DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| One Montvale Avenue<br>Stoneham, MA 02180<br>(781)-587-7500 Fax: (781) 587-7556<br>Industry Information: www.fda.gov/oc/industry | September 22 - 24, 2014 Oct 8, 2014<br>FEI NUMBER<br>1000120535 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: GINA F. MATHEWS, R.Ph. Pharmacy Manager

| FIRM NAME | STREET ADDRESS |
|---|---|
| New England Home Therapies, Inc. | 337 Turnpike Rd |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| Southborough, MA 01772-1760 | Producer of Sterile Drug Products |

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) (WE) OBSERVED:

1. Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically,
a. Gowns/coveralls with attached booties, face masks, hair bonnets, and goggles/glasses worn by clean room operators working inside ISO5 zones (Hoods (b) (4)) are not sterile.

b. On 09/22/14, clean room operators were observed to use non-sterile hand antiseptic (b) (4) ((b) (4)) on hands prior to putting on sterile gloves, then again apply the non-sterile hand antiseptic (b) (4) on gloved hands prior to working in ISO5 hoods.
c. On 09/22/14, (b) (4) clean room operators were observed to not wear goggles/glasses while working in ISO5 hood (b) (4) while processing sterile drug products. Facial areas surrounding eyes and eyes were exposed while working in ISO5 hoods.

d. Clean room operators were observed on 09/22 & 24/14 to put on gown/coveralls allowing the gown to touch the floor in the ante room.

e. On 09/24/14, a clean room operator was observed to have (b) (6) cheeks not completely covered by the face mask exposing facial skin while working in the ISO5 hood (b) (4) processing sterile TPNs.

2. Buildings used in the processing of a drug product are not maintained in a good state of repair.

Specifically,
On 09/24/14, the clean room operator said the sink was leaking from the pipe under the sink in the ante room. The ante room sink was used by clean room operators to wash hands and forearms prior to entrance into the clean room and is located on the clean side of the demarcation line of the ante room. The clean room operator was observed to (b) (4) when

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (Print or Type) | DATE ISSUED |
|---|---|---|---|
| | Susan F Laska | Sharon K. Thoma, Investigator<br>Susan F. Laska, Supervisory Investigator<br>Cameron E. Meaney Investigator | October 08, 2014 |

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| One Montvale Avenue<br>Stoneham, MA 02180<br>(781)-587-7500 Fax: (781) 587-7556<br>Industry Information: www.fda.gov/oc/industry | September 22 - 24, 2014 Oct 8 2014 |
| | FEI NUMBER<br>1000120535 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Gwa F. Mathews, R.Ph. Pharmacy Manager

| FIRM NAME | STREET ADDRESS |
|---|---|
| New England Home Therapies, Inc. | 337 Turnpike Rd |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| Southborough, MA 01772-1760 | Producer of Sterile Drug Products |

[redacted] entered the ante room for cleaning.

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

Specifically,
a. Your firm has not conducted cleaning efficacy studies to assure the suitability and effectiveness of the non-sterile (b) (4) (b) (4) non-sterile (b) (4) (b) (4), and Sterile (b) (4) used to disinfect ISO5 zones, clean room, (b) (4) (b) (4), and/or the ante room.

b. A sporicidal agent is not routinely used to clean ISO5 hoods (b) (4) Hoods (b) (4) are cleaned (b) (4) when the hood is used for compounding with (b) (4).

Your firm uses non-sterile (b) (4) (b) (4) during a (b) (4) clean procedure (b) (4)

For examples, the (b) (4) clean procedure was performed on the following dates: (b) (4) (b) (4) (b) (4) (b) (4)

c. (b) (4) Wipers (b) (4) used to disinfect ISO5 zones (Hoods (b) (4)) and equipment inside ISO5 hoods are not sterile. No information was provided to demonstrate that they are non-shedding.

