DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	2/15/2018-3/8/2018* FEI NUMBER 3010490167

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
William Chatoff, Owner and Managing Director

FIRM NAME	STREET ADDRESS
Edge Pharmacy Services, LLC	856 Hercules Dr
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 WE OBSERVED:

OBSERVATION 1

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

Specifically,

a) You do not monitor the air quality for viable and non-viable air particles for each product being compounded and filled in the ISO 5 environment. Your firm only monitors the air quality, viable and non-viable air particles, (b) (4) ISO 5 table. In addition, your environmental monitoring procedures are inadequate, as they aren't robust and don't reflect your current practices. The frequency, time, and the personnel conducting air sampling is not stated in any of your firm's procedures. According to your firm's management, air sampling is performed "(b) (4) " during (b) (4) for (b) (4) (b) (4) based on the determination of the compounding/filling operator.

Furthermore, your firm released product on 3/29/17, 7/20/17, and 10/27/17 without performing any non-viable air sampling. Products manufactured on these days were released by your firm for the sole stated reason being that there has not been a history of any environmental monitoring above action limits. This included Avastin, lots #03-2017-23@14 and #03-2017-27@9, Triamcinolone stock, lot #03-2017-22@10, Lidocaine/ Bupivacaine/ Hyaluronidase, lots #03-2017-28@4 and #03-2017-28@6, Ciprofloxacin/ Cyclopentolate/ Phenylephrine, lot #03-2017-22@3; Epinephrine/ Lidocaine, lot #07-2017-20@1; and, Phenylephrine, lot #10-2017-27@4, respectively.

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b) The surfaces in the ISO 5 environment are not sampled with contact plates as part of your environmental monitoring program for each product, but rather are sampled at the (b) (4) (b) (4). You compound different drug products on the same day for a specific ISO 5 table, regardless of how many products were made on that ISO 5 table that day. Disinfection of the ISO 5 environment is performed with sterile (b) (4) the compounding/filling operations of different products; however, surface sampling is not performed prior to disinfection for products produced earlier in the day.

c) Finger plating is not performed on each operator prior to leaving the cleanroom. Rather, personnel are finger plated (b) (4) " basis, which is based on the determination of the operator, at any time during compounding activities. Finger plating can be performed (b) (4) operators' lunch break in the ISO 7 cleanroom, during either the (b) (4) operations. Your plating procedure is not outlined in any of your firm's procedures. No personnel sampling is performed daily for the operators' gowns.

d) You have not performed smoke studies under dynamic conditions to demonstrate and assure proper air flow patterns in the ISO 5 environment, during normal working conditions. Currently, in your most recent smoke study report, dated 3/30/17, you only performed smoke studies for three (Tables (b) (4) and (b) (4)) of the (b) (4) ISO 5 tables used to compound, fill, and stage materials in the ISO 7 cleanroom (b) (4). Smoke studies were not performed for Tables (b) (4) in ISO 7 cleanroom (b) (4). This is a repeat observation from the previous January 2017 inspection.

e) Your firm released product compounded and filled based on the environmental monitoring data derived from expired plate media. On 11/16/17, media plates, used in fingertip touch tests (personnel monitoring) of your firm's ISO 7 cleanroom (b) (4) were past their expiry date of 10/22/17. Avastin, lot #11-2017-16@12, compounded/filled on Tables (b) (4) ; Potassium Phosphate, lot #11-2017-16@9, compounded/filled on Table (b) (4); and, Ciprofloxacin/ Ketorolac/ Cyclopentolate/ Phenylephrine, lot #11-

2017-16@11, compounded/filled on Table (b) (4), were all released using expired media. The justification provided for release by management was that a positive control was run, however, there is no documentation.

Additionally, air viable monitoring and surface sampling was not performed on 11/16/17 for Tables (b) (4) (b) (4), which were used to stage product. According to your firm's management, non-viable air, viable air, and surface environmental monitoring are to be performed on every ISO 5 table and BSC (b) (4), regardless of whether compounding or filling operations occurred on a specific table.

f) There is no assurance that the pressure differentials are maintained between the ISO 8 anteroom and the unclassified area. Your firm has not calibrated the only (b) (4) pressure gauge used for monitoring the pressure between these two areas. Additionally, there is no alarm or alert if there is a loss of pressure for any of your firm's devices that measure pressure differentials.

