



209 Route 101 Bedford, NH 03110
603-472-3919

October 22, 2017

Maya M. Davis
Compliance Officer
OPQO Division 1, New England District Office

Dear Ms. Davis,

On behalf of Mytilini Enterprises, LCC dba Bedford 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 (b)(4), 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: Mytilini Enterprises, LCC dba Bedford Pharmacy's letter dated 09/22/2017 excluding attachments/exhibits, which responds to FDA's Form 483 dated 08/17/2017.

Authorization is given to the 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 Mytilini Enterprises, LLC and my full name, title, address, telephone number and facsimile number is set out below for verification.

Sincerely,

Charles J. Fanaras, R.Ph., President
Mytilini Enterprises, LLC dba Bedford Pharmacy
209 Route 101
Bedford, NH 03110-5440
(603) 233-3111 (phone)
(603) 472-7448 (fax)



**Bedford
Pharmacy**

NWE DISTRICT OFFICE

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209 Route 101 Bedford, NH 03110
603-472-3919

09/22/2017

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

Attention: Joseph Matrisciano Jr., District Director
John P Mistler, Investigator

Re: Mytilini Enterprises, LLC dba Bedford Pharmacy 209 Route 101 Bedford, NH 03101
Response to FDA Form 483 Issued 08/17/2017

Dear Director Matrisciano and Investigator Mistler

The FDA conducted an inspection of Mytilini Enterprises, LLC dba Bedford Pharmacy on 08/02/17-08/17/17. At the conclusion of the inspection Bedford Pharmacy received an FDA Form 483 listing six observations.

We are providing 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 or when/if it is posted online issued to Mytilini Enterprises, LLC dba Bedford Pharmacy on 08/17/2017.

We would like to note that the FDA inspection and our response to the Form 483 has provided us the opportunity to review our procedures and look for improvements.

Prior to responding to each of the observations included in the Form 483 we believe it is important to provide background information. Mytilini Enterprises, LLC dba Bedford Pharmacy considers itself a 503A compounding pharmacy licensed by and subject to the jurisdiction of the New Hampshire Board of Pharmacy. Currently and at the time of the inspection, we are in good standing with the New Hampshire Board of Pharmacy. Mytilini Enterprises, LLC purchased Bedford Pharmacy on 01/01/2017 and this inspection was a follow up to a previous inspection conducted in 2015 with regards to sterile compounding. Mytilini Enterprises, LLC dba Bedford Pharmacy is not engaged in sterile compounding as has been so noted on the Form 483. During the consolidation of compounding three Hospice compounded products were being delivered to a sister pharmacy for patient specific dispensing. This situation was halted on 08/08/17 and all products not dispensed were destroyed. Mytilini Enterprises, LLC dba Bedford Pharmacy is only engaged in patient-specific, pharmacy-based compounding in compliance with the pharmacy practice and compounding guidelines set forth by the New Hampshire Board of Pharmacy.

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.

Response to Observation 1: Mytilini Enterprises, LLC dba Bedford Pharmacy is only engaged in patient-specific pharmacy-based compounding in compliance with the pharmacy practice and compounding guidelines set forth by the New Hampshire Board of Pharmacy.

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 procedures, 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 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 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 phenylpropranolamine. Firm personnel were observed using isopropyl alcohol 70% and a reusable green microfiber cloth to clean hood surfaces, non-dedicated equipment such as Ohaus electronic balance and non-dedicated utensils such as spatulas between drug product preparations. There has been no assessment related to the use of reusable green microfiber cloth and isopropyl alcohol as appropriate, to clean and prevent contamination of hood surfaces, equipment and utensils used for drug production.*

Response to Observation 2A: Mytilini Enterprises, LLC dba Bedford Pharmacy has reviewed its policy and procedures and has made appropriate changes and has enclosed the following SOPs 1.050 and 3.050 which conform to USP<795> and patient-specific pharmacy-based compounding in compliance with the pharmacy practice and compounding guidelines set forth by the New Hampshire Board of Pharmacy.

