



VIA EMAIL AND FEDERAL EXPRESS

January 11, 2017

Miriam Burbach  
District Director  
Food and Drug Administration  
Washington District Office  
22215 26th Avenue SE, Suite 210  
Bothell, Washington 98021  
Miriam.Burbach@fda.hhs.gov

**Re: First Pharma Associates, LLC, dba Riverpoint Pharmacy: Response to FDA Form 483 Issued December 16, 2016, FEI No. 3007500366/Gerald P. DeLeon, Investigator**

Dear Ms. Burbach,

On behalf of First Pharma Associates, LLC, dba Riverpoint Pharmacy, I authorize the United States Food and Drug Administration (FDA) to publicly disclose the information described in my response letter dated January 9, 2017, 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, 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: Riverpoint Pharmacy's letter dated 01/09/2017, excluding attachments/exhibits, which responds to FDA's Form 483 dated 12/16/2017.

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 of Riverpoint Pharmacy, and my full name, title, address, telephone number, and facsimile number is set out below for verification.

Sincerely,

Catherine Hudek, R.Ph.  
Owner  
528 E. Spokane Falls Blvd., #110  
Spokane, WA, 99202  
Telephone: (509) 343-6252  
Facsimile: (509) 343-6251



January 9, 2017

**VIA EMAIL AND FEDERAL EXPRESS**

Miriam Burbach  
District Director  
Food and Drug Administration  
Washington District Office  
22215 26th Avenue SE, Suite 210  
Bothell, Washington 98021  
Miriam.Burbach@fda.hhs.gov

**Re: First Pharma Associates, LLC, dba Riverpoint Pharmacy: Response to FDA Form 483 Issued December 16, 2016, FEI No. 3007500366/Gerald P. DeLeon, Investigator**

Dear Ms. Burbach:

First Pharma Associates, LLC, dba Riverpoint Pharmacy (“Riverpoint”) submits this written response to the Form 483 Observations dated December 16, 2016, issued by the Federal Food and Drug Administration’s (“FDA”) Washington District Office. FDA issued the Form 483 Observations at the conclusion of an Inspection at Riverpoint, which occurred on December 6-9 and 12-16, 2016. FDA investigators conducted a close-out meeting at the pharmacy, during which FDA issued its Form 483, listing four Observations. Set forth below are Riverpoint’s Responses to FDA’s Observations. If FDA posts the Form 483 Observations on its website, Riverpoint respectfully requests that FDA also post this Response to the same.

**Introduction**

Riverpoint is a small independent, family-owned pharmacy located in the University District of downtown Spokane, Washington. The pharmacy opened its doors in 2003 to meet demand for compounded formulations in the area when the only other local compounding pharmacy moved to Florida. Riverpoint specializes in hormone replacement therapy.<sup>1</sup> Riverpoint services patients in approximately ten states, but the majority of patients are located in Washington and Idaho, since the pharmacy is only 30 minutes from the Idaho border. The pharmacy also performs nonsterile and sterile compounding, which includes compounding hormone replacement therapy formulations for men and women, drugs for erectile dysfunction, intrathecal pain medications, among other formulations. Riverpoint employs ten full-time and

---

<sup>1</sup> One of the pharmacy owners (Cathy Hudek) is a NAMS (North American Menopause Society) Certified Menopause Practitioner, and regularly performs consultations with patients and health care providers concerning hormone replacement and other therapies.

two part-time employees. Riverpoint also has pharmacy interns who rotate through the pharmacy on a regular basis so that they may obtain retail and compounding pharmacy experience as part of their pharmacy education and training from Washington State University.

The pharmacy conducts its compounding operations pursuant to Section 503A of the Federal Food, Drug, and Cosmetic Act (“FDCA”). Riverpoint is committed to fulfilling unmet medical needs of our patients while conforming to Section 503A, federal guidance, and Washington State Board of Pharmacy requirements. Pursuant to Section 503A, the pharmacy compounds formulations only for individually identified patients based on a prescription order received by a prescriber. Importantly, Riverpoint engages in no “office use” compounding. Because the pharmacy acts in accordance with FDCA Section 503A, it is entitled to the exemptions set forth in that statute, including exemptions from new drug approval, adequate directions for use, and FDA’s current good manufacturing practice regulations applicable to drug manufacturers and outsourcing facilities.

Riverpoint understands, based on a Notice from FDA issued in July 2016, and certain communications from FDA’s investigator during the course of the inspection, that FDA would make a “preliminary assessment” at the inspection’s outset addressing whether to conduct the inspection in accordance with FDA’s cGMP or pharmacy standards as determined by state law. Specifically, that Notice states that “FDA investigators will make a preliminary assessment of whether such entities are compounding their human drugs in accordance with certain conditions of section 503A before closing the inspection. If the investigator issues a ‘Form FDA-483’ list of inspectional observations to the firm, the investigator will not include observations that represent deviations solely from FDA’s current good manufacturing practice (cGMP) requirements unless it appears, based on the investigator’s preliminary assessment, that the firm compounds drugs that do not qualify for the exemptions under section 503A.” It is still unclear what determination FDA made with regard to Riverpoint’s Section 503A status, and the investigator did not in fact make or definitively articulate such a “preliminary assessment” at the commencement of the inspection, two weeks after the inspection commenced, or at the conclusion of the inspection, contrary to FDA’s July 2016 Notice quoted above. Riverpoint respectfully asserts that any inspection standard or FDA Observation relying on a standard other than applicable state law and Section 503A is inappropriate.