OBSERVATION 2

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

Specifically,

a) On 2/15/18, we observed an operator disinfecting the ISO 5 Table (b) (4) working bench, steel container, syringes, and syringe plastic tip package, using only one-side of one sterile lint-free wipe, prior to the filling of Moxifloxacin HCl, lot #02-2018-14@1, 1mg/mL on ISO 5 Table (b) (4) in ISO 7 cleanroom (b) (4). Yet, according to your firm's management, sterile lint-free wipes used in the ISO 7 cleanroom and on ISO 5 tables are single-use only.

b) On 2/15/18 and 2/16/18, we observed sterile wipes used to clean and disinfect ISO 5 tables being stored opened in the ISO 7 cleanroom (b) (4) in a clear box. On 2/16/18, we observed this clear box to be

opened during compounding operations. According to your firm's management, the clear box containing the opened sterile wipes is kept overnight in the ISO 7 cleanroom in this plastic clear box until they are all used up and another box of sterile wipes is opened to replenish the clear plastic box.

OBSERVATION 3

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

Specifically,

a) Sterile bulk solutions are prepared for various high-risk products, including drug products where the active ingredient is received as a non-sterile ingredient and then (b) (4) to produce a sterile injectable solution. Your firm has not conducted any studies to support the sterility for the time periods that the sterile drug products are used, for the following products:

- Buffered Lidocaine HCl IV (PF), 1% and 2% strengths, 1mL and 10mL syringes, BUD 104 days
- Lidocaine HCl IV (PF), 0.1%, 500mL bag, BUD 104 days
- Glycopyrrolate IV (PF), 0.2mg/mL, 5mL syringe, BUD 104 days
- Methylene Blue IV (PF), 10mg/mL, 1mL, 5mL, and 10mL syringes, BUD 104 days
- Neostigmine Methyl Sulfate IV (PF), 1mg/mL, 5mL syringe, BUD 104 days
- Phenylephrine HCl IV (PF), 0.1mg/mL and 1mg/mL strengths, 5mL and 3mL syringes, BUD 104 days
- Phenylephrine HCl IV (PF), 100mg/250mL (0.4mg/mL), 250mL bag, BUD 104 days
- Succinylcholine IV (PF), 20mg/mL, 5mL and 10mL syringes, BUD 104 days
- Triamcinolone Acetonide IV (PF), 60mg/mL, 2mL vial, BUD 104 days
- Cefuroxime 10mg/mL ophthalmic (PF), 1mL syringe, BUD 104 days
- Phenylephrine HCl / Lidocaine HCl 1.5%/1% ophthalmic (PF), 1mL and 3mL syringes, BUD

104 days

- Droperidol IV (PF), 2.5mg/mL, 3mL syringe, BUD 74 days
- Neostigmine Methyl Sulfate IV, 1mg/mL, 10mL vial, BUD 74 days
- Potassium Phosphate IV (PF), 17.2mEq/12mmol/250mL, 250mL bag, BUD 74 days
- Promethazine HCl IV (PF), 6.25mg/50mL,12.5mg/50mL and 25mg/50mL strengths, 50mL bags, BUD 74 days
- Hydrochloric Acid 0.148 N IV (PF), 3mL syringe, BUD 50 days
- Lidocaine HCl / Bupivacaine HCl / Hyaluronidase 2% /0.375%/15units/mL ophthalmic (PF), 5mL and 10mL syringes, BUD 50 days
- Lidocaine HCl / Epinephrine / Bupivacaine HCl 4mg/0.004mg/1.25mg/mL ophthalmic (PF), 3mL syringe, BUD 50 days
- Buffered Lidocaine HCl / Epinephrine 1%/1:100,000 IV (PF), 5mL and 10mL syringes, BUD 44 days

b) You have not incorporated worst-case activities and conditions that provide a challenge to aseptic operations in your performed media fills. For instance, entering and exiting of the cleanroom during production to simulate the operators taking a lunch break, is not performed or documented in the media fill runs for the allergy treatment, Avastin, (b) (4) (b) (4) processes.

c) The media fill challenge test for allergy treatment sets, date of test 12/21/17, for one of your pharmacy technicians, has not been reviewed as of 2/27/18. This is beyond the (b) (4) day procedural time frame to review completed documents. Thus, the quality unit is not performing as expected.

