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 Industry Information: www.fda.gov/oc/industry	07/22/2014 - 08/20/2014* FEI NUMBER 3010490167

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. William M. Chatoff, CEO

FIRM NAME	STREET ADDRESS
Edge Pharmacy Services, LLC	856 Hercules Dr Suite 30
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Colchester, VT 05446	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

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of the sterilization process.

Specifically:

A. Your firm's system for validating environmental conditions in critical zones supporting aseptic operations in the production of various sterile drug products lacks an adequate assessment of air flow patterns under dynamic conditions. Inspectional review of video produced during your [redacted] (b) (4) - SMOKE TESTING" "Critical Manufacturing Area Smoke Test", completed 05/21/2014, found that the ISO 5 classified critical zones in each clean room were not evaluated under dynamic conditions with compounding equipment and components in place.

B. Your firm has not conducted validation studies to include bacterial retention capabilities and product compatibility of [redacted] (b) (4) product f[redacted] (b) (4) used to sterilize the bulk solutions of all sterile products.

C. Your firm does not test pH and growth promotion to verify the acceptable performance of commercial media [redacted] (b) (4)) prepared on site and used for aseptic simulations (media fills) intended to validate the sterilization and filling process for sterile drug products. For example: The media fill record for "Validation - High Risk Syringe 5cc Syringe to Syringe Transfer 5cc Syringes Syringe", made on 05/21/2014, includes steps for reconstitution of [redacted] (b) (4) media, Lot #[redacted], with [redacted] (b) (4) The media fill record does not include steps to test the prepared media pH and you do not test growth promotion on each lot of media.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Edmund F. Mrak Jr., Investigator	08/20/2014

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781) 587-7500 Fax:(781) 587-7556 Industry Information: www.fda.gov/oc/industry	07/22/2014 - 08/20/2014* FEI NUMBER 3010490167

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. William M. Chatoff, CEO

FIRM NAME	STREET ADDRESS
Edge Pharmacy Services, LLC	856 Hercules Dr Suite 30
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Colchester, VT 05446	Outsourcing Facility

OBSERVATION 2

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

Specifically, the following deficiencies were observed in your firm's sterility testing program for sterile drug products:

A. Since January 2014 your firm has routinely released and distributed sterile drug products based on results or pending results of sterility test methods that were not validated for the specific drugs. For example:

- Methocarbamol 7.5mg/ml, for injection, Lot number: 05-2014-07:47, was produced on 05/07/2014 and released on 05/15/2014. Final results of sterility testing of the lot by [redacted] (b) (4) were reported on 05/22/2014. The sterility test method was said to be validated on 06/18/2014.
- Proparacaine / Ciprofloxacin / Cyclopentolate / Phenylephrine 0.5% / 0.3% / 2% / 2.5% OPH SOLN, Lot number: 06-2014-23:53, was produced on 06/23/2014 and released on 07/01/2014. Final results of sterility testing of the lot by [redacted] (b) (4) were reported on 07/07/2014. The sterility test method validation was said to be in progress on 07/24/2014.
- Lidocaine Buffered - Sodium Phosphate 1% Aqueous Soln, Lot number: 06-2014-19:78, was produced on 06/19/2014 and released on 06/24/2014. Final results of sterility testing of the lot by [redacted] (b) (4) were reported on 07/03/2014. The sterility test method validation was said to be in progress on 07/24/2014.

B. Your firm has not established [redacted] (b) (4) bioburden limits and does not measure [redacted] (b) (4) bioburden in bulk product solutions prior to sterile[redacted] (b) (4)

C. Since January 2014 your firm has released up to [redacted] (b) (4) lots of various sterile drug products prior to having final sterility test results. Your firm does not always adequately document advanced release decisions or follow internal procedures requiring signatures of responsible individuals for advanced release (release before sterility testing is complete). For example:

- Proparacaine / Ciprofloxacin / Cyclopentolate / Phenylephrine 0.5% / 0.3% / 2% / 2.5% OPH SOLN, Lot number: 07-2014-07:84, was produced on 07/07/2014 and released on 07/12/2014. Final results of sterility testing of the lot by [redacted] (b) (4) were reported on 07/21/2014. The early release decision and approval was not documented by responsible individuals.

D. Your firm does not have sufficiently detailed procedures for [redacted] (b) (4) sterility testing currently performed on site. Your procedure for testing product lacks critical instructions recommended by the [redacted] (b) (4) sterility testing system vendor to ensure method success and that false negative results will not be reported.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
One Montvale Avenue Stoneham, MA 02180 (781) 587-7500 Fax:(781) 587-7556 Industry Information: www.fda.gov/oc/industry	07/22/2014 - 08/20/2014* FEI NUMBER 3010490167

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. William M. Chatoff, CEO

FIRM NAME	STREET ADDRESS
Edge Pharmacy Services, LLC	856 Hercules Dr Suite 30
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Colchester, VT 05446	Outsourcing Facility

OBSERVATION 3

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

Specifically, your firm documents daily readings of differential air pressure before using cleanrooms to produce sterile drug products. However, you do not have a system for more frequent recording and evaluation of cleanroom air pressure differential data while the rooms are in use.