Set forth below are FDA’s Observations and Riverpoint’s Responses. Please note that this Response does not constitute an admission or agreement concerning any of the Observations.

### **OBSERVATION 1**

**The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.**

**Specifically, on December 6, 2016 the following was observed during sterile drug production:**

**A) The walls inside the Buffer Room, Gowning Room, and Anteroom are composed of a drywall material that has been painted with an epoxy-based paint. A chip exposing the drywall material was**

{00285528}

material that has been painted with an epoxy-based paint. A chip exposing the drywall material was observed on the wall between the door and the metal table in the ISO 7 Buffer Room, where sterile drug processing occurs.

**B) The frame surrounding the metal HEPA filter screen installed in the ceiling of the Buffer Room, Gowning Room, and Anteroom is composed of an apparent wood material that has been painted with an epoxy-based paint.**

**C) The pass-through box installed between the Buffer Room and Anteroom is composed of a white, laminate wood material that is peeling away from the box frame.**

**D) An overhanging light with apparent dust buildup was observed installed above a metal table in the Prep Room where in-process drug components are mixed and heated. The Prep Room contains an ISO 5 biological safety cabinet (BSC) in which sterile drug processing occurs.**

**E) Wheeled stools observed in use in the Buffer Room and Anteroom has a seat composed of an apparent vinyl material, which appears difficult to clean.**

**F) Apparent black residue was observed between the seam of the metal workbench and front vent of the Labconco, Model 36209043726D, S/N 020923809E biological safety cabinet (BSC) located in the Prep Room.**

**G) Apparent orange buildup was observed between the metal frame and window inside the Buffer Room.**

**H) Apparent buildup was observed on a computer keyboard inside the Powder Hood located in the Prep Room where in-process drug components are prepared for sterile drug production. The computer keyboard was observed in use by an operator on December 6, 2016 during the preparation of in-process drug components.**

**I) Apparent black staining was observed on the floor of the Buffer Room and Anteroom.**

#### **RIVERPOINT'S RESPONSE**

A) In accordance with USP<797>, "Walls may be constructed of flexible material (e.g., heavy gauge polymer), panels locked together and sealed, or of epoxy-coated gypsum board." The ISO-classified areas at Riverpoint are constructed and maintained in compliance with USP<797>, which is the guideline applicable to the pharmacy. The small chip (approximately 0.5cm by 0.5cm) that FDA observed has been caulked and painted with epoxy-based paint. Most importantly, this room has never failed a particle count test, which tests have been performed semi-annually since 2004. (See attached photograph.) Furthermore, the pharmacy is engaging in a complete remodel of the room in order to become compliant with newly-adopted USP<800>, and will be installing a modular cleanroom, to be completed by or around July 1,

2018, at the latest.

B) Per USP<797>, “Any other penetrations through the ceiling or walls shall be sealed.” The material surrounding the HEPA filter screens is coated with several layers of epoxy-based paint and is “smooth, impervious, free from cracks and crevices and is non-shedding,” and easily cleanable, as required by USP<797> guidelines (which is applicable to the pharmacy). (See attached photograph.)

C) The very small area of white laminate that was “pulling away” from the frame has been reattached and the edges have been resealed with silicon caulk to eliminate any cracks or crevices. (See attached photograph.)

D) Contrary to the Observation or any other assertion by investigator, the referenced overhanging light is cleaned thoroughly and on a regular basis. There was no “apparent dust” anywhere upon observation, on a ladder, by both the investigator or Riverpoint’s Cathy Hudek. The investigator’s concern as articulated during the inspection specifically was that there “could be” dust on the light, not that there “was” in fact “apparent dust buildup.” The light has been replaced by a single bulb, in any event. (See attached photograph.)

Furthermore, contrary to the investigator’s observation that there is a biological safety cabinet (BSC) in which sterile processing occurs, the BSC in this room is not in fact used for terminal sterilization.

E) Contrary to the investigator’s Observation, the vinyl seat of the wheeled stools was easily and thoroughly cleaned after each use. The seats also showed no signs of wear or tearing. Notwithstanding, the pharmacy has removed the vinyl-covered stools and replaced them with metal stools until a suitable alternative can be found. (See attached photograph.)

F) The dark residue that the investigator observed “between the seam of the metal workbench and the front vent of the hood” was in fact a residue from compounding that had taken place that same day. The residue was easily removed through normal cleaning processes when the workbench was cleaned later that day.

G) The orange “buildup” is residue from the cleaning solution and wipes up easily. Notwithstanding, Riverpoint is in the process of revising its cleaning procedures to include attention to this particular area until the area is repaired/caulked to prevent cleaning solution from collecting in this area. The pharmacy also tested the “buildup” with a contact media paddle and after incubation it had zero growth. (See photograph of the window frame.)

