MEDICAP Pharmacy #8362
2790 W. Cherry Lane Ste 100
Meridian, ID 83642
(208) 288-1496 Phone
(208)-288-1812 Fax

VIA Overnight Mail and Fax

August 3, 2016

Miriam Burbach, Acting District Director
Food and Drug Administration
District Office
22215 26th Ave SE, Suite 210
Bothell, WA 98021
425-302-0340

RE: Trone Health Services, Inc. WAIVER for Publication of Response to Amended FDA Form 483 Issues July 15, 2016; FEI No. 3012086997

Dear Miriam Burbach,

On behalf of MEDICAP Pharmacy and Trone Health (hereafter referred to collectively as MEDICAP Pharmacy), located in Meridian Idaho, I hereby authorize the United States Food and Drug Administration (FDA) to publicly disclose the information described below on FDA's website. 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 0), 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: MEDICAP Pharmacy's, August 3, 2016 Response to FDA Form 483 Issued July 15, 2016; FEI No. 3012086997. The waiver shall extend only to MEDICAP Pharmacy's Response to the FDA Form 483 issued July 15, 2019 and not to any of the supporting or underlying documents implicated or involved in the FDA Form 483 issued July 15, 2016 such as Attachments and Exhibits.

Authorization is given to 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 MEDICAP Pharmacy's, and my full name, title, address, telephone number, and facsimile number is set out above for verification.

In the event there are any questions regarding the disclosure of such information, I hereby request pre-disclosure notification so that we can address any such questions prior to disclosure of the material. Thank you.

Very truly yours,

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

August 3, 2016

Miriam Burbach, Acting District Director
Food and Drug Administration
District Office
22215 26th Ave SE, Suite 210
Bothell, WA 98021
425-302-0340

RE: Response to Inspectional Observations Issues to Trone Health Services/MEDICAP Pharmacy

Dear Miriam Burbach,

MEDICAP Pharmacy would like to take this opportunity to respond to the inspectional observations listed on Form 483 dated July 15, 2016 FEI No. 3012086997. During FDA's inspection, MEDICAP Pharmacy engaged cooperatively and constructively with FDA. MEDICAP Pharmacy would like to ensure FDA that it is committed to providing patients with the highest quality compounded preparations and takes FDA's observations and its professional responsibilities very seriously.

MEDICAP Pharmacy is an Idaho licensed pharmacy, which compounds and dispenses in compliance with Idaho law, USP Chapter 795 and USP Chapter 797. and in compliance with Section 503A of the Federal *Food, Drug, and Cosmetic Act* ("Section 503A"). As indicated during inspection, MEDICAP Pharmacy provides compounded preparations for only individually identified patients.

MEDICAP Pharmacy is a Section 503A compounding pharmacy. Therefore, we would like to note, that many of the observations included within the Form 483 are based on current good manufacturing practices ("cGMPs"). Section 503A specifically exempts pharmacies from complying with Section 501(a)(2)(B) of the Federal *Food Drug and Cosmetic Act* ("FDCA"), which requires compliance with cGMPs. Therefore, MEDICAP Pharmacy is not required to meet the cGMPs that are cited within the Form 483. FDA further recognized this to be correct within the most recently released inspections notice.[1] As such, MEDICAP Pharmacy objects to any observation in the Form 483, which inappropriately applies cGMP standards. While MEDICAP Pharmacy is addressing all of FDA's inspectional findings, its cooperation with FDA should not be interpreted as MEDICAP Pharmacy's agreement that it is required to comply with cGMP, thereby leaving MEDICAP Pharmacy exposed to repeat citations for failing to confirm with cGMP.

As demonstrated in the following responses, MEDICAP Pharmacy is thoroughly addressing each of the observations presented in the Form 483. In this same vein, MEDICAP Pharmacy is evaluating its overall policies and procedures and will revise them as deemed necessary, to ensure compliance with FDA's expectations, in conjunction with those of the Idaho Board of Pharmacy.

We appreciate the opportunity to address the observations set form in the Form 483 and if FDA has any questions regarding our responses or would like to discuss these responses further, we welcome a meeting with the District Office to continue this dialogue to resolve any outstanding issues regarding the observations noted in the Form 483.

---

[1] See http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM510684.pdf

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

This letter is in response to Observations from Form FDA 483 FEI Number 3012086997 issued to MEDICAP Pharmacy.

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

MEDICAP PHARMACY'S RESPONSES TO FDA'S INSPECTION OBERSERVATIONS

FDA Observation 1:

Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically, you did not produce sterile drugs under ISO 5 conditions. All manipulations performed in the production of drug products, listed below which are required to be sterile are conducted in an unclassified enclosure, AirClean Systems PowderSafe 700 series Ductless Balance Enclosure located in an ISO 8 production laboratory. The interior top underside of this enclosure contained residue build-up and yellow stains. There are no controls to prevent microbial contamination, bacterial endotoxin and unintended chemical and physician contaminants for producing sterile drug products.

- *Acetylcysteine Ophthalmic 10% Solution*
- *Gentamicin Irrigation Solution 80 MG/60 ML solution*

Medicap Pharmacy's Response to Observation 1:

Medicap Pharmacy is a 503A pharmacy that compounds non-sterile compounded medications solely pursuant to a prescription from a licensed prescriber for an identified individual patient. As such, Medicap Pharmacy does not compound any sterile compounded preparations and does not compound pursuant to physician's orders for administration within the physician's office to a patient (often termed "office-use").

Before describing how we have addressed this observation. We want to take this opportunity to provide more clarity about this observation. MEDICAP Pharmacy has not compounded sterile preparations since last November 2015. After a thorough analysis that started in September 2015, MEDICAP Pharmacy made a decision to cease all sterile compounding and did cease all sterile compounding in November 2015. Following the decision to cease all sterile compounding, MEDICAP Pharmacy started notifying all patients of the decision to cease all sterile compounding. While the decision to cease all sterile compounding was made in September 2015, MEDICAP Pharmacy was responsible for providing a limited number of patients with their sterile compounded medications to preserve the patients' access to these vital medications until patients were able to find another method of receiving their medications. Even during this time, MEDICAP Pharmacy only provided sterile compounded medications to individual patients pursuant to a physician's prescription. We thought the last sterile compounding prescription was filled on November 17, 2015 as a veterinary prescription for a pet. The observation lists only 2 low risk sterile compounds provided to individual patients, in order to preserve patient access, which represents a very low quantity of the overall total of compounded prescriptions.

In order to address this observation, MEDICAP Pharmacy has sold the clean room and sterile hood and has removed any items needed to sterile compound, as witnessed by the FDA investigators. Furthermore, MEDICAP Pharmacy has deactivated the two low risk drug formulations to ensure that MEDICAP Pharmacy no longer will be compounding any sterile preparations. MEDICAP Pharmacy has re-educated the staff that not even low risk sterile compounds should be done and we will continue to be diligent to not accept any prescriptions that are or may be considered sterile compounds.