OBSERVATION 4

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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) Seven endotoxin failures were observed in the (b) (4) instrument for 2018, however, these failing results or reason for failure were not documented with any of the records associated with the finished product. The explanation provided, based on your firm's SOP #P6.11.1.1, entitled "Endotoxin Test Using (b) (4)," Version 3, effective date 2/2/17, allows the operator to (b) (4) (b) (4) and (b) (4). Management explained that all seven results were invalidated based on instrument malfunction or pipetting errors. The quality unit did not implement an investigation or determine root cause but the batches were re-tested and distributed. There was no data available for review in the instrument from 2015 to 2017, despite the machine being used approximately every day.

b) From August 2017 to March 2018, the following Out of Specification (OOS) results failing to meet the established specification for potency test were not investigated, but released upon passing of retest data. For example,

1) On 03/31/16, an OOS results was obtained by the contract testing laboratory during the testing of Buffered Lidocaine solution 1%, lot #12-2015-16@8, for stability sample at (b) (4) days. Your firm's quality unit did not implement an investigation for drug product failing to meet established specification (b) (4)) but the initial result (105.6%) was invalidated through repeated re-testing (Test #1: 104.5%, Test #2: 102.4%) performed by the contract testing laboratory. There was no investigation or root cause for this OOS and the drug product Beyond Use Date (BUD) was accepted at 104 days based on the re-test data from your contract laboratory.

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2) On 10/30/17, OOS investigation #PB-2017-014 was initiated for release of drug product Phenylephrine 2.5%, lot #10-2017-19@3 for potency test. Your quality unit did not implement an investigation for drug product failing to meet established specification (b) (4)) but the initial result (70.2%) was invalidated through repeated re-testing (Test #1: 99.2%, Test #2: 96.4%) performed by the same analyst. There was no investigation or root cause for this OOS and the drug product was released for distribution.

3) On 01/29/18, OOS investigation #PB-2018-007 was initiated for release of drug product Phenylephrine/Lidocaine Nasal Solution 1 /4%, lot #01-2018-29@7 for potency test. Your quality unit did not implement an investigation for drug product failing to meet established specification for Phenylephrine HCl (b) (4)) and Lidocaine HCl ((b) (4)) but the initial result (Phenylephrine HCl 76.5%, and Lidocaine HCl 80.4 %) was invalidated through repeated re-testing Phenylephrine HCl (Test #1: 91.9%, Test #2: 91.2%) and Lidocaine HCl (Test #1: 96.2%, Test #2: 95.2%) performed by the same analyst. There was no root cause for this OOS and the drug product was released for distribution.

c) On 10/12/17, method deviation #MD-2017-021 was initiated for system suitability failure prior to injection of following lots of finished product:

- Lidocaine 4%, lot #10-2017-12@12
- Parabens, lot #10-2017-12@12
- Phenylephrine 1mg/mL, lot #10-2017-12@8
- Lidocaine 0.1%, lot #10-2017-11@2
- Phen/Lido 1.5/1%, lot #10-2017-11@5
- Phen/Lido 1.5/1%, lot #10-2017-11@4

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Your firm released the above batches based on the passing of the system suitability data from the day before (10/11/17) and the day after (10/13/17). Your firm did not perform investigation on whether the failed system suitability affected the instrument's performance during the testing of the above lots.

d) On 05/30/17, deviation #MD-2017-008 was initiated for the drug product Epinephrine/Lidocaine (0.025%/0.75%), lot #05-2017-15@3 for a potency test. Your quality unit did not implement an investigation or determine a root cause for Lidocaine failing (115.4%) to meet the established specification (b) (4) , instead the batch was released based on online literature.

OBSERVATION 5

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically,

a) Your firm has not conducted adequate studies to support the stability of the following sterile drug products over the 104-day time period from the time that the bulk solution is prepared until its usage.

