

WINGATE'S



Pharmacy & Compounding

Caring for Our Community Since 1900

NW DISTRICT OFFICE

2016 MAR 4 AM 11 55

VIA OVERNIGHT MAIL

February 29, 2016

Mr. Matthew Pallo
Acting District Director, New England District
U.S. Food and Drug Administration
One Montvale Avenue
Stoneham, MA 02180

Dear Mr. Pallo:

On behalf of Anderson Holdings, inc dba Wingate's Pharmacy and Compounding, we authorize the United States Food and Drug Administration ("FDA") to publicly disclose the information described below on FDA's website. Specifically, we ask that the information described below be posted in ORA's electronic reading room next to the links to the Form 483 issued to Wingate's Pharmacy on February 19th, 2015.

Information to be disclosed: Letter from Anderson Holdings, inc dba Wingate's Pharmacy and Compounding to Acting District Director Matthew Pallo, New England District dated March 3, 2016 excluding attachments and/exhibits, which responds to FDA Form 483 dated February 19th 2016.

Wingate's Pharmacy understands 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. § 3310 and 5 U.S.C. § 552(b)(4) that is exempt from public disclosure under these statutory provisions and/or relevant FDA regulations. Wingate's Pharmacy agrees to hold FDA harmless for any injury caused by FDA's sharing the information with the public.

Sincerely,

Derick Anderson, PharmD

Pharmacist-In-Charge

WINGATE'S



Pharmacy & Compounding
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March 3, 2016

Mr. Matthew Pallo
Acting District Director, New England District
U.S. Food and Drug Administration
One Montvale Avenue
Stoneham, MA 02180

Attention: Matthew Pallo, Acting District Director
Stacey S. Degarmo, Investigator

**Re: Anderson Holdings, inc dba Wingate's Pharmacy and Compounding,
Nashua, NH (NH Pharmacy License #0003)
Response to FDA Form 483 Dated February 19th, 2016**

Dear Acting Director Pallo and Investigator Degarmo,

The FDA conducted a routine inspection of Anderson Holdings, inc dba Wingate's Pharmacy and Compounding ("Wingate's Pharmacy") on 2/01/2016, 2/02/2016, 2/04/2016, 2/11/2016, and 2/19/2016 upon which day a Form FDA 483 was issued.

The following is our response to the inspectional observations contained within the Form 483. We request that this response excluding attachments/exhibits is included with the Form 483 anytime the FDA provides the Form 483 to any party and update its website area specifically the ORA's electronic reading room next to the links to the issued Form 483 within reasonable timeframe. The attached SOPs, worksheets, processes and etc. are proprietary and confidential trade secrets and should not be released in this fashion. Please, see attached disclosure letter.

Of note, it is important to explain that Wingate's Pharmacy is currently licensed and in good standing with the New Hampshire Board of Pharmacy and complies with all NH BOP Rules and Regulations as they pertain to retail pharmacy operations which include the practice of compounding as well as USP general chapters relating to pharmacy compounding. Wingate's Pharmacy is not a manufacturer and prepares compounded medicines based on individual provider prescriptions therefore is not held to the standards that apply to Current Good Manufacturing Practice.

We feel it important to mention this difference due to the fact some of the observations include, what may be best categorized, as standards that are more typical of either FDA

registered manufacturers or those pharmacies that have completed the registration process to be characterized as a 503(B) facility. Due to Wingate's Pharmacy's current practices and standing with the NH BOP we would be correctly categorized as a 503(A) facility.

The FDA inspection and the provided Form 483 gave Wingate's Pharmacy the opportunity to look closely at its operation and make changes or enhancements in areas that will allow our pharmacy to improve our practices and ultimately the treatment we provide to our patients.

Wingate's Pharmacy would like to mention the respect and professionalism your investigators showed throughout our time together. We hope that our mutual respect for their positions came across as well.

We have tried to outline our response as neatly as possible and provided attachments to cross reference any relevant documentation.

Observation 1: Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

A. The firm's cleaning process involves the full opening of the front panel of the ISO 5 glove box for cleaning at the beginning and end of each day of use. During the cleaning process, the aseptic processing area inside the glove box is exposed to non-sterile gowning worn by firm operators as well as air in the surrounding ISO 8 room. There has been no evaluation of the impact the opening of the ISO 5 glove box may have on the quality of sterile drug products.

Response to Observation 1A: Wingate's Pharmacy understands the potential for particulate matter to enter the ISO 5 glove box during open conditions. The pharmacy has updated its policies to only open the observation window on a weekly basis at the end of the day. As with any ISO 5 area USP <797> does not require the use of sterile garb which is a manufacturing, or GMP, requirement. Nonetheless, we have adjusted our cleaning SOP to only open the observation window once weekly at the end of the day. This gives the chamber a full overnight period to remove particles. (attached Cleaning Process)

Corrective Action: Updated SOP to reflect reduction in opening glove box observation window.