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

MEDICAP Pharmacy made the FDA inspectors aware of these facts during the inspection that generated the July 15, 2016 Form 483.

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

FDA Observation 2A:

There is no written testing program designed to assess the stability characteristics of drug products.

Specifically, there is no stability data to demonstrate that it was suitable to use expired Active Pharmaceutical Ingredients (APIs) and components in the production of drug products. In addition, drug products with expired APIs and components were assigned Beyond Use Date (BUDs) and/or Discard After dates exceeding that of the expired component in a compound.

MEDICAP Pharmacy's Response to Observation 2A:

MEDICAP Pharmacy is a Section 503A compounding pharmacy that strictly adheres and is in compliance with Section 503A, all Idaho regulations and laws, and USP Chapter 795. The FDA inspector also determined during their preliminary determination that MEDICAP Pharmacy is acting as a Section 503A pharmacy and not a drug manufacturer of 503B outsourcing facility. As a 503A pharmacy that only prepares non-sterile compounded medications, MEDICAP Pharmacy strictly complies with USP 795. Based on USP 795 standards, MEDICAP Pharmacy does not agree that its system for monitoring environmental conditions is deficient or poses any risk of harm to patients. MEDICAP Pharmacy operates in compliance with USP 795 and tests its systems, processes, and equipment regularly in accordance with USP 795 standards.

MEDICAP Pharmacy did not use expired APIs or components in any of the products that were compounded and noted in Observation 2A. Furthermore, MEDICAP Pharmacy does not have any expired APIs or compounding components. The Consumer Safety Officers found no outdated product in the MEDICAP Pharmacy. Therefore, the components in the compounds were not expired and to the contrary in complete compliance with the designated BUD dates.

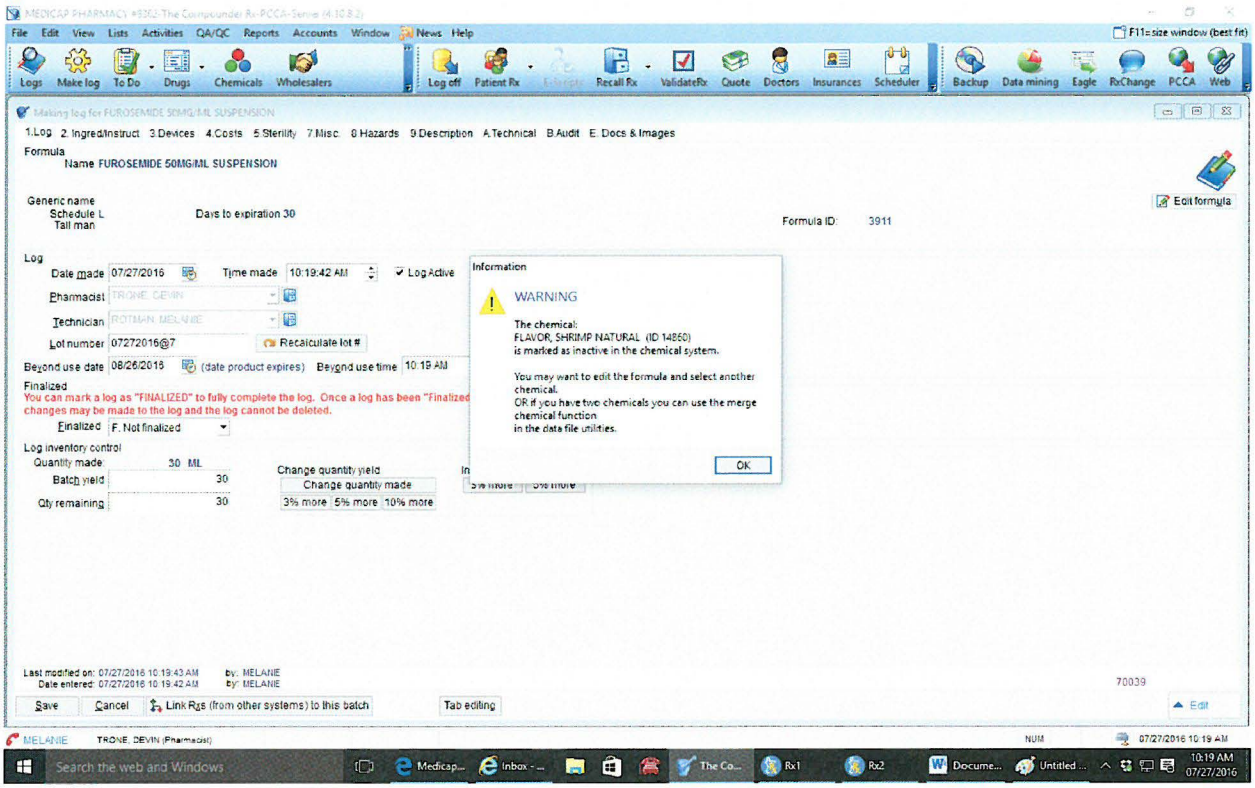
In order to address Observation 2A, a thorough investigation was conducted. MEDICAP Pharmacy found that the compounding software utilized by MEDICAP Pharmacy, PK software, did not process the logged compound as MEDICAP Pharmacy had been previously instructed. As such, during the inspection, it appeared as MEDICAP Pharmacy had used expired or outdated product in compounds when MEDICAP Pharmacy is in complete compliance with all BUD requirements.

Through a thorough investigation, MEDICAP Pharmacy has determined that despite the fact that MEDICAP Pharmacy is in complete compliance with all BUD requirements, the compounding software that has been used led to confusion and conclusions to the contrary. A thorough investigation concluded that clerical issues exist with the PK software that is utilized. Following this thorough investigation, MEDICAP Pharmacy has taken many steps to address Observation 2A.

To provide more detailed insight into the Observation 2A, below is a more thorough account of what was discovered during the investigation and how MEDICAP Pharmacy has diligently addressed each finding.

When MEDICAP Pharmacy logs a compound to be made in the lab, the PK compounding Software automatically uploads ingredients into the log and arbitrarily selects ingredients, even if the amount on hand is negative and the product is expired, in order to use the older and smaller amounts on hand in inventory to help rotate inventory. Therefore, the ingredients that load, may not be the ingredients actually on hand. As the ingredients upload into the formula log, it checks lot expiration. If an ingredient is expired or about to expire, a warning will pop up in a box as shown below:

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com



It was previously MEDICAP Pharmacy's understanding that when the lab tech scanned the ingredient bottle to be used in the compound, it would update the log to that product, lot, and expiration. However, a thorough investigation has provided that instead of updating this information in the software program, it only confirmed that the correct product was being utilized.

Specifically, MEDICAP Pharmacy took the following steps during this investigation. MEDICAP Pharmacy contacted PK software to research this issue and learned that the positive scan would indicate correct product, but that the system did not automatically update the product in hand with its lot and expiration date. Through this investigation, MEDICAP Pharmacy now knows that MEDICAP Pharmacy must manually go into the log if a warning screen pops up and verify the correct ingredient is being used and verify the expiration of the actual drug product that is on hand.

