EASTERN STATES
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April 22, 2015

On behalf of Northern New England Compounding Pharmacy, LLC dba Eastern States Compounding Pharmacy, I authorize the United States Food and Drug Administration (FDA) to publicly disclose the information described below on FDA's web site. I understand that the information that is disclosed may contain confidential commercial or financial information or trade secrets within the meaning of 18 U.S.C. § 1905, 21 U.S.C. § 331 (0), and 5 U.S.C. § 552(b)(4) that is exempt from public disclosure under those statutory provisions and/or relevant FDA regulations. I agree to hold FDA harmless for any injury caused by FDA's sharing the information with the public.

Information to be disclosed: Northern New England Compounding Pharmacy, LLC dba Eastern States Compounding Pharmacy's letter dated 10/8/2014 excluding attachments/exhibits, which responds to FDA's Form 483 dated 9/30/2014.

Authorization is given to FDA to disclose the above-mentioned information which may include confidential commercial or financial or trade secret information. As indicated by my signature, I am authorized to provide this consent on behalf of Northern New England Compounding Pharmacy, LLC dba Eastern States Compounding Pharmacy and my full name, title, address, telephone number, and facsimile number is set out below for verification.

Sincerely,

David Rochefort, RPh
Pharmacist-In-Charge
338 Union Street
Littleton, NH 03561
Phone 603-444-0094
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October 8, 2014

U.S. Food and Drug Administration
New England District
1 Montvale Ave
4th Floor
Stoneham, MA 02180

Attention: CAPT Mutahar Shamsi, District Director
Stacey S. Degarmo, Investigator

Re: Northern New England Compounding Pharmacy, LLC dba Eastern States Compounding Pharmacy, Littleton, NH (FEIN 3005636558)
Response to FDA Form 483 Issued September 30, 2014

Dear Director Shamsi and Investigator Degarmo,

The FDA conducted an inspection of Northern New England Compounding Pharmacy, LLC, dba Eastern States Compounding Pharmacy ("Eastern States Compounding Pharmacy") on 9/17/2014, 9/18/2014, 9/30/2014. At the conclusion of the inspection, Eastern States Compounding Pharmacy received an FDA Form 483 (the "Form 483") listing five observations.

We provide to you this response to the Form 483. We request that this response, excluding the attached SOPs, is included with the Form 483 anytime the FDA provides a copy of the Form 483 to anyone outside the FDA when/if the Form 483 is posted online. The attached SOPs are proprietary and confidential and should not be released.

Before we respond to each of the observations listed in the Form 483, we believe that it is important to discuss the FDA's inspection and application of the Form 483 to Eastern States Compounding Pharmacy. Eastern States Compounding Pharmacy has operated as a pharmacy licensed by and subject to the jurisdiction of the New Hampshire Board of Pharmacy. Currently, as well as at the time of the inspection, we are in good standing with the New Hampshire Board of Pharmacy. Eastern States Compounding Pharmacy engages patient-specific, pharmacy-based compounding pursuant to and in compliance with the pharmacy practice and compounding guidelines set forth by the New Hampshire Board of Pharmacy.

Eastern States Compounding Pharmacy respects and understands that the FDA maintains the necessary authority to regulate the manufacture of drugs. However, Eastern States Compounding Pharmacy does not manufacture drugs. This distinction is important because the FDA's regulation of drug manufacturers and the New Hampshire Board of Pharmacy's regulation of compounding pharmacies are not uniform and differ significantly. As a compounding pharmacy, Eastern States Compounding Pharmacy complies with regulations that govern compounding pharmacies, not drug manufacturers.

In addition to complying with the regulations of the New Hampshire Board of Pharmacy, Eastern States Compounding Pharmacy also complies with the very stringent, nationally-accepted quality control, quality assurance, and quality improvement standards defined in the USP <797>, which are specifically required by the New Hampshire Board of Pharmacy.

