DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	12/08/2015 - 12/29/2015* FEI NUMBER 1000371043

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Andrew J. Komuves, President and CEO

FIRM NAME	STREET ADDRESS
Dougherty's Pharmacy	5959 Royal Ln Suite 515
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dallas, TX 75230-3856	Producer of Sterile Drug Products

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

Each batch of drug product purporting to be sterile and pyrogen-free is not laboratory tested to determine conformance to such requirements.

Specifically,

A. Lack of sterility testing for sterile products produced from 6/2015 to 9/2015. From 6/1/2015 to 9/13/2015 your firm produced and released approximately (b) (4) lots of product containing Alprostadil USP (Prostaglandin E1) (PGE) (a non-sterile (b) (4) to sterile product) without performing sterility testing.

B. Sterile to sterile products were (b) (4) and tested for sterility using an In-house sterility test method that has not been validated.

C. Lack of endotoxin testing for non-sterile to sterile products produced from 6/1/2015 to date.

D. Per your Logged Formula Worksheets non-sterile products are issued extended Beyond Use Dates (BUDs), these products lack sterility testing and verification of sterility.

a. For example the following products containing PGE (a non-sterile (b) (4)) were released between (b) (4) (b) (4) with 90 day BUD according to the Logged Formula Worksheets.

Date Compounded	Lot Number	Product Name	Route of Admin	BUD	BUD Info	Storage	Starting Material
(b) (4)	(b) (4)	PAP+PHEN+PGE 30/1/0.02 MG/ML INJECTABLE	Injection	8/31/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PGE (b) (4)	(b) (4)	(b) (4)		(b) (4)	(b) (4)
		PAP+PHEN+PGE+ATRO 20/3/0.04/0.1 MG/ML INJECTABLE	Injection	9/1/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PAP+PHEN+PGE 30/1/0.015 MG/ML INJECTABLE	Injection	9/1/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PAP+PHEN+PGE 30/1/0.01 MG/ML INJECTABLE	Injection	9/1/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PAP+PHEN+PGE 30/0.25/0.02 MG/ML INJECTABLE	Injection	9/1/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile

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EMPLOYEE(S) SIGNATURE
Shelby N. Marler, Investigator
Ademola O. Daramola, Investigator

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TYPE ESTABLISHMENT INSPECTED

Producer of Sterile Drug Products

Date Compounded	Lot Number	Product Name	Route of Admin	BUD	BUD Info	Storage	Starting Material
(b) (4)	(b) (4)	PAP+PHEN+PGE+ATRO 9/1/0.01/0.1 MG/ML INJECTABLE	Injection	9/1/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PGE(b) (4)	(b) (4)	(b) (4)		(b) (4)	
		PAP+PGE 15/0.005 MG/ML INJECTABLE	Injection	9/2/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PAP+PHEN+PGE 30/0.5/0.01 MG/ML INJECTABLE	Injection	9/2/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PAP+PHEN+PGE 30/1/0.02 MG/ML INJECTABLE	Injection	9/3/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PAP+PHE+PGE+ATRO 9/1/0.01/0.1 MG/ML INJECTABLE	Injection	9/7/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PAP+PHEN+PGE 30/1/0.02 MG/ML INJECTABLE	Injection	9/7/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PAP+PHEN+PGE 30/1/0.01 MG/ML INJECTABLE	Injection	9/7/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PAP+PHEN+PGE 30/1/0.04 MG/ML INJECTABLE	Injection	9/7/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PGE 40 MCG/ML VIAL	Injection	9/7/2015	90 days	Refrigerator	Non-Sterile to Sterile
		PAP+PHEN+PGE 30/0.25/0.01 MG/ML INJECTABLE	Injection	9/8/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PAP+PHEN+PGE 15/0.125/0.005 MG/ML INJECTABLE	Injection	9/9/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PAP+PHEN+PGE+ATRO 20/3/0.04/0.1 MG/ML INJECTABLE	Injection	9/9/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		(b) (4)	(b) (4)	(b) (4)		(b) (4)	
		PAP+PHEN+PGE 30/1/0.02 MG/ML INJECTABLE	Injection	9/10/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PAP+PHEN+PGE 30/1/0.0025 MG/ML INJECTABLE	Injection	9/10/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PAP+PHEN+PGE 18/0.5/0.006 MG/ML INJECTABLE	Injection	9/13/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile
		PAP+PHEN+PGE 30/0.25/0.02 MG/ML INJECTABLE	Injection	9/13/2015	90 days	Refrigerator & Protect from Light	Non-Sterile to Sterile

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OBSERVATION 2

Written records are not made of investigations into unexplained discrepancies.