In addition, MEDICAP Pharmacy spoke diligently with PK Software regarding the fact that ingredients will upload into a log even if the on hand is negative. Therefore, when a stock bottle of compound ingredient has been completely used, MEDICAP Pharmacy now zeros out the on hand amount so that the used ingredient will no longer load and the next stock of ingredient will become the default.

In order to provide more details on the process that MEDICAP Pharmacy has adopted following this investigation, MEDICAP Pharmacy has attached screen shots of the software and outlined the steps of the process in order to avoid the appearance of usage of expired APIs.

Please find those screen shots attached as Attachment 1.

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

MEDICAP Pharmacy has worked diligently to coordinate with the PK software and to train, resolve and understand how it can prevent these clerical software issues from occurring in the future. MEDICAP Pharmacy has addressed and fixed this observation by making certain that compound ingredients will match the correct expiration dates on the paper logs, and therefore, be consistent with the BUD date, and not have product or components appearing to have an expiration sooner than the BUD date.

FDA Observation 2B:

There is no stability data to explain the inconsistency between the BUD affixed to the product and discard date on the Rx label, for several drug products noted.

MEDICAP Pharmacy's Response Observation 2B:

As stated above, this observation is also related to a clerical software issue. MEDICAP Pharmacy uses Pk Software to house formulations and log what needs to be compounded to fill compounded prescriptions medications. MEDICAP Pharmacy then uses the main pharmacy software, Computer Rx, to adjudicate or process all the prescriptions to insurances and to create the main pharmacy label, for regular commercial NDC prescriptions and for compounded prescriptions.

When we first started compounding over 10 years ago, the Computer Rx label had no suggested discard date printed on them, as it was not a requirement to have a discard date printed on an Rx label to dispense. As such, there was no suggested discard date, only our PK Software printed auxiliary label stating the compounded medications lot and BUD/expiration date. It was our, and is our process to always affix the PK software Lot and expiration sticker to the compounded prescription as part of our prescription labeling. Requirements evolved and eventually Computer Rx was upgraded and started printing out discard dates on the prescription labels. These dates default to 6 months or a year depending upon pharmacy preference or state law.

When dispensing a compounded prescription MEDICAP Pharmacy's SOP is to use the PK Software Lot and expiration label as the true lot and expiration. MEDICAP Pharmacy has the ability on a compounded prescription to update Computer Rx with the BUD/expiration date so that the suggested discard date and the PK Software lot and BUD match.

In order to address this Observation, MEDICAP Pharmacy performed a thorough investigation in order to better communicate with patients as to which date should be adhered to. As MEDICAP Pharmacy's top priority is our patients, we want to make certain that we are communicating with patients in the best manner possible and creating no confusion.

As part of our investigation, MEDICAP Pharmacy reviewed the current process with Computer RX and provided additional training to pharmacy staff regarding Computer Rx the BUD date needs to be input so that the Computer Rx suggested discard date matches the PK software lot and expiration date label.

The result is no confusion by the patients on when their compounded prescription should be discarded.

After MEDICAP Pharmacy conducted this thorough investigation into the Observation cited, MEDICAP Pharmacy has now implemented a process that matches the Computer RX suggested discard date with the

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

PK Software Lot and expiration date. This process along with screen shots that detail the process are provided in ATTACHMENT 2.

MEDICAP Pharmacy has worked diligently to investigate, address, and fix this Observation within the Form 483. MEDICAP Pharmacy now has processes in place that adequately addresses and eliminates this Observation.

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

FDA Observation 3:

Control Procedures fail to include adequacy of mixing to assure uniformity and homogeneity.

Specifically, there was no data to support the adequacy of the blending process for encapsulated drugs. Mixing a coloring of Riboflavin USP to the API and excipient in a mortar and pestle to make a DHEA capsule preparation and manually mixing until the coloring appears to have evenly dispersed has no assurance that a homogeneous mixture is achieved. In addition, there is no potency testing on this product. The most recent potency testing on a similar product was done 05/15/2009.

MEDICAP Pharmacy's Response to Observation 3:

As stated previously MEDICAP Pharmacy is a Section 503A compounding pharmacy. As such, MEDICAP Pharmacy is in full compliance with Section 503A as well as all Idaho laws and regulations and USP Chapter 795. Section 503A specifically exempts pharmacies from complying with Section 501(a)(2)(B) of the Federal *Food Drug and Cosmetic Act* ("FDCA"), which requires compliance with current good manufacturing practices ("cGMP"). 21 U.S.C. 353a(a)(1)-(2). Therefore, MEDICAP Pharmacy is not required to meet cGMPs. FDA further recognized this within the most recently released inspections notice. [2] As such, MEDICAP Pharmacy objects to any observation in the Form 483, which inappropriately applies cGMP standards.

USP instructs to use a coloring when triturating and mixing and compounding powders until the powders are homogenous. There is nothing within USP 795 or 797 that states testing is required or necessary when fulfilling a prescriber's prescription for *a single patient* that requires compounding. In fact, even for sterile compounding, USP 797 requires testing only in groups of more than 25 identical single-dose packages or in multi-dose vials for administration to multiple patients. As such, MEDICAP Pharmacy's compounding procedures for individual identified patients do not trigger the USP requirements for testing.

MEDICAP Pharmacy nonetheless follows procedures and protocols and has positive data showing that the adequacy of the formula. In order to address this Observation within the Form 483, MEDICAP Pharmacy, has sampled its most recent order for DHEA 6 mg DR capsule and found the results to be fully in compliance. In addition, while MEDICAP Pharmacy is not required to meet cGMP standards, in order to work effectively with the FDA, MEDICAP Pharmacy will implement a regular testing program to test for potency, purity, etc. to demonstrate that processes and formulations are fully in compliance. In addition, MEDICAP Pharmacy has created a new Standard Operating Procedure (SOP) to conduct testing of compounded products.

The test results for the DHEA 6 mg DR capsule that demonstrate the formula's adequacy is attached as ATTACHMENT 3.

While MEDICAP Pharmacy is a Section 503A pharmacy and does not have to comply with cGMPs including testing procedures, MEDICAP Pharmacy has nonetheless worked diligently to address this

---

[2] See http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/PharmacyCompounding/UCM510684.pdf

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

Observation, conducted further testing that demonstrates full compliance of all applicable laws and regulations, and adopted additional testing processes within MEDICAP Pharmacy's SOPs.

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

FDA Observation 4:

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

Specifically, analytical testing, including potency testing was not performed on the baclofen suspension in the Medwatch report 11801434 or any baclofen containing products. Analytical testing has never been done to determine finished product potency for several products, including the top three non-sterile drug products produced from 03/01/2016 to 06/25/2016. Progesterone E4M 100mg, Progesterone 200mg/gm Versabase, Estriol 2mg/gm Versabase.

