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	8/2/2017-8/17/2017* FEI NUMBER 3003687986

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Charles J. Fanaras , President

FIRM NAME	STREET ADDRESS
Mytilini Enterprises LLC dba Bedford Pharmacy Inc.	209 Route 101
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Bedford, NH 03110-5440	Producer of Non-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

Testing and release of drug product for distribution do not include appropriate laboratory determination of satisfactory conformance to the final specifications and identity and strength of each active ingredient prior to release.

Specifically, during the last 3 months your firm prepared and dispensed approximately 1,500 drug products. These drug products along with non-patient specific drug products such as Atropine 1% Oral Solution, Diazepam 10mg Suppositories, Phenobarbital 100mg Suppositories and Lorazepam 1mg Suppositories, were prepared and dispensed without testing to determine conformance with identity or potency.

OBSERVATION 2

Equipment and utensils are not cleaned, maintained and sanitized at appropriate intervals to prevent malfunctions and contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically,

A. Per your firm's procedure, all compounding areas and equipment shall be cleaned in between preparations or after use. Your firm lacks cleaning records for non-dedicated equipment and utensils used for the production of potent drug substances including hormones, antibiotics and controlled

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substances, and your firm lacks cleaning validation data to support the use of a household dish soap and multipurpose cleaner as appropriate cleaning agents for drug production equipment and utensils.

B. Your firm cleans drug production equipment and utensils with a household dish soap and/or multipurpose cleaner and tap water. Purified water is not used for a final rinse after cleaning and drug production equipment and utensils are placed on a rack adjacent to the sink for drying. No quality testing of the tap water has been performed and you failed to provide documentation to support the use of tap water in place of purified water and a drying rack adjacent to the sink as an appropriate practice.

C. Your firm uses non-dedicated equipment and utensils within two PowderSafe AirClean Systems Ductless Balance Enclosure hoods for the production of human drug products including hormones, antibiotics and controlled substances as well as veterinarian drug products including cisapride, diethylstilbestrol and phenylpropanolamine. Firm personal were observed using isopropyl alcohol 70% and a reusable green microfiber cloth to clean hood surfaces, non-dedicated equipment such as an Ohaus electronic balance and non-dedicated utensils such as spatulas between drug product preparations. There has been no assessment related to the use of a reusable green microfiber cloth and isopropyl alcohol as appropriate, to clean and prevent contamination of hood surfaces, equipment and utensils used for drug production.

OBSERVATION 3

Protective apparel is not worn as necessary to protect drug products from contamination.

Specifically, your firm's gowning procedures and practices are inadequate or not followed. Per your firm's procedures, proper garbing is performed to prevent contamination. Firm personnel are required to don nitrile or latex gloves and have covered arms while working in the powder hood. There is no requirement for firm personnel engaged in the production of drug products to wear hair covers and face

masks. Firm personnel engaged in the production of drug products were observed wearing short sleeve scrubs with exposed forearms and not observed wearing hair covers and face masks.

OBSERVATION 4

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

Specifically, a Fillmaster FMF 940 Pharmatap water filtration system is used to filter water used as an ingredient in drug products produced by your firm. You failed to provide evidence of maintenance of the Fillmaster filtration system such as filter replacement as required per Fillmaster Filtration installation instructions and service guide. Additionally, your firm has not sampled or tested this filtered water and failed to provide documentation supporting this water meets purified water standards.

OBSERVATION 5

Drug products are not stored under appropriate conditions of temperature and humidity so that their identity, strength, quality, and purity are not affected.

Specifically, your firm is not currently using calibrated thermometers or hygrometers for temperature and/or humidity sensitive drug component and drug product storage.

- Your firm uses a compact Haier refrigerator for storage of all drug product ingredients requiring refrigeration such as cyclophosphamide USP and nystatin USP. No thermometer is used and no temperature records are maintained for this refrigerator.
- Your firm uses an All Purpose Cold Beverage Air refrigerator for storage of all drug products

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awaiting dispensing, all finished drug products, and all commercial products requiring refrigeration. These drug products include lorazepam, diazepam, and phenobarbital suppositories as well as Novolog and Humulin insulins. An uncalibrated EL-USB-TC-LCD Thermocouple Data Logger is used to maintain temperature records for this refrigerator. Between 4/10/17 and 8/10/17, multiple temperature excursions below 32 degrees F were identified. There has been no assessment related to product stability and product impact regarding storage conditions below 32 degrees F or incurring freeze thaw cycles.

OBSERVATION 6

The calibration of instruments is not done at suitable intervals in accordance with an established written program and with provisions for remedial action in the event accuracy and/or precision limits are not met.

Specifically, your firm has failed to calibrate two Ohaus electronic balances used to weigh active pharmaceutical ingredients and components for your drug products. No external weights checks are documented and there are no written procedures describing the requirements for the calibration of the balances and calibrations weights.

***DATES OF INSPECTION**

8/02/2017(Wed),8/03/2017(Thu),8/04/2017(Fri),8/08/2017(Tue),8/10/2017(Thu),8/11/2017(Fri),8/17/2017(Thu)

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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 judgment, 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."