Specifically,

During the (b) (4) certification of your firm's ISO 7 (b) (4) conducted on (b) (4), the viable air was sampled (b) (4) Four out of (b) (4) tested air samples (Air sample # (b) (4) and (b) (4) yielded a 'FAILED' result. The total viable air CFU result exceeded the action level concentration of (b) (4) for air sample # and # while actionable microorganisms were detected in air sample # and # as follows:

A. Sample # 24 CFU (Gram positive rods, micrococcus, S. coagulase, and other Fungi)
B. Sample # 4 CFU (Alternaria, non-sporulating fungi)
C. Sample # 36 CFU (Bacillus, gram positive rods, Micrococcus, S. coagulase, and other Fungi)
D. Sample # 4 CFU (Cladosporium fusarium)

Although the failure was recorded on the test report, however the final certification report showed the status of 'PASS' for all samples taken.

The firm did not conduct an investigation to determine the root cause of the failed certification and to assess the preventative and corrective action for the failure. Additionally, the firm continued to use the clean room to manufacture and distribute the following sterile drug products.

Date Made	Lot Number	Product	BUD
(b) (4)	(b) (4)	Methotrexate - PF	09/03/2015
		Mitomycin - PF	09/14/2015
		Mitomycin - PF	09/18/2015
		Mitomycin - PF	10/05/2015
		Methotrexate - PF	10/05/2015
		Mitomycin - PF	10/26/2015
		Mitomycin - PF	10/29/2015
		Methotrexate - PF	11/04/2015
		Ganciclovir - PF	11/09/2015
		Mitomycin - PF	11/24/2015
		Methotrexate - PF	12/02/2015

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OBSERVATION 3

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

Specifically,

A. Your firm failed to conduct environmental monitoring of air, personnel and surface during daily production periods, within the ISO 7 cleanroom and ISO 5 LFH used to prepare your sterile drug products.

For example:

a. During the period covering June 2015 to December 2015, no environmental monitoring of air, personnel, or surface was performed by your firm. During this period, an average number of (b) (4) sterile drug product formulations were manipulated, filled and distributed from your facility per day.

b. There are (b) (4) ISO 5 (b) (4) Laminar Air Flow Hood (LFH) (b) (4) (b) (4) (b) (4) located within the ISO 7 Areas. These (b) (4) ISO 5 (b) (4) However, your firm only performs environmental monitoring of these ISO 5 (b) (4) (b) (4) (b) (4) (b) (4)

B. On 12/8/2015, we observed drug product manipulation activities in the ISO 5 LFH located in the ISO 7 Buffer Room during this time we did not observe any passive air monitoring in the ISO 5 LFH or any other environmental monitoring to ensure aseptic technique. Furthermore, there is a lack of personnel monitoring for daily aseptic operations.

OBSERVATION 4

Drug products do not bear an expiration date determined by appropriate stability data to assure they meet applicable standards of identity, strength, quality and purity at the time of use.

Specifically,

Review of your firms Logged Formula Worksheets from 6/2015 to 12/2015 showed that drug products are produced into (b) (4) and given (b) (4) (b) (4) these (b) (4) No potency and impurity testing were performed to ensure these drug products continue to meet the applicable standards of identity, strength, quality, and purity. Furthermore, no stability testing or data has been performed.