MEDICAP Pharmacy's Response to Observation 4:

As stated previously, MEDICAP Pharmacy is a Section 503A compounding pharmacy. As such, MEDICAP Pharmacy operates in full compliance with Section 503A, all Idaho laws and regulations, and USP Chapter 795. MEDICAP Pharmacy is not manufacturing, but only compounding non-sterile medications for individual prescription as a 503A pharmacy based upon USP 795 standards.

The Observation that is cited as Observation 4 is based upon cGMPs, 21 CFR Section 211.165(a), which specifically states that "there shall be appropriate laboratory determination of satisfactory conformation to final specifications for the drug product, including the identity and strength of each active ingredient...." As such, Observation 4 is based upon the wrong quality standard as MEDICAP Pharmacy is a Section 503A compounding pharmacy and as such operates in full compliance with Section 503A and all applicable Idaho state laws and regulations.

MEDICAP Pharmacy purchases all products from FDA approved wholesalers whom provide analytical Certificate of Analysis (C of A). MEDICAP Pharmacy respectfully submits that its current process of verifying that it receives valid certificates of analysis is compliant with the relevant provisions of Section 503A as well as all applicable state regulations. MEDICAP Pharmacy is not aware of any Federal or state law or any FDA guidance that requires a pharmacy compliant with Section 503A to perform laboratory testing of incoming Active Pharmaceutical Ingredients (APIs) to verify that it is receiving valid C of A. MEDICAP Pharmacy's current process for qualifying API suppliers and verifying the validity of a C of A is consistent with both requirements in Section 503A that it obtain a valid C of A for its APIs and the Idaho Board of Pharmacy requirements.

While MEDICAP Pharmacy is a Section 503A compounding pharmacy and as such operates in full compliance with all State and regulatory laws including USP 795, in order to work cooperatively with FDA, MEDICAP Pharmacy will implement a regular testing program to test for potency and purity as detailed under MEDICAP Pharmacy's response to Observation 3. This testing will demonstrate that MEDICAP Pharmacy's our processes and formulations are in full compliance. As stated above, MEDICAP Pharmacy has now developed SOPs that detail a regular testing process.

While MEDICAP Pharmacy is a Section 503A pharmacy and does not have to comply with cGMPs including testing all APIs purchases from FDA wholesalers and performing additional steps in verifying the validity of C of A's, MEDICAP Pharmacy has nonetheless worked diligently to address this Observation, conducted further testing that demonstrates full compliance of all applicable laws and regulations, and adopted additional testing processes within MEDICAP Pharmacy's SOPs.

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

FDA Observation 5:

Written records were not made of the investigation into unexplained discrepancies and the failure of a batch or any of its components to meet specifications. Specifically, failed to adequately conduct and document investigations regarding the use of API baclofen in the production of prescription drug products which had been recalled by two suppliers.

5(A) - Attix Pharmaceutical API Baclofen USP, Lot 131009, product was pulled and destroyed, but did not document quantity on hand and date destroyed. Did not conduct an investigation as to what prescription drug products were produced from the API to discuss with physician or patient risks.

5(B) - Medisca Warning letter API Baclofen USP lot 12584/C. This lot was used to manufacture the baclofen suspension identified in the Medwatch Report 11801434, and did not document their investigation into this product for super potency. Did not document investigation of any other batches using the recalled baclofen.

MEDICAP Pharmacy's Response to Observation 5:

Before describing the actions to be taken to address this observation, MEDICAP Pharmacy would like to provide a more detailed insight into the observation itself regarding the Baclofen prescription in the Medwatch report 11801434, and the 2 recalls surrounding the baclofen used in compounding. This information is needed to gain a more accurate understanding of the situation.

Regarding the Medwatch Report, in order to preserve patient confidentiality, a detailed analysis of the actions taken by MEDICAP Pharmacy and the steps that led to the Medwatch Report are included in ATTACHMENT 4.

As detailed in ATTACHMENT 4, MEDICAP Pharmacy diligently took all steps required and performed above the steps required in order to communicate with the patient, the physician, and to solve all outstanding issues. MEDICAP Pharmacy's top priority is patient safety and strictly adheres to all protocols for addressing any outstanding concerns.

Regarding FDA's observation that "[w]ritten records were not made of the investigation into unexplained discrepancies and the failure of a batch or any of its components to meet specifications. As noted by the Pharmacist's statement in ATTACHMENT 4, MEDICAP Pharmacy conducted a thorough investigation of the complaint. It was determined that the formulation was compounded perfectly and was created correctly as per the electronic log sheet in the PK software. The Certificates of Analysis also indicated that the product sent to us by our FDA approved suppliers were also up to specifications. MEDICAP Pharmacy took even additional steps to reach the patient, physician, and to seek testing on the compounded medications.

It has been confirmed that all records were electronic or Certificates of Analysis were on file and that we were not at fault for said adverse drug effects. Therefore, it was not felt that a quality related event report was needed.

Despite MEDICAP Pharmacy having no further required duty, MEDICAP Pharmacy took even additional steps in order to address patient safety and held training meetings to educate staff how and when a quality

related event needs to be conducted. The training sessions occurred on 07/28/2016. All staff received additional training and education that a QRE Report needs to be filled out regardless of whether MEDICAP Pharmacy is at fault.

MEDICAP Pharmacy's top priority is patient safety. While MEDICAP Pharmacy took an abundance of steps to address this issue going above the required process in reaching out to the patient and physician on multiple attempts in order to take all effort to preserve patient safety, MEDICAP Pharmacy will be taking additional steps in the future to address this observation.

Although there was an investigation completed, the documentation was left in electronic form and a QRE report was not filled out. MEDICAP Pharmacy has now conducted training and explanation as to what is expected in the future if there is a Med error or complaint. Our goal is now when in doubt, fill one out. A Quality Related Event Report (QRE report).

As ATTACHMENT 4 demonstrates, MEDICAP Pharmacy compounded the drug product perfectly in full compliance with all laws and regulations. While the Medwatch report lacked merit, MEDICAP Pharmacy diligently investigated the matter, attempted many times to communicate with the prescribing physician and patient, and took all steps to address any concerns. Thus, MEDICAP Pharmacy has addressed and placed procedures in place to solve Observation 5.

MEDICAP Pharmacy's Response to Observation 5A:

Regarding the Attix Pharmaceuticals API Baclofen recall, the following is the account of the recall of the baclofen from Attix Pharmaceutical.

Patient safety is MEDICAP Pharmacy's top priority and in review of the Attix recall that we received, MEDICAP Pharmacy took all necessary procedures and steps to preserve patient safety. The recall letter received from Attix was an abnormal recall letter compared to industry standard. The recall notice was faxed, contained both typed and handwritten information, and included an exclusions list of product instead of the industry standard recall list that pharmacies generally receive. I, personally, have never seen a recall letter with exclusions versus what was actually being recalled, especially with a hand written note on a typed page.