It should be noted that the FDA inspection and response to the Form 483 has given us an opportunity to review our procedures and look for improvements. We provide this response and plan of action to the Form 483

Observation 1: *Protective apparel is not worn as necessary to protect drug products from contamination.*

Specifically,
The firm requires personnel producing sterile drug products to wear sterile gloves but only low particulate gowning (not sterile) while working in the ISO 5 hood. There has been no evaluation of the impact of the use of non-sterile gowns, face masks, safety glasses, and bouffants may have on the quality of sterile drug products.

Response to Observation 1: Observation 1 documents Eastern States Compounding Pharmacy complies with all New Hampshire Board of Pharmacy and USP <797> requirements for protective apparel for the compounding of sterile products. Eastern States Compounding Pharmacy is not a pharmaceutical manufacturer. In USP <797> and the New Hampshire Board of Pharmacy requirements, sterile gowns, sterile face masks, sterile safety glasses, and sterile bouffants are not required for compounding pharmacies.

- Corrective Action: Eastern States Compounding Pharmacy complies with the New Hampshire Board of Pharmacy and USP <797> requirements regarding protective apparel.
- Responsible individual: Pharmacist-In-Charge, David Rochefort

Observation 2: *Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions*

Specifically,

A. The firm rotates the use of two non-sterile solutions, OxyVir TB and a 2% bleach solution, for cleaning and disinfecting of surfaces of the ISO hoods. There has been no assessment related to the use of non-sterile disinfectants to clean and disinfect ISO 5 surfaces where sterile products are produced.

B. There is no data to support that the 2% bleach solution used by the firm to disinfect the ISO 5 hood is sporicidal at the concentration and contact time being used (5-10 minutes).

Response to Observation 2A: Observation 2A documents Eastern States Compounding complies with all New Hampshire Board of Pharmacy and USP <797> requirements for the use of disinfectants to be used on the surfaces where sterile compounding products are made. Eastern States Compounding Pharmacy is not a pharmaceutical manufacturer. In USP <797> and the New Hampshire Board of

Pharmacy requirements, sterile disinfectants are not required for compounding pharmacies.

- Corrective Action: Eastern States Compounding Pharmacy complies with the New Hampshire Board of Pharmacy and USP <797> requirements regarding the use of disinfectants used for the cleaning and disinfecting of surfaces of ISO 5 hoods.
- Responsible individual: Pharmacist-In-Charge, David Rochefort

Response to Observation 2B: Observation 2B documents that there is no data to support that the bleach solution used is sporicidal at the contact time being used (5-10 minutes). Eastern States Compounding Pharmacy will purchase a proprietary sporicidal where contact times for sporicidal activity have been determined by the manufacturer. Specifically, Dispatch(TM) Bleach Germicidal Cleaner with an established contact time of 5 minutes for killing spore-producing bacteria.

- Corrective Action: Eastern States Compounding Pharmacy will begin using Dispatch(TM) Bleach Germicidal Cleaner
- Timeline: To be Completed October 13, 2014
- Responsible individual: Pharmacist-In-Charge, David Rochefort

Observation 3: *Each batch of drug product required to be free of objectionable microorganisms is not tested through appropriate laboratory testing.*

Specifically,

The firm's procedure required sterility and endotoxin testing for batches of sterile drug products consisting of 25 or more dosage units or in multiple dose vials for administration to multiple patients. There is no sterility testing required for batches of sterile drug products consisting of less than 25 dosage units.

Response to Observation 3: Observation 3 documents Eastern States Compounding Pharmacy complies with all New Hampshire Board of Pharmacy and USP <797> requirements for endotoxin and sterility testing for batches consisting of 25 or more dosage units or in multiple dose vials for administration to multiple patients. Furthermore, Observation 3 documents Eastern States Compounding Pharmacy complies with all New Hampshire Board of Pharmacy and USP <797> requirements for endotoxin and sterility testing for batches consisting of less than 25 dosage units. Eastern States Compounding Pharmacy is not a pharmaceutical manufacturer and is therefore exempt from the current Good Manufacturing Practices that are required of pharmaceutical manufacturers, not pharmacies.