For example:

A. Bulk (b) (4) Alprostadil USP (Prostaglandin E1 (b) (4) is used to produce the following (b) (4)

a. (b) (4) Alprostadil (PF) (b) (4) Production Date: (b) (4); Lot Number: (b) (4) (b) (4) (b) (4) PGE (b) (4)

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(b) (4) Expiration Date: (b) (4)

1. PGE (b) (4) Production Date: (b) (4) Lot Number: (b) (4)
2. PGE (b) (4) Production Date: (b) (4); Lot Number: (b) (4)
3. PGE (b) (4) Production Date: (b) (4) Lot Number: (b) (4)
4. PGE (b) (4) Production Date: (b) (4); Lot Number: (b) (4)
5. PAP+PGE 15/0.005 MG/ML INJECTABLE; Production Date: 10/19/2015; Lot Number: (b) (4) Expiration Date: 1/17/2016

b. (b) (4) Alprostadil (PF) (b) (4) Production Date: (b) (4); Lot Number: (b) (4) Expiration Date: (b) (4)

i. (b) (4) PGE (b) (4) Production Date: (b) (4); Lot Number: (b) (4) Expiration Date: (b) (4)

1. PGE (b) (4) Production Date: (b) (4); Lot Number: (b) (4) Expiration Date: (b) (4)
2. PGE (b) (4) Production Date: (b) (4) Lot Number: (b) (4) Expiration Date: (b) (4)
3. PAP+PHEN+PGE 18/0.5/0.006 MG/ML INJECT; Production Date: 11/02/2015; Lot Number: (b) (4) Expiration Date: 1/31/2016

OBSERVATION 5

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the identity and strength of each active ingredient prior to release.

Specifically,

A. Your firm failed to conduct potency testing of your sterile finished products at the time of release. From June 2015 to December 8 2015, your firm produced and distributed about (b) (4) batches of sterile drug products. Out of the (b) (4) batches distributed, (b) (4)% had extended Beyond Use Date (BUD) of 90 - 180 days. The drug products were not tested for potency to ascertain that the suitability throughout the BUD.

B. Your firm failed to conduct preservative content testing of your sterile finished products at the time of release. Your firm uses several different sterile formulations which contained (b) (4) and (b) (4) preservatives, or (b) (4) preservatives and were released for patients use without performing preservative content testing.

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OBSERVATION 6

Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure that drug product containers conform to appropriate standards of identity, strength, quality and purity.

Specifically,

Your firm's product inspection process is deficient in that you do not perform 100% visual checks, against a contrasting background of your sterile liquid formulations prior to release. According to the "Compounding" Manager, about (b) (4) of the finished products are visually inspected. Additionally, your firm has not established a written procedure for performing visual checks within products.

OBSERVATION 7

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

Specifically, your cleanroom practices are deficient to prevent product contamination.

For example:

A. From 12/8/2015 to 12/11/2015, we observed an approximately two (2) feet by three (3) feet silver color metal cart used for the (b) (4) in the ISO 7 Buffer Room directly in front of a return air vent located on the base of the wall next to the rear of the ISO 5 (b) (4) Laminar Air Flow Hood (LFH). We also observed a chair with an approximate 3" diameter silver color metal base being placed directly in front of the return air vent located on the base of the wall in the ISO 7 Buffer Room next to the front of the ISO 5 LFH. This chair is only positioned in this location during drug manipulation activities. The certification of your ISO 7 Buffer Room and ISO 5 LFH was not done during drug manipulation activities. Furthermore, there is an approximately two (2) feet by four (4) feet silver shelving unit with cleaning and gowning material stored in front of the return air vents in the ISO 7 Gowning/Preparation Room.

B. There is no evidence that smoke studies were conducted under dynamic conditions within ISO 5 areas used to sterilize by (b) (4) and fill drug product unit containers.

C. On 12/8/2015, we observed your technicians manipulating multiple drug products (non-sterile to sterile and sterile to sterile) using the same LFH at the same time. Per the certification of the LFH done on (b) (4), the maximum occupancy is (b) (4) Furthermore, no precautions are taken to prevent potential cross contamination caused by sharing a single ISO 5 LFH.