A MEDICAP Pharmacy pharmacist received the recall letter. Nothing on the front of the letter stated that the recall included a list of items excluded. Therefore, the pharmacist looked at the list and compared it to our stock for items to be removed assuming that the list was of items to be recalled. MEDICAP Pharmacy did not possess any products on the list.

Shortly thereafter, the same pharmacist was informed that the Attix recall was actually issued in an abnormal fashion and included an exclusion list. Immediately following this notification, MEDICAP Pharmacy pulled the Baclofen that was on the shelf and put it in the return destruction box for the next time Guaranteed Returns reverse distributed came to receive our outdates and other items needing to be destroyed. MEDICAP Pharmacy contacted Guaranteed returns to schedule a pick up and confirmed an itemized return. However, Guaranteed returns confirmed that it only itemizes returnable products and that bulk compounded powders and returned expired compounds are not itemized. Instead, these products are destroyed.

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

To take additional action to prevent this type of confusion from occurring in the future, MEDICAP Pharmacy called Attix to discuss the recall and how the recall letter was misleading and abnormal for the industry due to the fact that the recall listed exclusions versus what was actually being recalled. The company's customer service representative confirmed the recall and stated that it was a voluntary recall due to the concern that there "may have been" cross contamination, and that it was not a class 1 or 2 recall. The customer service representative further confirmed that there have not been any reports of beta lactam or penicillin reactions reported to them or the FDA and thus no patient harm.

Patient safety is MEDICAP Pharmacy's top priority. Therefore, after receiving this confirmation via call with a customer service representative, MEDICAP Pharmacy sought further confirmation of patient safety via a letter by Attix. As you can see from the attached letter sent by Attix, no patients suffered any adverse reactions and no reactions were ever reported regarding the potential cross contamination by Attix.

In addition, below are copies of the confusing Attix Recall Insert (Note that the information hand written that the recall was an exclusion list was not seen until page 3). The customer service representative confirmed that the recall was not a Class 1 or 2 Recall, but rather a voluntary recall and only due to potential.

Even though the recall was obtained from the wholesaler in a very odd format that is not standard for the industry, as soon as MEDICAP Pharmacy was alerted that the recall was actually an exclusion list and not a recall list, MEDICAP Pharmacy took every measure at its disposal to pull the product in question and destroy it. After multiple steps to confirm that the recall was in fact a voluntary recall and was not an FDA class 1 or class 2 recall, MEDICAP Pharmacy diligently took all necessary steps to dispose of the product in question.

MEDICAP Pharmacy disagrees with FDA's assertion that MEDICAP Pharmacy bore a burden to notify patients or physicians. FDA is siting requirements on manufacturers and wholesalers. As a 503A pharmacy, MEDICAP Pharmacy is exempt from manufacturing processes including recalls. PCAB and other accrediting bodies have processes and protocols for recalls that compounding pharmacies follow. MEDICAP Pharmacy not only took all reasonable steps to address this recall, but due to MEDICAP Pharmacy's priority in preserving patient safety, MEDICAP Pharmacy diligently sought confirmation that no patients suffered harm and that all duties were met.

Furthermore, there is clear documentation that MEDICAP Pharmacy received that no patients suffered harm. Thus, in this situation where it is a voluntary recall and not classified as Class 1 and Class 2, the wholesaler or manufacturer does not even bear a duty to notify the patient or the physician.

As such, MEDICAP Pharmacy bore no duty to notify patients or physicians as Observation 5 states. Instead, MEDICAP Pharmacy bore a duty to pull the product from the pharmacy's shelf and destroy it. Steps were taken to not only meet this burden but to also follow-up with the wholesaler to make certain no patients suffered harm.

Regarding the destruction documentation goes on the baclofen. It was the understanding that my reverse distributor, Guaranteed Returns was itemizing bottles of bulk compound ingredient that were sent for destruction. MEDICAP pharmacy has now learned that that they only itemize product that has a dollar amount returnable to manufacturers, everything else gets destroyed with no itemization. MEDICAP Pharmacy has talked to two other reverse distributors and received the same answer. As such, none of the

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

reverse distributors interviewed by MEDICAP Pharmacy itemizes compounded bulk powders. To the contrary, they destroy them. In talking with them we have learned that if we want itemization and amounts of bulk compounding powders notated, then we will have to be the ones to document it. Then they will put that information with the rest of their documentation.

As such, MEDICAP Pharmacy has now adopted procedures to itemize compounding bulk powder ingredients, then have their representative acknowledge that they received them for destruction.

14: 48
Attix Pharmaceuticals SOP-14ö29 Version 02

URGENT PRODUCT RECALL

Trone Health Services Inc.
2790 W. Cherry Ln
Merdian. 10 83642 USA
Dear Customer:

This is to inform you of a product recall involving:

ALL LOTS OF PRE-PACKAGED PRODUCTS DISTRIBUTED BY ATTIX PHARMACEUTICALS

The recall of products due to the potential that they might have been exposed to penicillin product have been extended to include all products, with the exception of penicillin related products repackaged at the Attix Pharmaceuticals facility since January 05 2012, All lot numbers are included in this recall. The majority of patients with known penicillin allergies, consumption are application of a product that may contain penicillin may experience limited or reversible adverse health consequences such as itching, rash, headache, and hives. Rarely generalized hypersensitivity may occur requiring medical intervention and be potentially life-threatening.
Products in their original manufacturers packaging are excluded from this recall. These products are in the packaging format of 5 kg of larger in bageldrurn$ and sealed aluminum bags in the packaging format of 100 g or larger. For additional products in their original manufactured packaging please see Attachment #1, We began shipping these products on January 05, 2012.

Immediately examine your inventory and quarantine product subject to recall. In addition, if you have further distributed these products or have made finished products using the recalled product(S), please conduct a recall of these products from your customers. Your notification to your customers may be enhanced by including a copy of this recall letter.
Reason for Recall:
P0$lUiljgygfgugaurg_to beta-lactam
You are requested to destroy or return ail remaining inventory of the above bulk products to: Attix Pharmaceuticals 184 Front Street East, Unit 301,Toronto, ON MSA 4N3 Canada

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

Tel: (416) 594-1881, Fax: (416) 548-4232. Email: inna@attixpharmaceuticals.com .

This recall is being made with the knowledge of the U.S. Food and Drug Administration.

QA Signature: _____ Date: May03/2015

Tel: (4d6) 594-1331 , Fax: (416) 543.4232. Email:

Customer Acknowledgement:
I received this notification on (dd/mm/yyyy): 3/25/17

List of products in stock.

Product	L#	Quantity in Stock	To be returned	To be destroyed
	NONE			

1 of 2

Please complete the part below and the next page and the completed form (or scan and e-mail the completed form) as indicated above,
I received this notification on (dd/mm/yyyy):
List of products in Stock.

lof2
14:48

Attix Pharmaceuticals
List of products in stock,

SOP-14029 Version 02

Devin R Trone, PharmD
Medicap Pharmacy
2790 W Cherry Ln Ste 100
208-288-1496
devin.trone@gmail.com

EXCLUSION LIST.