OBSERVATION 4

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:

Your firm does not routinely perform release testing on various finished sterile drug products to include identity and strength of the active ingredient(s). For example:

- Methocarbamol 750mg NS 7.5mg/ml Aqueous Soln, Lot number: 07-2014-10:56, was produced on 07/10/2014 and released on 07/22/2014 without testing the finished product for identity and strength of the active ingredient.
- Lidocaine Buffered - Sodium Phosphate 1% Aqueous Soln, Lot number: 06-2014-19:78, was produced on 06/19/2014 and released on 06/24/2014 without testing the finished product for identity and strength of the active ingredient.
- Atropine Sulfate 1mg 1mg/ml 1ml (PF) Aqueous Soln, Lot number: 05-2014-08:92, was produced on 05/08/2014 and released on 05/13/2014 without testing the finished product for identity and strength of the active ingredient.

OBSERVATION 5

Each component is not tested for conformity with all appropriate written specifications for purity, strength, and quality.

Specifically:

A. Your firm routinely accepts a Certificate of Analysis (or equivalent) from suppliers of components including non-sterile drug substances and excipients to determine whether the lot can be used in production of sterile drug products. You have

not established the reliability of each supplier's analyses through appropriate steps to confirm the supplier's test results for those tests relevant to the specifications established for each compounded drug product, and to confirm that the ingredients meet the applicable USP or NF monographs. For example:

- Methocarbamol, USP, Lot: [redacted] (b) (4) received from [redacted] (b) (4) under Certificate of Analysis verified 03/20/2014 was used as a component of Methocarbamol 750mg NS 7.5mg/ml Aqueous Soln, Lot number: 07-2014-10:56, released on 07/22/2014. You have not documented reliability of the supplier's analyses or confirmation that Methocarbamol, USP, Lot [redacted] (b) (4) meets requirements of the applicable USP monograph.

B. Your firm reportedly does not perform at least one identity test to confirm that raw material components are received as specified in your purchase orders. For example:

- Methocarbamol, USP, Lot: [redacted] (b) (4) received from [redacted] (b) (4), under Certificate of Analysis verified 03/20/2014, was used as a component of Methocarbamol 750mg NS 7.5mg/ml Aqueous Soln, Lot number: 07-2014-10:56, released on 07/22/2014. You did not perform at least one identity test to confirm that Methocarbamol, USP, Lot: [redacted] (b) (4) was received as specified in your purchase order.

C. Purified Water (PW) generated on site from [redacted] (b) (4) using a self-contained [redacted] (b) (4) apparatus [redacted] (b) (4) with [redacted] (b) (4) storage tank is not routinely tested to meet USP requirements and microbial and endotoxin specifications appropriate for the intended use. PW from this use point is reportedly used to [redacted] (b) (4). PW from this use point is also used as [redacted] (b) (4)
For example:

- The media fill record for "Validation - High Risk Syringe 5cc Syringe to Syringe Transfer 5cc Syringes Syringe", made on 05/21/2014, includes steps for reconstitution of [redacted] (b) (4), Lot # [redacted] (b) (4), with [redacted] (b) (4) [redacted]

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 Industry Information: www.fda.gov/oc/industry	07/22/2014 - 08/20/2014* FEI NUMBER 3010490167

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: Mr. William M. Chatoff, CEO

FIRM NAME	STREET ADDRESS
Edge Pharmacy Services, LLC	856 Hercules Dr Suite 30
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Colchester, VT 05446	Outsourcing Facility

OBSERVATION 6

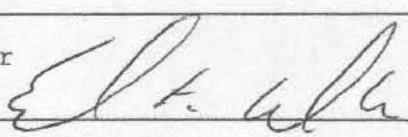
The labels for the drug products and drug product containers you produce do not contain information required by section 503B(a)(10).

Specifically, the following information is not found on your drug product labels (e.g., Chlorpheniramine Maleate/Phenylephrine HCl 8mg/20mg SR , Chlorpheniramine/Methscopolamine/Pseudoephedrine 8mg/2.5mg/120mg , and Chlorpheniramine/Methscopolamine/Phenylephrine 8mg/2.5mg/10mg) :

1. The statements, "This is a compounded drug," and "Not for resale."
2. A list of active and inactive ingredients, identified by established name and the quantity and proportion of each ingredient.
3. Information to facilitate adverse event reporting: ---www.fda.gov/medwatch and 1800FDA1088 <http://www.fda.gov/medwatch and 1800FDA1088>.
4. Storage and handling instructions.

Additionally, labels for some of your drug products [(e.g., Methocarbamol , Atropine Sulfate , and Chlorpheniramine Maleate/Phenylephrine HCl 8mg/20mg SR , Chlorpheniramine/Methscopolamine/Pseudoephedrine 8mg/2.5mg/120mg , Chlorpheniramine/Methscopolamine/Phenylephrine 8mg/2.5mg/10mg , and Neostigmine Sulfate vials 1mg/mL] do not contain information regarding the dosage form of the drug product.

*** DATES OF INSPECTION:**
07/22/2014(Tue), 07/23/2014(Wed), 07/24/2014(Thu), 07/25/2014(Fri), 08/01/2014(Fri), 08/15/2014(Fri), 08/20/2014(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Edmund F. Mrak Jr., Investigator 	08/20/2014