- Corrective Action: Eastern States Compounding Pharmacy complies with the New Hampshire Board of Pharmacy and USP <797> requirements regarding endotoxin and sterility testing of batches less than, and greater than 25 dosage units and multiple dose vials for administration to multiple patients.
- Responsible individual: Pharmacist-In-Charge, David Rochefort

Observation 4: *Procedures designed to prevent microbiological contamination of drug products purporting to be sterile do not include adequate validation of sterilization process.*

Specifically,

The firm uses an autoclave for the terminal sterilization of two sterile drug products. The cycle used for the steam sterilization of the prednisolone acetate ophthalmic suspension and budesonide nasal irrigation has not been validated for the drug products.

Response to Observation 4: Eastern States Compounding complies with all New Hampshire Board of Pharmacy and USP <797> requirements for the use of steam sterilization for term sterilization of drug preparations. Eastern States Compounding Pharmacy is not a pharmaceutical manufacturer. The autoclave that is used for terminal sterilization of the drug products listed is routinely validated on a monthly basis using biological indicators according to the intent, standards, and rules defined by USP <797> and the New Hampshire Board of Pharmacy.

- Corrective Action: Eastern States Compounding Pharmacy complies with the New Hampshire Board of Pharmacy and USP <797> requirements regarding the use and validation of the autoclave for the terminal sterilization of the two drug products listed.
- Responsible individual: Pharmacist-In-Charge, David Rochefort

Observation 5: *Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.*

Specifically,

A. The firm conducts volumetric air sampling on a monthly basis and surface contact monitoring of the classified rooms (including hoods) on a weekly basis. There is no daily monitoring of the ISO 5 hoods used for the production of sterile drug products. At least one of the ISO 5 hoods is used by firm personnel for the production of sterile drug products daily.

B. Written procedures related to the environmental monitoring do not define actions to be taken when the limit for microbial contamination in the ISO 5 hood is exceeded (>1 CFU) beyond notification of the supervising pharmacist.

Response to Observation 5A: Observation 5A documents Eastern States Compounding Pharmacy not only complies with, but exceeds, all New Hampshire Board of Pharmacy and USP <797> requirements for frequency of environmental monitoring. Eastern States Compounding Pharmacy is not a pharmaceutical manufacturer. USP <797> and the New Hampshire Board of Pharmacy state that volumetric air sampling is required biannually, Eastern States Compounding Pharmacy conducts this sampling monthly. USP <797> and the New Hampshire Board of Pharmacy state that weekly monitoring of ISO 5 hoods used for the compounding of sterile drug preparations is required and Observation 5A documents this monitoring.

- Corrective Action: Eastern States Compounding Pharmacy complies with the New Hampshire Board of Pharmacy and USP <797> requirements regarding the frequency of environmental sampling of ISO 5 hoods used for the compounding of sterile drug preparations.
- Responsible individual: Pharmacist-In-Charge, David Rochefort

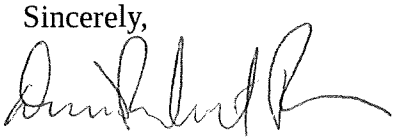
Response to Observation 5B: Eastern States Compounding complies with all New Hampshire Board of Pharmacy and USP <797> requirements for the development of a plan of action when the limit for

microbial contamination in the ISO 5 hood is exceeded (>1 CFU). However, we agree that the current plan could be improved upon. Improvements included a very structured response made available to all staff members, not just the supervising pharmacist. The plan will include not only defined actions but also an identification, when possible, of the offending CFU(s), education of sources of contamination, re-training of cleaning and disinfecting procedures, and suspension of activities within the affected ISO 5 hood until the hood is retested and no growth is observed. SOP XXXXXX is attached.

- Corrective Action: Eastern States Compounding Pharmacy will write and implement SOP 5.10 Action Response When Environmental Monitoring Action Levels are Exceeded
- Timeline: Completed October 8, 2014
- Responsible Individual: Pharmacist-In-Charge, David Rochefort

I hope that the FDA appreciates the work that Eastern States Compounding Pharmacy has taken to ensure patient safety. We sincerely appreciate Investigator Degarmo's, suggestions and professional approach throughout the inspection process. Thank you for considering this response. If you should have any questions, please do not hesitate to contact me at 603-444-0094, x4.

Sincerely,



David Rochefort, R.Ph.
Pharmacist-In-Charge