- Buffered Lidocaine HCl IV (PF), 1% and 2% strengths, 1mL and 10mL syringes, BUD 104 days
- Lidocaine HCl IV (PF), 0.1%, 500mL bag, BUD 104 days
- Glycopyrrolate IV (PF), 0.2mg/mL, 5mL syringe, BUD 104 days
- Methylene Blue IV (PF), 10mg/mL, 1mL, 5mL, and 10mL syringes, BUD 104 days
- Neostigmine Methyl Sulfate IV (PF), 1mg/mL, 5mL syringe, BUD 104 days
- Phenylephrine HCl IV (PF), 0.1mg/mL and 1mg/mL strengths, 5mL and 3mL syringes, BUD 104 days
- Phenylephrine HCl IV (PF), 100mg/250mL (0.4mg/mL), 250mL bag, BUD 104 days
- Succinylcholine IV (PF), 20mg/mL, 5mL and 10mL syringes, BUD 104 days
- Triamcinolone Acetonide IV (PF), 60mg/mL, 2mL vial, BUD 104 days

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- Cefuroxime 10mg/mL ophthalmic (PF), 1mL syringe, BUD 104 days
- Phenylephrine HCl / Lidocaine HCl 1.5%/1% ophthalmic (PF), 1mL and 3mL syringes, BUD 104 days

b) Your firm lacks any data confirming that the containers and closures used are at least as protective of the product as the original manufacturer's container/closure for products made from commercially available products. Your firm currently compounds 106 sterile drug products, in 17 different container closure systems, including syringes, vials, bags, dropper bottles, and irrigation bottles. Integrity testing of drug product container closure systems has not been performed to verify your ability to maintain the quality of the finished drug product and sterility over the expiry period. Currently, your firm has only tested four droptainer and vial products for container closure integrity via a contract laboratory. No products packaged in syringes, bags, and irrigation bottles were tested for container closure integrity.

OBSERVATION 6

Employees engaged in the manufacture, processing, packing and holding of a drug product lack the training required to perform their assigned functions.

Specifically,

a) There is no assurance that operators who perform visual inspections are trained to detect visual deficiencies, such as particulates, discoloration, and/or leaks. Your firm lacks a specific training and verification schedule to evaluate the skills and expertise needed for operators engaged in visual inspection of finished products.

- Your firm does not have a representative standard to evaluate operators with for visual inspections. According to your firm's management, visual inspectors are given a visual assessment, consisting of an undetermined number of containers containing drug product. This

assessment is not documented or recorded and is not outlined in any written procedure.

- Eye exams of operators performing visual inspections are not collected or documented. No eye exam is performed or documented to test for color-blindness and/or the ability to distinguish color.
- Your procedures do not establish breaks for operators performing visual inspections. Per your firm's management, operators can perform visual inspections for up to (b) (4) at a time for a maximum of (b) (4) per day, with at least a (b) (4) interval "break" in between where they can complete another task.
- There is no acceptance limit for the number of visually inspected finished products that can be rejected before the whole batch is to be rejected.

b) Employees are not trained in the particular operations they perform as part of their function and/or written processes. For example:

- Your Science Director has not completed any of your firm's area-specific trainings although she performs operations in many of these areas. For example, on 2/19/18, the Science Director was observed performing visual inspection of finished product, but no visual inspection training documentation could be provided.
- Two of your pharmacy technicians have not completed your firm's Standard Operating Procedure Sign-Off Sheet, which documents the review of your firm's written processes and procedures. The Standard Operating Procedure Sign-Off Sheet is an uncontrolled document, which does not appear to be updated and changed to account for new procedures established by your firm.

OBSERVATION 7

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Establishment of the reliability of the component supplier's report of analyses is deficient in that the test results are not appropriately validated at appropriate intervals.

Specifically,

Your firm has not established the reliability of the supplier's Certificates of Analysis (COA) through validation of their test results for incoming APIs used to produce finished drug products (e.g. (b) (4)). Instead, only a loss on (b) (4) and (b) (4) test is performed for (b) (4) . The remaining incoming lots of API are accepted based on a COA review.

OBSERVATION 8

Adequate lab facilities for testing and approval or rejection of drug products are not available to the quality control unit.