Lot Number	Product Name

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(b) (4)	
	SODIUM CHLORIDE 6%/2ML U.D> INHAL SOLN
	CEFTAZIDIME 22.5MG/ML 1ML V 2.25MF/0.1 INJECTABLE
	PILOCARPINE 0.5%0/S
	BEVACIZUMAB 0.12 ML FILL 25MG/ML INJECTABLE

D. On 12/8/2015, we observed drug product manipulation activities in the ISO 7 Buffer Room, during this observation we observed (b) (4) technicians working in a small area which required (b) (4) technician to stop working and leave the ISO 5 hood each time the (b) (4) technician needed to leave the room. Furthermore, we observed the technicians making frequent trips in and out of the Buffer Room to the Gowning/Prep Room without proper sanitization of hands.

E. Your firm (b) (4) per your firms "Compounding" Manager this activity is done in the ISO 5 LFH in the ISO 7 Buffer Room where other drug product manipulation takes place instead of in the ISO 7 (b) (4) Room as the Logged Formula Worksheet records require. Furthermore, the only cleaning done between products is wiping the area with sterile

F. On 12/8/2015, we observed trash being stored in the ISO 5 LFH during processing this trash is stored between the (b) (4) technicians manipulating different drug products in a shared ISO 5 LFH.

G. On 12/8/2015, we observed your Technicians moving components and in-process material from the (b) (4) (b) (4) without first sanitizing the items. For example, sterile (b) (4) wipe packaging was not disinfected prior to placing in the ISO 5 LFH.

H. On 12/8/2015, we observed your Technician and the "Compounding" Manager holding open both the door from the unclassified area to the ISO 7 Gowning/Preparation Room and the door from the ISO 7 Gowning/Preparation room to the ISO 7 Buffer Room where the ISO 5 LFH is located and sterile drug product manipulation activities were being performed.

I. On 12/8/2015 during the production of sterile human drug product (Pilocarpine Lot number 20151208@5) we observed your technician reaching over open containers containing sterile solutions and open sterile containers waiting to be filled. Furthermore, your technician's forearms are covered with non-sterile gowning.

OBSERVATION 8

Clothing of personnel engaged in the manufacturing and holding of drug products is not appropriate for the duties they perform.

Specifically,

A. On 12/8/2015, we observed your Technicians during aseptic processing of sterile human drugs inside the ISO 7 Buffer Room and ISO 5 (b) (4) Laminar Air Flow Hood (LFH), wearing non-sterile gowns and non-sterile hair

nets. We observed this practice during the production and filling of the following sterile drug products.

Lot Number	Product Name
(b) (4)	SODIUM CHLORIDE 6%/2ML U.D> INHAL SOLN
	CEFTAZIDIME 22.5MG/ML 1ML V 2.25MF/0.1 INJECTABLE
	PILOCARPINE 0.5%0/S
	BEVACIZUMAB 0.12 ML FILL 25MG/ML INJECTABLE

B. On 12/8/2015, the Technicians had their forehead, eyes, and neck region exposed during aseptic processing (manipulation and filling) of sterile human drugs (Pilocarpine; lo(b) (4) During the performance of this sterile operation, they had their foreheads inside the ISO 5 LFH where there was no physical barrier between their exposed skin and non-sterile gowning materials and the open Pilocarpine (b) (4) devices on the LFH work surface.

During this time we observed that gowning for sterile operation is inadequate in that

A. Employees wore non-sterile gowns, hair nets, and shoe covers during aseptic processing of sterile drug production in the ISO 5 LFH.

B. Employees', engaged in sterile drug manipulation, eyes and the area around their eyes were left exposed during production of sterile products.

C. Employees facial, neck, and head skin were uncovered and left exposed while working in ISO 5 LFH during production of sterile products.

D. According to your "Compounding" Manager the only gowning requirement for entering the ISO 7 Gowning/Preparation Room is (b) (4) this area is used for (b) (4) (b) (4) (b) (4) (b) (4) (b) (4). Furthermore, we observed your Technicians don gowns to enter the ISO 7 Buffer Room then return to the ISO 7 Gowning/Preparation Room without removing or replacing gowning items prior to re-entry into the ISO 7 Buffer Room.