Timeline: Immediate

- B. *The firm uses non-sterile solutions (e.g. Process LpH st, Vesphene IIse, and Sporididin) for cleaning and disinfecting of surfaces in the ISO 5 glove box.*

Response to Observation 1B: Wingate's pharmacy is a duly registered pharmacy in the State of New Hampshire and in good standing with the New Hampshire Board of Pharmacy. Wingate's Pharmacy prepares compounds on a prescription basis, is compliant with NH BOP regulations and USP <797>, and is not a manufacturer. USP <797> does not require the use of sterile disinfectants for pharmacy compounding.

Corrective Action: Compliant

- C. *Two of the cleaning agents used by the firm require dilution prior to use (Process LpH st and Vesphene IIse). The firm does not document the preparation of the cleaning agents. The firm uses distilled water for the dilution of the cleaning agents.*

Response to Observation 1C: Wingate's Pharmacy has created a formula worksheet to be used when diluting disinfectants. Furthermore the cleaning policies have been updated to reflect the use of sterile water for irrigation, documenting when a new disinfectant is introduced into service. (attached SOP 1.40, cleaning process, worksheets)

Corrective Action: SOP updated to document preparation of disinfectants.

Timeline: Immediate

- D. *The firms cleaning log does not document which cleaning agents were used for the daily and monthly cleanings of the ISO 5 glove box and ISO 8 room.*

Response to Observation 1D: The cleaning policies have been updated to document when a new disinfectant is placed into service. (attached SOP 1.40, cleaning process, worksheets)

Corrective Action: SOP updated to document preparation of disinfectants.

Timeline: Immediate

- E. *The firm uses non-sterile non-shedding wipes to clean and disinfect the interior of the ISO 5 glove box.*

Response to Observation 1E: Wingate's pharmacy is a duly registered pharmacy in the State of New Hampshire and in good standing with the New Hampshire Board of Pharmacy. Wingate's Pharmacy prepares compounds on a prescription basis, is compliant with NH BOP regulations and USP <797>, and is not a manufacturer. USP <797> does not require the use of sterile wipes for means of cleaning nor disinfection.

Corrective Action: Compliant

Observation 2: Aseptic areas are deficient regarding the system for monitoring environmental conditions.

Specifically,

- A. *The firm conducts volumetric viable air sampling and surface contact monitoring of the ISO classified areas on a monthly basis. There is no routine monitoring of the processing area of the ISO 5 glove box during each occurrence of aseptic operations, which are conducted approximately three to four days each week.*

Response to Observation 2A: Wingate's pharmacy is a duly registered pharmacy in the State of New Hampshire and in good standing with the New Hampshire Board of Pharmacy. Wingate's Pharmacy prepares compounds on a prescription basis, is compliant with NH BOP regulations and USP <797>, and is not a manufacturer. USP <797> requires twice annual viable air sampling and surface contact monitoring. Our policies surpass this requirement with a monthly viable air and every other week surface testing program.

Corrective Action: Compliant

- B. *The firm conducts personnel monitoring (fingertip plating) only at the time of semi-annual media fills. There is no personnel monitoring following routine sterile processing....*
....The firm does not currently adhere to the fingertip sampling frequency specified in their procedure (initially weekly for three weeks then every other week).

Response to Observation 2B: Wingate's pharmacy is a duly registered pharmacy in the State of New Hampshire and in good standing with the New Hampshire Board of Pharmacy. Wingate's Pharmacy prepares compounds on a prescription basis, is compliant with NH BOP regulations and USP <797>, and is not a manufacturer. USP <797> requires twice annual fingertip plating...

...Our firm has been implementing policies that are designed to be more stringent than USP <797>. The environmental portions have been fully implemented as of January 2016; however, our more stringent personnel fingertip monitoring is targeted to begin March 2016. Our firm does currently meet the USP <797> twice annual requirement.

Corrective Action: Compliant with USP <797> and implementing new SOP for fingertip testing.

Timeline: March 2016 for new policy

- C. *The firm documents the air pressure of the ISO 8 room once each day. There is no continuous monitoring of the pressure differentials for the ISO 5 glove box to ensure the maintenance of appropriate pressure during aseptic operations.*

Response to Observation 2C: Wingate's pharmacy is a duly registered pharmacy in the State of New Hampshire and in good standing with the New Hampshire Board of Pharmacy. Wingate's Pharmacy prepares compounds on a prescription basis, is compliant with NH BOP regulations and USP <797>, and is not a manufacturer. USP <797> does not require continuous monitoring of ISO pressure controls.

