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	1/3/2017-1/20/2017* FEI NUMBER 3010490167

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
William M. Chatoff , Managing Director

FIRM NAME	STREET ADDRESS
Edge Pharmacy Services, LLC	856 Hercules Dr Ste 30
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Colchester, VT 05446-8014	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 I OBSERVED:

OBSERVATION 1

Equipment for adequate control over air pressure and micro-organisms is not provided when appropriate for the manufacture, processing, packing or holding of a drug product.

Specifically, your air flow pattern studies do not represent actual room and equipment conditions during production. Also, you lack adequate control of cleanroom doors to maintain the designed room pressure cascade. For example:

A. On 01/03/2017, I observed that (b) (4) trash receptacles were placed in front of the (b) (4) air return within the ISO 5 (b) (4) in cleanroom (b) (4) during the aseptic filling of allergen test syringes. Your firm has not demonstrated acceptable air flow patterns in the critical zone of aseptic manipulations in the configuration observed with (b) (4) trash receptacles placed in front of the (b) (4) air return of the (b) (4) .

B. The positions of (b) (4) located in the ISO 5 zones of cleanroom (b) (4) are not fixed or otherwise controlled to assure that conditions during routine production are as evaluated during air flow pattern studies and periodic room certification. Spacing from the (b) (4) to the wall is variable and may affect airflow to room air returns located in the walls below the (b) (4) .

C. You do not have systems to prevent the simultaneous opening of doors between different ISO 7 and ISO 5 classified cleanrooms. Additionally, you do not limit the time that these doors may be opened and you have not demonstrated that the designed room pressure cascades are maintained between rooms during open door conditions.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Edmund F Mrak, Investigator 1/20/2017 X Edmund F Mrak Edmund F Mrak Investigator Signed by: Edmund F. Mrak Jr -S	1/20/2017

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OBSERVATION 2

Separate or defined areas to prevent contamination or mix-ups are deficient regarding the manufacturing and processing operations.

Specifically, the design and operation of your cleanrooms do not provide adequate containment and prevention of cross contamination with hazardous drugs as follows:

A. The ISO 5 (b) (4) and cleanroom used to produce Mitomycin (cytotoxic) drug for ocular injection are not dedicated to potent or cytotoxic compounds and are also used for aseptic filling of allergen test injections.

B. Your room and equipment cleaning procedures to changeover from potent or cytotoxic compounds to non-hazardous sterile product processing are not validated to reduce drug residues to any pre-determined level of acceptance to reduce risks of cross contamination.

OBSERVATION 3

Drug product production and control records, are not reviewed and approved by the quality control unit to determine compliance with all established, approved written procedures before a batch is released or distributed.

Specifically, you do not follow (b) (4) sterilization (b) (4) specified in the Logged Formula Worksheet for sterile drug products for injection. Also, you lack approval from the Quality Unit for deviation from the (b) (4) sterilization (b) (4) in the Logged Formula Worksheet. For example:

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According to the Logged Formula Worksheet for Triamcinolone Ophthalmic Injection 60mg/ml the Triamcinolone Acetonide suspension requires (b) (4) . The (b) (4) record for Triamcinolone Acetonide suspension for Triamcinolone Ophthalmic Injection 60mg/ml, Lot number: 08-2016-11@7, produced on 08/11/2016, indicates that the suspension was (b) (4) . There was no documented investigation or explanation and approval from the Quality Unit for deviation from the (b) (4) sterilization (b) (4) in the Logged Formula Worksheet before the lot was released.

OBSERVATION 4

Test procedures relative to appropriate laboratory testing for pyrogens are not written and followed.

Specifically:

A. Review of your executed endotoxin test and (b) (4) validation and routine endotoxin testing using the (b) (4) for sterile products found that you do not qualify each new lot of (b) (4) before use as instructed by the vendor in the (b) (4) (b) (4)

B. Your endotoxin (b) (4) validations for use of the (b) (4) for sterile products did not include (b) (4) as instructed by the vendor in the (b) (4) (b) (4)

***DATES OF INSPECTION**

1/03/2017(Tue),1/04/2017(Wed),1/05/2017(Thu),1/06/2017(Fri),1/20/2017(Fri)

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