E. Employee's ungloved hands were placed inside the ISO 5 LFH with exposed skin while donning of gloves in preparation for sterile drug manipulation. Employees enter the ISO 7 Buffer Room and ISO 5 LFH with ungloved hands. Furthermore, once gloves are donned, technicians move between the ISO 7 Buffer Room and the ISO 7 Gowning/Preparation Room without changing gloves. Non-sterile (b) (4) components and in-process materials are(b) (4)

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OBSERVATION 9

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

Specifically,

A. The firm has not conducted equipment qualification to show that (b) (4) and (b) (4) used to sterilize and depyrogenate glassware achieve appropriate log reduction of microbes. The firm does not use any (b) (4) (b) (4) during the sterilization of glassware and liquid suspensions. Furthermore, the firm failed to conduct temperature mapping studies of refrigerators and freezers used to store finished compounded drugs and (b) (4)

B. The following equipment lack calibration, validation, and verification of conformance although they are being used to process, hold, and pack sterile drug products:

a. (b) (4) (b) (4) for sterilization of suspensions. The following suspensions were sterilized in the (b) (4) between (b) (4)

Date Made	Product	Lot Number	Expiration Date
(b) (4) (b) (4)	MEDROXYPROGESTERONE ACETATE 15%	(b) (4)	09/23/2015
	PREDNISOLONE ACE – (PF) 1%		09/27/2015
	PREDNISOLONE ACE – (PF) 1%		02/10/2016

b. (b) (4) for depyrogenation of glassware.

c. Incubator (b) (4) serial # (b) (4) (b) (4) used for sterility and EM samples.

OBSERVATION 10

The distribution system is deficient in that each lot of drug product cannot be readily determined to facilitate its recall if necessary.

Specifically,

Finished products are issued lot numbers (b) (4)
The prescription labels do not contain the (b) (4) Per the "Compounding" Manager the only way to know what (b) (4) (b) (4) however, review of your Logged Formula Worksheets and provided labels shows that not all (b) (4) (b) (4)

For example:

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Lot Number	Date Made	Fill Date on RX Label
(b) (4)	06/17/2015	06/16/2015
	06/17/2015	06/16/2015
	06/17/2015	06/15/20150
	08/10/2015	08/07/2015
	08/10/2015	08/08/2015
	06/19/2015	06/15/2015
	06/22/2015	06/19/2015

OBSERVATION 11

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

A. Your firm produces an average of (b) (4) batches of sterile drug products using ISO 7 Cleanrooms and ISO 5 (b) (4) Laminar Air Flow Hood (LFH). Your firm uses (b) (4) sporicidal agent during the (b) (4) (b) (4) cleaning and sanitization of the ISO 5 LFH and ISO 7 cleanroom.

B. Your firm failed to conduct a disinfectant efficacy studies involving the (b) (4) sporicide and other disinfectants in use at the facility. In addition, there is no defined and established contact time and frequency of use for the disinfectants.

OBSERVATION 12

Complaint procedures are deficient in that written complaint records are not maintained in a file designated for drug product complaints.

Specifically,

Per your firm's "Compounding" Manager your firm does not keep records of drug product complaints.

*** DATES OF INSPECTION:**
12/08/2015(Tue), 12/09/2015(Wed), 12/10/2015(Thu), 12/11/2015(Fri), 12/14/2015(Mon), 12/22/2015(Tue), 12/28/2015(Mon), 12/29/2015(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Shelby N. Marler, Investigator SM Ademola O. Daramola, Investigator AOD	12/29/2015

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
4040 North Central Expressway, Suite 300 Dallas, TX 75204 (214) 253-5200 Fax:(214) 253-5314 Industry Information: www.fda.gov/oc/industry	12/08/2015 - 12/29/2015* FEI NUMBER 1000371043

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Andrew J. Komuves, President and CEO

FIRM NAME	STREET ADDRESS
Dougherty's Pharmacy	5959 Royal Ln Suite 515
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dallas, TX 75230-3856	Producer of Sterile Drug Products

	EMPLOYEE(S) SIGNATURE	DATE ISSUED
SEE REVERSE OF THIS PAGE	Shelby N. Marler, Investigator Ademola O. Daramola, Investigator	12/29/2015

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."