Specifically,

a) There are no agreements or procedures in place with any of the contract laboratories to inform your firm about issues that occur during laboratory testing such as deviations and out of specification (OOS) results.

b) There is no assurance that the contract laboratory used for the testing of potency in drug product batches (e.g. Moxifloxacin HCL, lot #01-2018-12@5, Vancomycin, lot #11-2017-8@4, Triamcinolone Acetonide, lot #08-2017-29@15, Promethazine, lot #09-2017-08@1) has the capability to perform the required testing in an accurate, precise, and reliable way. The laboratory was evaluated based on only a paper questionnaire.

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c) There is no assurance that the contract laboratory used for the sterility testing for the following products has the capability to perform the required testing in an accurate, precise, and reliable way. The laboratory was evaluated based on only a paper questionnaire.

- Phenylephrine HCl / Cyclopentolate HCl / Tropicamide / Ciprofloxacin / Ketorolac
- Ciprofloxacin / Ketorolac / Phenylephrine / Tropicamide (PF)
- Moxifloxacin HCl
- Phenylephrine HCl / Tropicamide / Tetracaine HCl
- Ciprofloxacin / Cyclopentolate HCl / Phenylephrine HCl

d) There is no assurance that the contract laboratory used for the endotoxin testing for the following products has the capability to perform the required testing in an accurate, precise, and reliable way. The laboratory was evaluated based on only a paper questionnaire.

- Methylene Blue
- Brilliant Blue G

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,

User roles and responsibilities are not designated for each user type for the (b) (4) Higher Performance Liquid Chromatography System (HPLC)(b) (4), which is used for testing stability and finished drug product samples. All employees who utilize this HPLC, the Science Director (Chemist), Pharmacy Manager in charge, and Managing Director have full administrative rights and therefore can alter data/methods/enable and disable audit trail.

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OBSERVATION 10

Laboratory records do not include complete data derived from all tests, examinations and assay necessary to assure compliance with established specifications and standards.

Specifically,

Your firm's laboratory records do not include a complete record of all data secured during each test for potency and endotoxin, that is performed in-house or by a contract control laboratory.

a) The potency tests performed in-house and by the contract laboratory for Vancomycin, lot #11-2017-08@4, and Glycopyrrolate, lot #10-2017-04@1, respectively, did not contain the system suitability, sequence, test method, and processing method in the data package. The QC chemist stated that your firm only receives Certificate of Analysis (CoA) from the contract laboratory and that the raw data is not available for review. These drug products are approved and released by QA without verifying the results with the raw data.

b) The potency tests performed in-house for Neostigmine Methyl Sulfate, lot #02-2018-06@6 respectively, did not contain the system suitability, sequence, test method, and processing method in the data package. The drug product was approved and released by QA without verifying the results with the raw data.

c) The potency tests performed by the contract laboratory for Moxifloxacin HCl, lot #01-2018-12@5 respectively, did not contain the system suitability, sequence, test method, and processing method in the data package. The drug product was approved and released by QA without verifying the results with the raw data.

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OBSERVATION 11

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

Specifically,

a) Your firm performs potency tests on finished products using (b) (4) High Performance Liquid Chromatography System (HPLC)(b) (4) and the data is collected using (b) (4) software.

b) The system suitability is run (b) (4) using (b) (4) of a (b) (4) standard and not an actual reference standard for the product. In addition, (b) (4) system suitability run is performed (b) (4) (b) (4) regardless of how many times the machine is used.

c) Your firm does not make injection of working standards during potency tests for finish product analysis of drug product. Instead (b) (4) of a sample is made and (b) (4) from the (b) (4) is used to calculate the potency result. (b) (4) (b) (4) are not performed under the same chromatographic conditions.

OBSERVATION 12

Procedures for the preparation of master production and control records are not described in a written procedure.

Specifically,

Procedures for the preparation of master production records are not defined in a written procedure. Currently, your firm uses formula sheets, as these master production records. It is unknown how these formula sheets are prepared.

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OBSERVATION 13

Strict control is not exercised over labeling issued for use in drug product labeling operations.