Corrective Action: Compliant

- D. *The firm failed [to] assess the potential impact of positive low level viable air monitoring results at the work table in the ISO 8 clean room on 11/27/15, 12/14/15, and 12/18/15. The firm uses the work table for the preparation of drug products prior to aseptic filtration in the ISO 5 glove box. No corrective actions were implemented outside the routine scheduled cleanings following the positive results. The bacterial isolates were not sent out for identification. To date, the firm has not considered these results during their ongoing evaluation of the Cyclosporine 2% ophthalmic solution sterility failure for Lot #121415-28, which was prepared on 12/14/15.*

Response to Observation 2D: Wingate's Pharmacy has used USP <797> Table 4

“Recommended Action Levels for Microbial Contamination” which states the level for ISO 8 areas as greater than 100 CFUs. Even with the USP recommendation we evaluated each test result. We discussed cleaning methodology with staff and conducted a more thorough cleaning after which the test returned to zero CFUs. Also, we have updated our SOP to reduce the ISO 8 action levels and included a definition for trending including a trigger point for further testing. Separately, we have completed our draft investigation report on the cyclosporine failure which does take into consideration the test results. (attached SOP 1.4, cyclosporine report)

Corrective Action: Updated SOP to surpass USP action levels and define trending and associated response to microbial growth during routine environmental testing. Completed cyclosporine report.

Timeline: Immediate

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

Specifically,

A. The firm's procedures require sterility and bacterial endotoxin testing for batches of sterile drug products consisting of 25 or more units or multi-dose vials. The firm does not require bacterial endotoxin testing for batches of sterile drug products comprised of less than 25 units.

Response to Observation 3A: Wingate's pharmacy is a duly registered pharmacy in the State of New Hampshire and in good standing with the New Hampshire Board of Pharmacy. Wingate's Pharmacy prepares compounds on a prescription basis, is compliant with NH BOP regulations and USP <797>, and is not a manufacturer. USP <797> does not require endotoxin testing on all batches of less than 25 units.

Corrective Action: Compliant

B. The firm does not have data to support sterility assurance of prepared sterile drug products for the duration of the extended beyond use dates assigned to the products.

Response to Observation 3B: Wingate's pharmacy is a duly registered pharmacy in the State of New Hampshire and in good standing with the New Hampshire Board of Pharmacy. Wingate's Pharmacy prepares compounds on a prescription basis, is

compliant with NH BOP regulations and USP <797>, and is not a manufacturer. USP <797> does not require sterility testing at end of beyond use dates.

Corrective Action: Compliant

Observation 4: Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established, written and followed.

Specifically,

A. The firm's procedure for the dry heat oven is inadequate for the following reasons:

- 1. The procedure does not address the validation of the dry heat sterilization or depyrogenation cycles allowed by the firm.*
- 2. The procedure allows for a 90 day clean hold time for depyrogenated glassware and utensils. The firm does not have data to support the 90 day clean hold time allowed.*

Response to Observation 4A(1): Wingate's Pharmacy has updated the policy for the convection oven and created formula worksheets that lay out each process to allow for adequate documentation. (attached SOP 2.210, worksheets)

Corrective Action: Policy updated to allow for greater documentation and created worksheets for staff to follow.

Timeline: Immediate

Response to Observation 4A(2): USP <797> does not require any certain expiration dating for depyrogenated glassware or instruments and only states "Such items are either used immediately or stored until use in an environment suitable for compounding". Due to this discrepancy in guidance we feel it appropriate to reduce our clean hold time from 90 days to 30 days which is more appropriate for our level of usage.

Corrective Action: Policy updated to reflect lesser clean hold time.

Timeline: Immediate

B. Firm personnel stated that semi-annual media fill simulations are required for personnel conducting aseptic operations. There is no written procedure that covers the firm's media fill simulation process or requirements.

Response to Observation 4B: Wingate's Pharmacy has updated its policy to reflect the simulation and requirements for media fill testing. (attached SOP 1.51 and worksheets)

Corrective Action: Media fill testing protocol outlined in SOPs.

Timeline: March + April Employee revalidations

- C. *The firm media fill simulation does not represent the most challenging or stressful condition. For example, the firm failed to include the use of reusable glassware during the semi-annual media fill.*

Response to Observation 4C: The detailed worksheets used for media fill testing have been updated to reflect the use of reusable glassware. (attached worksheets)

Corrective Action: Media fill worksheets now stipulate use of reusable glassware.