Product	L#	Quantity in Stock	To be returned	To be destroyed

Title: Tech

ure: [illegible] Date: 3/25/17

Name:
Signature:
14: 48

Attix Pharmaceuticals

Attachment #1	
	Isosorhidé Ojnltrete 100B Base Lot *214083ßA '99tretlnoln

5-Aminofg-vullnle Acld HGI 'ioøg begs Lot B-AminoIevuiinie Acid 10g bags Lot#:14111t	Ittaconazolä IOOg begs Lot#:1403255 Ivermectih Ikg 1kg bags bags
6-FluorourteIi Ikg bege ACTH 1-24 (TetracuectldaAcetate), Actlnomycin D lg Viat9	Ketoconazole 1k1 kg baga Lot #140927 LtupvoeelIn/Leupro'idö Acetate
Ad.mattonxlne 1.4•suWnedIaulfonate 5kg bag* Lot#:140829B	Magnesium Stearate •tkg bass Lot #:140814
Adenosine5'-Mønopttosphate DfE0dium sate •10kg Lot #141027	Made tomid ino ie HCl 25g Bags Lot #:140426A 00g bags Lot #:140313B
Adenosine 3'-Monopnqsph8te (Free ACW) begs	Melphalan 1009 bags Lot
Adrenel Cortex EXtreot Ikg ba[95]gs Amlkecln Sulfa" 5kgmn	Memantine Hydrochloride bag* Lot N:140S06A Methotrexate 100g Lot *141014
Amnoride HCI 25g bags Lot *141120B Amitrez 5kg bags	Metroaidazole 25kg bags Metrontaaæele Benzoate 25kg base
AmitriptYIine 'kg bB9E Lot "140922	Milbemycln Oxlme sog baas
AmoxicillinlCtavu!anatB Potassium 5kg bags f AhdNgraphi8 PaniGülata begs	Milk Thistlé Plant Extract Ikg MittefQ*tne 2Sg Bass 'Ot #140601A
Atipamezole HCl 50g Bags Lot #:141104 Sulfate Monohydrate Ikg Tins Lot*140801B Azitm•omyctn Oihydrate "kg Bags Lot #141121 140706B, •Id0706D	MInoeyellne HOI Ikg bags Lot #h44025A Minoxidil 5kg bags Minoxidil 1kg Bags Lot #:140902A Mirtazapine Hemihydrate 1kg bags Lot #:141212D
Benazepri' HOI IOOg Lot Benznidü419 IOOg begs #541178	MIgopr0EtoI 1% 5004 Lot *140B08A 1220 Mompesonä Furoate 4ÖOg begs Lot #141220
BetahiEtine Dihydroghloride 1009 LOt#'.1d4220B Sodium PhuphBtA IODg bags Bimato•j'å$t 'Ig	Möxidectin 2[5kg bags] 5kg Moxifloxacin HCl 1kg bags Lot #:140907A Mupirocin 100g Bags Lot #:140308A
Bleomytitl Sulf8te	Myco tate Mofetlt 'kg begs Lot nosR roph0HphBte OTTP) IOOg sage
euplvacelne HGI bag* Låt 14G9DB	yo•M0$I ephate (ITTP) Hexasodlum SBft IOOg bl Trispyropli Bags Lot *15010"
suproplon HGI Ike bage Butephosphan 25k$ bagg Ca!eltriol	N"Ace 'arni e 25kg%a s tyi.L. htonl 5kj bags Nieardlplne .14102ZA Hell
ICalc!um Levulinaté bage Gantharidln Bags Lot #131025A Gapecltablne •IOOg begs Lot	Nitrowranteln50 150111 Octecitinib 1009 Olealezine SadiUE-n 1004
Garbi,,tazete begs *150102 25g Bxgs Lot	Orneprazole 5kø bags Oxytetracycline HOI 500g
carprefen Ikg begs Lot 100g Bags Lot	Oxytacin Acetate IS VialS pantoprazole Sodium Monohydrate 9kg bags Lot
Cefix(me 2kg bags Gafixime 500* Lot Gepha{eXin Monohydrate Skg bagE	Paraxetino Ikg bags 500B Bags Lot pontoean Polysulfate Sodium 1k9 bags Phen.xy»enzamlna 'kg Lot

IChlQrembucil 'tog, 100* bag' Chtoramphenlaoi 2Skg bass Ghiorampnenlcoi Palmitate 5kø baga Chloroxylenol 5kg begs	Phentolamine Me$YIate Ikg bags Phenylbuæzone 2SkgIdrum Ptoglltazone HOI Ikg bags Lot Pltchar plant extract '1k9 baas Lot
Choline Chloride bags Chondrgi*in SUIF*tQ Sodium 'kg Bags Lot Chlorlde Hexahydrate 1004 bags Lot Chromtum Picollnatø 1Kg bags #2141212A CfdeféVit' At-myaroue 50g bags	Ponazurit 25kg bags Polymyxtn Sutfßte potaæ(um Bltartnte 10kg bags HCI Ike bags Lot
Cidofovir DihYdt•ate 50S Cisspride Monohydrate 10kg bags Cßsprlde Monohydrate 5004 Bags #140S20B	{kg bege Lot *140923A Procälhå NCI äkg Procamazjne HGI 1.5kg bags

* products on this list do not need to be recalled.
(please note of the lot # & quantity)

14: 48

Attix Pharmaceuticals

Attachment #1

Cisplettn bagg Lot ilOA Citatoprem Hydrobrotiide 5000 bage Lot #140926A Chtoride 2.5kø coléhlcinø	Procarbaztne HCI 500g, 100g, Lot e;1408UA ProtirøliO Acetate via19 Pyrazinmtde 5kg bagg Pyrld06tigmtne Bromidé '1 kg bngE
Comfrey Extract IOkg bage Cß$povidono 'tkg BagE Lot Gyanocokatamln SOOg Atumlnum Tih$ Lot Cyc10Fhogphamid* Monohydrate 5600 cyclosporine A 5kg Tins D.Catcium Pähtethenate Ikg begn Lot	Ranltldinø HGI Lot 144018 P•Hydroxybonxyl AcetonB (Raspberry Køtone tkg Lot *141i2GA Resveratrol Ikg Ribarivin IKg bagg Lot *140611A Rifaximrn {kg Rivaroxaban 100g bagg Lot #2140708A
DantC91ene Södlum $kg bags Daptomyetn 40g #2141104A Dagatinib Monohydrate 50g beg6 Lot *141020A	Ropivacäih9 HOI 'kg Bags Lot 8:140723A _____ 5004 Bagg Lot ___ Secnldazote 5kg bags #2140M5A
Demecarium Bromidø 5fJG Baga Lot Desloreliti Acetate lg Vidl$ Desmopreggin Acetate 5mg Or 19 Viat Di-B.propylarnlne DIchloroatåt9te äkg bagg	6ermørelin Acetate via}$ 6ertralirtB HGI {OOg bags Lot #441116, '141'M6A ildonafil Citrate 5kg bag$ Silicon oxidB 325 5kg snyb