Specifically,

a) Records do not include the disposition of rejected labeling. The practice of the disposition of rejected labels due to the pharmacist's label review is not specified in any procedure.

b) Your firm neither has label controls in place nor performs container label reconciliation for the repackaging of product prior to distribution. Currently, your firm (b) (4) and (b) (4) following compounding after the correct number of labels is printed by the pharmacist. The (b) (4) (b) (4) and (b) (4) is then (b) (4). When your firm receives an order for a particular drug product, the pharmacist then prints a new container label and repackages the product pursuant to the order. The number of container labels printed, discarded, and/or used during these repackaging operations is not documented or evaluated.

c) Prior to the distribution of labeled product, the production pharmacist reviews the labeled finished products for accuracy and thoroughness; however, this review is not documented.

d) Your firm does not establish an acceptance limit for the number of labels that can be rejected before it is required that the whole batch of printed labels is to be rejected.

OBSERVATION 14

The labels of your outsourcing facility's drug products are deficient.

Specifically, the labels of your outsourcing facility's drug products do not include information required by section 503B(a)(10)(A). The address and phone number of your outsourcing facility, the dosage form of the drug product, and the date the drug was compounded are not on your firm's drug product labels.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Niketa Patel, Investigator Rachael A Moliver, Investigator	X Rachael A Moliver Investigator Signed By: Rachael Moliver -S Date Signed: 03-08-2018 10:07:02	3/8/2018

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
158-15 Liberty Avenue Jamaica, NY 11433 (718) 340-7000 Ext:5301 Fax:(718)662-5661	2/15/2018-3/8/2018*
	FEI NUMBER 3010490167

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

William Chatoff, Owner and Managing Director

FIRM NAME	STREET ADDRESS
Edge Pharmacy Services, LLC	856 Hercules Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Colchester, VT 05446-8014	Outsourcing Facility

The following list contains examples of labels for drug products which do not contain the required information:

- Ceftazidime, 22.5mg/mL, lot #01-2018-25@7, BUD 3/10/18
- Cefuroxime, 10mg/mL, lot #12-2017-14@2, BUD 3/28/18
- Cefuroxime/Carbachol/Dexamethasone, 10mg/0.009mg/4mg/mL, lot #11-2017-30@7, BUD 1/19/18
- Epinephrine/Lidocaine HCl, 0.025%/0.75%, lot #01-2018-23@9, BUD 3/15/18
- Lidocaine HCl/Epinephrine/Bupivacaine HCl, 4mg/0.004mg/1.25mg/mL, lot #01-2018-30@5, BUD 3/21/18
- Methacholine Chloride, 0.0625mg/mL, lot #01-2018-19@6, BUD 3/10/18
- Mitomycin-C, 0.4mg/mL, lot #01-2018-25@11, BUD 4/9/18
- Moxifloxacin HCl, 1mg/mL, lot #01-2018-12@5, BUD 3/27/18
- Neostigmine Methyl Sulfate, 1mg/mL, lot #01-2018-17@3, BUD 5/8/18
- Phenylephrine HCl, 0.1mg/mL, lot #01-2018-31@5, BUD 5/15/18
- Phenylephrine HCl/Tropicamide, 2.5%/1%, lot #02-2018-01@3, BUD 4/17/18
- Triamcinolone Acetonide, 60mg/mL, lot #12-2017-14@3, BUD 3/28/18
- Vancomycin, 10mg/mL, lot #12-2017-06@5, BUD 3/20/8
- Verapamil HCl, 100mcg/mL, lot #11-2017-16@6, BUD 2/27/18

***DATES OF INSPECTION**

2/15/2018(Thu), 2/16/2018(Fri), 2/19/2018(Mon), 2/20/2018(Tue), 2/21/2018(Wed), 2/22/2018(Thu), 2/23/2018(Fri), 2/26/2018(Mon), 2/27/2018(Tue), 2/28/2018(Wed), 3/07/2018(Wed), 3/08/2018(Thu)

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

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William Chatoff, Owner and Managing Director

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Edge Pharmacy Services, LLC	856 Hercules Dr
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Colchester, VT 05446-8014	Outsourcing Facility

X Niketa Patel
Investigator
Signed By: 2001636807
Date Signed: 03-08-2018 10:09:37

SEE REVERSE OF THIS PAGE

EMPLOYEE(S) SIGNATURE

Niketa Patel, Investigator
Rachael A Moliver, Investigator

X Rachael A Moliver
Investigator
Signed By: Rachael Moliver -S
Date Signed: 03-08-2018 10:07:02

DATE ISSUED
3/8/2018