Timeline: Immediate

- D. *The firm uses Logged Formula Worksheets to document depyrogenation cycles. The worksheets fail to document what equipment and/or components were included in the cycle load. The documentation records do not include equipment printouts for the depyrogenation cycles to ensure the time and temperature specifications for the cycles were met.*

Response to Observation 4D: The Logged Formula Worksheets utilized for depyrogenation cycles has been updated to reflect an inventory of each load. The worksheets now also contain a requirement for documenting start and stop times as well as temperature. (attached worksheets)

Corrective Action: Worksheets were updated to include inventory of load, cycle timing and temperature recordings.

Timeline: Immediate

Observation 5: Clothing of personnel engaged in the processing of drug products is not appropriate for the duties they perform.

Specifically,

The firm does not require the gowning worn by personnel performing operations in the ISO 5 glove box to be sterile, with the exception of sterile gloves. The following non-sterile items are used when firm personnel gown for sterile operations: disposable gown, bouffant, beard cover (when applicable), face mask, and shoe covers. There is no requirement for sterile gowning during the cleaning of the glove box in which the entire front panel is opened and the operator reaches into the aseptic processing area to clean the walls and work surfaces of the ISO 5 glove box.

Response to Observation 5: The stated observation denotes that Wingate's Pharmacy meets all NH Board of Pharmacy and USP <797> requirements for garb worn by personnel performing aseptic functions. USP <797> does not require sterile garb, other than gloves, for personnel for either operational or cleaning functions. Wingate's Pharmacy is not a manufacturer and is not required to meet GMP standards consistent with sterile garbing.

Corrective Action: Compliant

Observation 6: Laboratory controls do not include the establishment of scientifically sound and appropriate test procedures designed to assure the drug products conform to appropriate standards of identity, strength, quality, and purity.

Specifically,

The alternate test method (Rapid ScanRDI Microbial Detection) used by the firm in place of USP 71 sterility testing has not been validated for use with the sterile drug products produced by the firm. For example, the firm used the Rapid ScanRDI Microbial Detection results in lieu of sterility testing results for the 250mL (50 vial) batch of Tri-Mix 30-1-10, Lot#101515-01.

Response to Observation 6: Wingate's Pharmacy utilizes the most current and technologically advanced methodology for determination of microbiological presence in its sterility testing. The ScanRDI system has not only been proven to detect the requisite 6 organism mandate by USP but has further been shown to have greater sensitivity than the reference standard to those organisms as well as thousands of other organisms including some not detected by USP <71> method. Inasmuch as the ScanRDI is becoming more and more an accepted practice we have chosen to update our policy to reflect a mandatory USP <71> reference method for batches greater than 25 units. (attached SOP 4.3)

Corrective Action: Batches greater than 25 units will now require the use of a

standard USP <71>.

Timeline: Immediate

Observation 7: There is a failure to thoroughly review any unexplained discrepancy whether or not the batch has been already distributed.

Specifically,

The firm failed to investigate two instances of potency results above the allowed 90-110% for Quad Mix 20/0.8mg/8.3/160mcg/mL from the potency over time testing conducted on Lot #100215-26. The potency analysis on 11/6/15 revealed a potency of 0.896 mg/mL (112%) for the phentolamine mesylate component of the product. The potency analysis on 12/1/15 revealed a potency of 186 mcg/mL (116%) for the atropine sulfate component of the product.

Response to Observation 7: The policy on potency testing has been updated to look at each data point in tests utilizing a series of data points and the requirement of immediate action if any single data point is outside USP <795>90-110% requirements. (attached SOP 4.50)

Corrective Action: SOP updated to reflect reporting of any individual data point not meeting USP requirements.

Timeline: Immediate

Observation 8: 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,

The firm does not conduct routine potency testing for prepared sterile drug products prior to release.

Response to Observation 8: Wingate's pharmacy is a duly registered pharmacy in the State of New Hampshire and in good standing with the New Hampshire Board of Pharmacy. Wingate's Pharmacy prepares compounds on a prescription basis, follows USP <797> and NH BOP regulations, and is not a manufacturer. USP <797> does not

129 Main Street • Nashua, New Hampshire 03060 • (603) 882-9733 • Fax (603) 882-9734

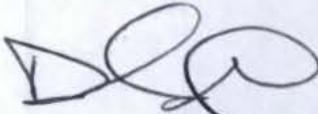
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require potency testing to be done on all compounded preparations prior to their being dispensed.

Corrective Action: Compliant

Wingate's Pharmacy would like to stress how serious we take all observations made by your investigators and the opportunity it has allowed us to examine our policies. We feel we have put forward our best effort into complying with New Hampshire Board of Pharmacy regulations, USP relevant chapters, and FDA oversight. Please, feel free to contact myself at any time if you have questions as it pertains to our response to the issued FDA Form 483.

Respectfully,



Derick Anderson, PharmD

Pharmacist-In-Charge