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	09/17/2014 - 09/30/2014* FEI NUMBER 3005636558

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

TO: David A. Rochefort, Pharmacist in Charge

FIRM NAME	STREET ADDRESS
Northern New England Compounding Pharmacy, LLC	338 Union Street
CITY, STATE, ZIP CODE, COUNTRY	**TYPE ESTABLISHMENT INSPECTED**
Littleton, NH 03561	Producer of Sterile Drugs

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

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.

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 5 hoods. There has been no assessment related to the use of non-sterile disinfectants to clean and disinfect ISO 5 surfaces where sterile drug 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).

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 requires sterility and endotoxin testing for batches of sterile drug products consisting of 25 or more

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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.

OBSERVATION 4

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

OBSERVATION 5

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

Specifically,

A. The firm conducts volumetric viable 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 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.

*** DATES OF INSPECTION:**
09/17/2014(Wed), 09/18/2014(Thu), 09/30/2014(Tue)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Stacey S. Degarmo, Investigator	09/30/2014

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."