scratches, and some were observed with UPC stickers, on the bottom side of the tote and on lids, which and appeared to be shedding. In addition, in July 2023, the firm performed a tote study to determine bioburden found on the totes. Sampling results following the firm's standard sanitization process and within the firm's ISO-7 environment found 3% of samples collected yielded microbial recoveries. Of that, 60% were attributed to the genius Bacillus. Bacillus is a spore-forming bacterial microbe.

OBSERVATION 8

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

Specifically,

Specifically, the firm failed to adequately investigate customer complaints. For example:

A)CUS-2023-0066, CUS-2023-0067, and CUS-2023-0068 were initiated on 25-Jul-23 regarding

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suspected super potency and three patients who experienced loss of consciousness, lethargy and inability to move, and issues moving legs, respectively, following administration of lot# 1223046077 (Fentanyl 2 mcg/mL and Ropivacaine HCl 0.2% in 0.9% Sodium Chloride 100 mL Bag). The firm's investigation stated the complaints were not able to be confirmed; however, the firm failed to test returned products which were identified as integral. The investigation was approved and close by Quality Assurance 25-AUG-23, 23-AUG-23, and 28-AUG-23 respectively.

B)CUS-2021-0051 (AE-21-009-W and AE-21-010-W) were initiated on 24-May-21 regarding suspected super potency and two patients who experienced severe decrease in heart rate and QRS complexes, respectively, following administration of lot# 1221027041 (Phenylephrine HCl 100mcg/mL in 0.9% Sodium Chloride 10 mL fill 12 mL Syringe). The firm's investigation stated the complaints were not able to be confirmed; however, the firm failed to test returned products. The investigation was approved and close by Quality Assurance 30-JUN-21.

OBSERVATION 9

Appropriate controls are not exercised over computers or related systems to assure that changes in master production and control records or other records are instituted only by authorized personnel.

Specifically,

A)Partially completed original GMP documents including but not limited to laboratory sheets and stability study sheets were found in the firm's shred bins. The firm's procedure, SOP QA0001 – Good Documentation Practices, prohibits this practice.

B)Multiple copies of blank fillable original GMP documents including but not limited to

sterility worksheets and additional laboratory worksheets were found in the firm's shred bins. The firm maintains GMP documents in MasterControl QMIS which allows authorized personnel to download documents to individual computer terminals with a 24-hour restriction; however, there are no restrictions on the number of copies that can be printed.

OBSERVATION 10

The labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically,

Specifically, some of your drug product labels did not include the complete established name of the drug product, as the established name did not include the name of the salt (e.g., citrate, bitartrate, and hydrochloride) in addition to the base on the label.
For example,

A. Fentanyl 100 mcg/2 mL. The label does not include the full name Fentanyl Citrate
B. Norepinephrine 4 mg in 0.9% Sodium Chloride 250 mL bag. The label does not include the full name Norepinephrine Bitartrate.
C. Ketamine 100 mg/10 mL does not include the full name Ketamine HCL (Hydrochloride).

***DATES OF INSPECTION**

9/18/2023(Mon), 9/19/2023(Tue), 9/20/2023(Wed), 9/21/2023(Thu), 9/22/2023(Fri), 9/25/2023(Mon), 9/26/2023(Tue), 9/27/2023(Wed), 9/28/2023(Thu), 9/29/2023(Fri), 10/10/2023(Tue), 10/11/2023(Wed), 10/12/2023(Thu), 10/13/2023(Fri), 10/20/2023(Fri)

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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."