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

Specifically,
a. Environmental monitoring (viable monitoring) is not conducted during aseptic processing of sterile injectable drug products in the ISO5 zones (Hoods (b) (4)). Your firm only monitors viable counts (b) (4) by an outside contract firm. Last test was completed on 08/19/14.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (Print or Type) | DATE ISSUED |
|---|---|---|---|
| | Susan F Laska | Sharon K. Thoma, Investigator<br>Susan F. Laska,<br>Cameron E. Moore, Investigator | October 08, 2014 |

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| One Montvale Avenue<br>Stoneham, MA 02180<br>(781)-587-7500 Fax: (781) 587-7556<br><br>Industry Information: www.fda.gov/oc/industry | September 22 - 24, 2014<br>Oct 8, 2014<br><br>FEI NUMBER<br>1000120535 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: GINA F. MATTHEWS, R.Ph Pharmacy Manager

| FIRM NAME | STREET ADDRESS |
|---|---|
| New England Home Therapies, Inc. | 337 Turnpike Rd |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| Southborough, MA 01772-1760 | Producer of Sterile Drug Products |

b. Environmental monitoring measuring non-viable particulates is not conducted during aseptic processing of sterile injectable drug products in the ISO 5 zones. Your firm does not have equipment to conduct non-viable particulates and monitors non-viable particulates (b) (4) by an outside contract firm. Last test completed on 08/19/14.

c. Personnel monitoring is not conducted following daily aseptic processing / exit of the cleanroom for sterile injectable drug products in ISO 5 zones. Personnel monitoring was explained to be conducted (b) (4) . Personnel monitoring does not include forearms, forehead, chest and goggles/glasses. No documentation and results were provided for review during the inspection on (b) (4) tests completed.

d. (b) (4) (b) (4) (b) (4) for molds/yeasts for work surface monitoring were observed in a clear (b) (4) bag (b) (4) and not in a 20-25°C incubator. Your firm does not have a 20 – 25°C incubator. (b) (4) (b) (4) (b) (4) (b) (4) per the manufacturer's instructions (b) (4) .

5. 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, injectable finished drug products are not tested for assay.

6. Each batch of drug product purporting to be sterile is not laboratory tested to determine conformance to such requirements. Specifically, injectable finished drug products are not tested for sterility.

7. The separate or defined areas necessary to prevent contamination or mix-ups are deficient.

Specifically,
a. Your firm is processing penicillin drug products (e.g., Penicillin G Potassium, Nafcillin) in ISO5 hoods (b) (4) with non-penicillin drug products. There is no isolated structural area and a potential for cross contamination between Penicillin and non-penicillin drug products if penicillin powder vials accidentally break.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (Print or Type) | DATE ISSUED |
|---|---|---|---|
| | Susan F Laska | Sharon K. Thoma, Investigator<br>Susan F. Laska,<br>Comerson E. Moore, Investigator | October 08, 2014 |

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

| DISTRICT OFFICE ADDRESS AND PHONE NUMBER | DATE(S) OF INSPECTION |
|---|---|
| One Montvale Avenue<br>Stoneham, MA 02180<br>(781)-587-7500 Fax: (781) 587-7556<br>Industry Information: www.fda.gov/oc/industry | September 22 - 24, 2014<br>Oct 8, 2014<br>FEI NUMBER<br>1000120535 |

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Gina F. Matthews, R.Ph. Pharmacy Manager

| FIRM NAME | STREET ADDRESS |
|---|---|
| New England Home Therapies, Inc. | 337 Turnpike Rd |
| CITY, STATE AND ZIP CODE | TYPE OF ESTABLISHMENT INSPECTED |
| Southborough, MA 01772-1760 | Producer of Sterile Drug Products |

b. Your firm is processing cephalosporin drug products (e.g., Cefazolin, Cefoxitin, Cefepime, etc.) in ISO5 hoods (b) (4) with non-cephalosporin drug products. There is no isolated structural area and a potential for cross contamination between cephalosporin and non-cephalosporin drug products if cephalosporin powder vials accidently break.

c. There is no isolated structural area and a potential for cross contamination between cytotoxic agents and other sterile penicillin, non-penicillin, cephalosporin, and non-cephalosporin drug products. The ante room is attached to the (b) (4) used to process cytotoxic agents and to the clean room used to process penicillins, cephalosporins, non-penicillin, and non-cephalosporin products. Entrance / Exit of both clean rooms is through the common ante room.

| SEE REVERSE OF THIS PAGE | EMPLOYEE(S) SIGNATURE | EMPLOYEE(S) NAME AND TITLE (*Print or Type*) | DATE ISSUED |
|---|---|---|---|
| | Susan F. Laska | Sharon K. Thoma, Investigator<br>Susan F. Laska, | October 08, 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."