Response to Observation 2B: Mytilini Enterprises, LLC dba Bedford Pharmacy has reviewed its policy and procedures and has made appropriate changes and has enclosed the following SOP 1.050 which conforms to USP<795> and patient-specific pharmacy-based compounding in compliance with the pharmacy practice and compounding guidelines set forth by the New Hampshire Board of Pharmacy.

Response to Observation 2C: Mytilini Enterprises, LLC dba Bedford Pharmacy has reviewed its policy and procedures and has made appropriate changes and has enclosed the following SOP 1.050 which conforms to USP<795> and patient-specific pharmacy-based compounding in compliance with the pharmacy practice and compounding guidelines set forth by the New Hampshire Board of Pharmacy.

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

Response to Observation 3: Mytilini Enterprises, LLC dba Bedford Pharmacy has reviewed its policy and procedures and has made appropriate changes and has enclosed the following SOP 9.130 which conforms to USP<795> and patient-specific pharmacy-based compounding in compliance with the pharmacy practice and compounding guidelines set forth by the New Hampshire Board of Pharmacy.

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.

Response to Observation 4: Mytilini Enterprises, LLC dba Bedford Pharmacy has reviewed its policy and procedures and has made appropriate changes and has enclosed the following SOP 4.120 which conforms to USP<795> and patient-specific pharmacy-based compounding in compliance with the pharmacy practice and compounding guidelines set forth by the New Hampshire Board of Pharmacy. Mytilini Enterprises, LLC dba Bedford Pharmacy has also contracted with Fillmaster to perform annual maintenance in compliance with Fillmaster's service guide. Mytilini Enterprises, LLC dba Bedford Pharmacy has also contracted with a local

water testing firm to perform bi-annual water testing of the Fillmaster 3400 and our local city tap water.

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.

- A. *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.*
- B. *Your firm uses an All Purpose Cold Beverage Air refrigerator for storage of all drug products 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 04/10/17 and 08/10/17, 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.*

Response to Observation 5A: Mytilini Enterprises, LLC dba Bedford Pharmacy has reviewed its policy and procedures and has made appropriate changes and has enclosed the following SOP 4.020 which conforms to USP<795> and patient-specific pharmacy-based compounding in compliance with the pharmacy practice and compounding guidelines set forth by the New Hampshire Board of Pharmacy. Mytilini Enterprises, LLC dba Bedford Pharmacy has also contracted with a local firm to provide yearly maintenance on all refrigeration units.

Response to Observation 5B: Mytilini Enterprises, LLC dba Bedford Pharmacy has reviewed its policy and procedures and has made appropriate changes and has enclosed the following SOP 4.020 which conforms to USP<795> and patient-specific pharmacy-based compounding in compliance with the pharmacy practice and compounding guidelines set forth by the New Hampshire Board of Pharmacy.

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 check are documented and there are no written procedures describing the requirement for the calibration of the balances and calibrations weights.

Response to Observation 6: Mytilini Enterprises, LLC dba Bedford Pharmacy has reviewed its policy and procedures and has made appropriate changes and has enclosed the following SOP 4.070 which conforms to USP<795> and patient-specific pharmacy-based compounding in compliance with the pharmacy practice and compounding guidelines set forth by the New

Hampshire Board of Pharmacy. Mytilini Enterprises, LLC dba Bedford Pharmacy has also contracted with a local firm to conduct annual calibration of all balances used in compounding.

We appreciate Investigator Mistler's, professional approach throughout the inspection process. We appreciate the opportunity to provide this response and for your consideration. Please feel free to contact me at 603-223-3111 if you have any questions.

Sincerely,

A handwritten signature in black ink, appearing to read 'Charles J. Kanaras', written over a horizontal line.

Charles J. Kanaras, RPh
President