Oi•$ådium sucelnate G-Hydrate Gkg 4412ZOA	
Dietgzuril 5kg bags DiCMenac Sodium 2$kg bags Diphenyeyclopropønono iOg bags 14<005B	Sineallde 'ig viat$ gBa LOt#: 0221B Sodium Lot 4A $o uÆ Tøtr Sulfate 50"
DIEu1firam 5kg 141218A	
DMP$ 141222 er OMSA1412<2 Ikg Doxycycune Hyclate 25kg bsgs	gutph Sk Sulfanilamide IkgB '441102, 1411ö2A
ACId 5D0g bag$ Enroaexacln Base 'kg bage Enronoxacin HOI 5kg bsgs	Gumetriptan aucclnet 1 kg9 Tacrolimue Monohydrate 50A Tadalafit IRg bagg
59 Lot Escitatopram OXB1ato 509 Lot Eetrediol Benzoate Lot Bagg Lot	Tetra-sub$tltuted GRF 1-29 ig Vla1E DihydwchloridÄ log Bagg Lot #140910B Thymosin Beta 4 V*819 Tlaprontn fkg baBE
Ezetimlbe IDOg büä$ Lot Famcjeiovirlkg bagg Lot #140817	Tocoranib PhasphBto Toltrazurit 5kg bags
Fenbendazo'g 25kg bags Fiumazenif 50g baga Meglumfnø Z5Kg baga	460g Tretltlåln (All-trans Réttnølc Acld) 100#agg Lot TYltalne Mosylato Ikg, 300g bags Lot
Flurbipro@n 5kg baøs Fomepizot9	Trlfluridine 503 bag* TrilO$tane Ikg bags
FLtvegemlde 500g bagg Lot	Tripetonnamlne HCI Ikg bags Lot #141212B
Gabapontin5kg t-øt "114D502A,A, 140806A	rnpelennamihé HOI Ikg bags Lot Lot #:150114 #150114
eatWloxacin So$quthydrnte 100g bagg Lot Gantamycln Sulfate 5kg/6kg 9.Skg Tins GHRP-2Aaetata or GHRPÆ Acetate lg Gtyeyrhlzlc Acid A sogg Bngs Lot #141046 Green Coffeø Bean Extract Ike Bage 4MU/5MU HIEtrolin Acetate lg Via15 HYOluronIdase IM" viels	Tylosin Tartrate 5kg bags Ubiquinol 1kg bags Ursodeoxycholic Acid (Ursodiol) 1kg bags Lot #:1410100, 141017 Valacyclovir HCl 1kg bags Lot #:140719 Vardenafil HCl Trihydrate 1kg bags
HyaturonEa Acid sodlum Hydroqujnone Lot Ikg bags #21407043	
Imlquimott ø ogbagg Lot #1407230 Ipamorelin Acetate 1g vials	

The following is the Attix follow up letter stating that there are have been no issues or adverse events from the recalls.


Attix Pharmaceuticals

STATEMENT

(Regarding Recall 2015)

As per GMP regulations, beta-lactam products can only be repacked in a dedicated facility. Attix was not aware of this requirement although we did have complete cleaning procedures for each clean room. When we realized this, we decided to conduct the voluntary recall under FDA's guidance and instruction due to possibility of beta-lactam cross contamination, not because of any product quality issue. To date, we have not received any adverse report due to possible cross contamination.

We have implemented a more stringent quality control system to ensure products we distribute meet our North American Standards, and completed regulatory processes with both Health Canada and FDA. We have obtained our Drug Establishment License recently implemented by Health Canada which confirms our GMP compliance. US FDA has registered our new facility by issuing Attix a new FEI number.
Attix Quality System monitors each batch being received to ensure product quality as always.

QA & QC in Charge
Attix Pharmaceuticals
March 161 2016
481 University Avenue, Unit 502, Toronto, Ontario M5G 2E9, Canada; Teli (416) 594-1881; Fax: (416) 594 3737 www.attixpharmaceu ticals.com

MEDICAP Pharmacy's Response to Observation 5B:

Due to an abundance of caution for patient safety, regarding the Medisca Baclofen, MEDICAP Pharmacy's treated the warning letter as a recall even though, the letter from the wholesaler, Medisca, stated that it was not a recall. Instead the letter stated that it was only a warning letter and specifically a warning to not use their API in sterile compounded product. The wholesaler, Medisca, stated that the warning was not issued for non-sterile product and MEDICAP Pharmacy took steps to confirm that MEDICAP Pharmacy used the baclofen only for non-sterile product.

As you will see from the below letters, Medisca was able to show that their product was not at fault. They too suspect that high dosing was the most likely reason for the Medwatch report 11801434.

Regarding Observation 5B, about the Medisca Warning letter API Baclofen USP lot 12584/C. This lot was used to manufacture the baclofen suspension identified in the Medwatch Report 11801434, and did not document their investigation into this product for super potency. Did not document investigation of any other batches using the recalled baclofen.

MEDICAP Pharmacy conducted an investigation as noted and documented above. MEDICAP Pharmacy pulled the Medisca API Baclofen Lot 12584/C from our Lab and we did send it to be destroyed by Guaranteed Returns. It is documented within the pharmacy logs that MEDICAP Pharmacy discontinued the use of that lot in all baclofen products coinciding with the recall date.

MEDICAP Pharmacy went further to assess that the issue was not super potency, but rather to high of a prescribed dose. Furthermore, we could not get the product back from the mother to test, even though we did try and request the return of the product.

Medisca confirmed that the recall was not a true recall but a warning letter about using the product in sterile preparations. Medisca indicated that non-sterile preparations were cleared and that is why they did not issue a true recall, but rather a warning letter.

There was nothing in the warning letter about super potency concerns and nowhere does it state that it was a level 1 or 2 recall, indicating that we would need to research end user use. In fact, the letter only states to contact those where the product was used in sterile preparations, not non-sterile preparations. Had the recall been a class 1or 2 recall, or had the recall noted measures to seek out end users for non-sterile compounded product, we would have surely reached out. It does not state anywhere in the documentation that we had a responsibility to reach out to patients. Furthermore, we have included the letter above from Medisca stating that they re-tested the baclofen lot in question and all checked out within specifics. There was no super potency or endotoxin or microorganism issues. Had there been issues with potency or organisms, a class 1 or 2 recall would have occurred and MEDICAP Pharmacy would have taken all necessary steps to meet all requirements under a Class 1 or 2 Recall.

As a 503A pharmacy, MEDICAP Pharmacy is exempt from manufacturing recall processes and does not bear the burden that is stated within Observation 5 where the recall is not a Class 1 or Class 2 recall. As a 503A pharmacy, MEDICAP Pharmacy seeks and acquires Certificates of Analysis and takes all required steps to address all recalls that MEDICAP Pharmacy receives notice.

MEDICAP Pharmacy took steps above its duty as a 503A pharmacy to ensure patient safety and address the warning letter. Upon receipt of the letter MEDICAP Pharmacy's staff immediately pulled the Baclofen Lot off the pharmacy shelf and quarantined it to be shipped out to Guaranteed Returns to be destroyed on the next shipment. As a 503A pharmacy, MEDICAP Pharmacy did not bear a duty to notify

patients or physicians as the recall did not rise to a Class 1 or Class 2 recall and thus even the wholesaler and manufacturer in these cases did not bear the duty that Observations outlines on a 503A pharmacy.

In order to continue to ensure patient safety, MEDICAP Pharmacy continues to take steps to even further educate MEDICAP Pharmacy staff regarding recalls and to document all steps taken during a recall.

12-23-2e15 12 : z 5143321633 Medicap Pharmacy #8362 ID 22-288-1812

Route 3, Unil C, Plattsburgh, New York 12901 USA
Toll Free : 1.800.932.1039 | Fax : 1.855.850.5855
Addf09B 661 Website : www.medisca.com

'MEDISCA

YOUR TRUSTED PARTNER IN COMPOUNDING

December 22, 2015

RE: FDA Warning - Baclofen. USP (0388) Manufactured by Taizhou Xinyou Pharmaceutical & Chemical Co., Ltd

Dear Valued Customers,

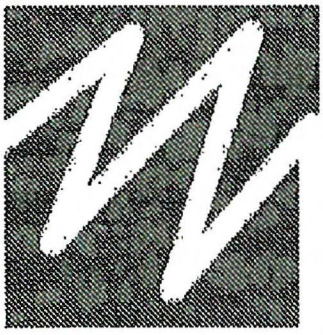
This is further to the FDNs recently-issued warning on the potential contamination of certain lots of Baclofen, USP manufactured by Taizhou Xinyou Pharmaceutical & Chemicai Cor, Ltd., dated 12/9/2015. MEDISCA purchased Baclofen, USP from Taizhou Xinyou Pharmaceutical & Chemical Co., Ltd. among other manufacturers. The following is a list of the MEDISCA lots of Baclofen which were purchased from Taizhou Xinyou Pharmaceutical & Chemical Co., Ltd:

55394 97282 105571 112624 125185 57487 98402107946 11565412974S
5783398403107947119917129746
5783499142 110957 121111 600043 58851 99840 110959 121113 600316 58852 99841 110963 121874 603990 96158 102138 110965 122657 604381 96822 103623 112519 122658 604531
97281 104470 112521 12S184 605

The FDA has indicated that certain lots of Baclofen, USP manufactured by Taizhou Xinyou Pharmaceutical &. Chemical Co., Ltd. may be at risk for contamination with particuEates,, as well possible contamination with endotoxin or microorganisms.

Please note that this notice only applies to the tots indicated above.

Based on the latest available Information received from the FDA, Talzhou Xinvou Pharmaceuticel & Chemical Co., Ltd. and MEDISCRs Interne' testing results. we urge you to follow FDA's recommendation to not manufacture or compound any Inlectable or sterile fln15hed product with Baclofen USP manufactured by Teizhou Kinyou Pharmaceutlul & Chemical Co. Ltd,

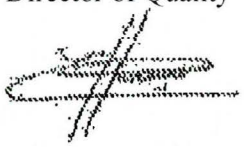


12-23-2015 12 : z 5143381693 Medicap Pharmacy #8362 ID za-Add ('Dt;s : 661 Route l.Jnil. 3, Plattsburgh, New 12901 1.J$A t•oll Free : •1.800.932,T39 ! Fax :1.855.8

ebsite: www.roadiet.q.(:ortl

MEDISCA

Should you have further distributed this API, please provide this notification to your customers that received the affected material. Should you have compounded or manufactured an injectable or a sterile finished product with Baclofen API from Taizhou Xin you Pharmaceutical & Chemical Co., Ltd. in addition to immediate cessation of the API for that use, it is recommended that you immediately contact your local FDA District Office, Health Canada, Therapeutic Goods Administration (TGA) or local health regulatory authorities for guidance.
MEDISCA would like to apologize for any inconvenience this might have caused you and your clients.
If you have any further questions regarding this product or any other products, please contact your sales representative at M EDISCA
Sincerely,
Chadi Harmouche
Director of Quality



End

See

USA

Toll

Insert.

insert below:

Medisca PB Controls01/15/2016 AM -0500
Address : 661 Route 3, Unit C, Plattsburgh, New York 12901

Free : 1.800.932.1039 Fax : i 855.850.5855
Website : www»medisca.com

MEDISCA

YOUR-TRUSTED PARTNER EN
January 15, 2016
Medicap Pharmacy #8362 ID 2790 W Cherry Lane Suite 100
Meridian, D 83642
Re: Inquiry# 1601-0004 on Baclofen, USP— Lot 125184/C
Dear John Amin!}
in response to the adverse drug experience reported for patient "T' (DOB 07/0511998) through the FDA's Drug Quality Reporting System, MEDISCA conducted a full review of the document associated with the receipt, testing release, repackaging, and distribution of this lot. No deviations were noted; lot 125184 passed all applicable inspections and tests upon its initial receipt.
Due to the FDA's MedWatch alert on Baclofen USP posted on 12/09/20#5, MEDISCA fully retested this batch and again it conformed to alt monograph requirements. The FDA's warning related only for sterile

injectable compounds, whereas T received an Oral suspension; thus the adverse experience is not likely related to the MedWatch advisory.

Based on our investigation into this lot, and our interviews with you and with the mother of the patient, it appears more likely that the adverse experience resulted from high dosing than from any quality issue with the raw material provided by MEDESCA.

Thank you for your full and thoughtful cooperation with our investigation. MEDISCA shares your priority of promoting patient safety. Your input and feedback contribute to our continuous improvement strategy. This investigation has been logged in our Quality Management System. which Is routinely reviewed and analyzed for Irends.

Sincerely,

M. Alex Nagy, QS Specialist— Investigations

FDA Observation 6:

It was noted that the particle board surface above our dish washer had weathered due to the steam, heat, and years of service. Some of the surface had weathered away revealing the particle board surface that is porous. The exposed board is not easily cleanable and is porous potentially harboring bacteria.

MEDICAP Pharmacy's Response to Observation 6:

MEDICAP Pharmacy has taken all steps to address and fix Observation 6.

On Wednesday, 07/27/2016, MEDICAP Pharmacy hired a repairman to remove the old particle board cover and replace it with a non-porous surface cover, so it will not weather and flake in the future due to heat and steam.

See Dishwasher pic after fix.