H) The apparent “build-up” on the keyboard was actually a couple of small perforations in the plastic of the keyboard. The keyboard itself did not have any “build up” on it. This keyboard was cleaned and stored away from the compounding area after each day’s use. It has been replaced with a new keyboard and a removable, cleanable plastic cover to protect the plastic from any degradation.

I) The stools that were in the Buffer Room and the Anteroom had black wheels and these wheels were leaving marks on the floor. These stools have been removed as noted in E) above. In addition, pharmacy

{00285528}

personnel spent additional time cleaning the floors to remove the black marks the next time they entered Buffer Room and Anteroom and the stains have been removed. (See photograph.)

## **OBSERVATION 2**

**Sinks or drains are present in the cleanroom where the ISO 5 area is located.**

**Specifically, a hand wash sink in Prep Room was observed installed approximately four feet behind a Powder Hood where in-process drug components are weighed. In addition, a biological safety cabinet (BSC) where sterile drug production occurs and a metal table where in-process drug ingredients are mixed and heated are located in the Prep Room.**

## **RIVERPOINT RESPONSE**

Riverpoint respectfully disagrees with FDA's Observation. First, the sink is not "installed" in the Prep Room. This is a *moveable* sink that is located in the Prep Room to allow for thorough hand washing prior to weighing and mixing drug components as per USP<797> guidelines. Specifically,

*After* donning dedicated shoes or shoe covers, head and facial hair covers, and face masks, a hand cleansing procedure shall be performed by removing debris from underneath fingernails using a nail cleaner ***under running warm water followed by vigorous hand washing.*** Hands and Forearms shall be washed to the elbows for at least 30 seconds with soap (either non-antimicrobial or antimicrobial) and water ***while in the ante-area.***

Thus, USP<797> requires the sink to be placed in the Prep Room which is the ante-area. The sink is three feet away from the powder hood, and the technician stands between the sink and the powder hood so there is no water splashing into that mixing area. Lastly, the BSC that is used in this area is NOT used for terminal sterilization, and is located more than 4 feet away from the sink. Furthermore, the sink *is only used when entering this area* and not during any other time. Thus, the sink is only used before compounding has started and when there are no in-process drug components lying out in the open. All in-process drug components are covered or capped in sterile syringes when on the metal table. Therefore, nothing is, or would be, exposed during hand washing. (See photograph of location of sink in Prep Room with technician.)

## **OBSERVATION 3**

**The ISO 5 area is located within a non-classified room.**

**Specifically, the Prep Room, where the ISO 5 BSC is located, is not supplied by HEPA filtered air. The Prep Room is exposed to the surrounding unclassified Laboratory environment that is supplied with air from a floor vent that is not HEPA filtered.**

## **RIVERPOINT REPOSE**

{00285528}

Riverpoint respectfully disagrees with FDA's characterizations in this Observation. The pharmacy has had its suite of clean rooms tested for particles and viable organisms every 6 months by an independent third party since Riverpoint opened in this location in September 2007. We have passed each of these tests and have had all of the rooms certified after each such assessment. The most recent visit (June 2016) by Technical Safety Services, Inc. (TSS), prior to the FDA inspection, showed that the Prep Room was not tested. This was an oversight by the technician performing the testing; a letter from TSS documents that testing of the Prep Room was included on the work order, but it was not done. Notwithstanding this one-time oversight, the room has never failed to qualify as an ISO 8 room. In addition, Riverpoint had the room tested on December 14<sup>th</sup>, 2016, while the FDA investigator was here, and the enclosed documentation shows that it did pass as an ISO 8 environment.

The air entering the Prep Room comes from a vent in the door leading to/from the Anteroom, which is in fact supplied with HEPA filtered air. The pressure between the rooms is constantly monitored to show that the air is moving out of the Anteroom and into the Prep Room.

As previously stated, the BSC located in the prep area is not used for terminal sterilization and the room has repeatedly and consistently passed testing as an ISO 8 environment. The hood that is used for terminal sterilization is located in the buffer room and passes all guidelines set forth in USP <797> as an ISO class 7 environment. (See attached TSS Reports for December 2016, the letter from TSS regarding their error in testing the "Prep Room," and a diagram of the rooms.)

#### **OBSERVATION 4**

**ISO 5 classified areas were not certified under dynamic conditions.**

**Specifically, an in situ air pattern analysis (smoke study) of the following has not been conducted to demonstrate unidirectional airflow and sweeping action over and away from sterile drug products under dynamic conditions:**

**A) The Isolation Tech CAW4, S/N 05-DF08P01 vertical laminar flow hood (LFH) located in the Buffer Room.**

**B) The Labconco, Model 36209043726D S/N 020923803E BSC located in the Prep Room.**

#### **RIVERPOINT RESPONSE**

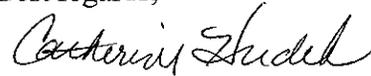
Riverpoint respectfully disagrees with FDA's Observation. The referenced two pieces of equipment are tested under dynamic conditions every time TSS certifies them, as is documented on the certificate that is issued when the testing is completed. **This is also documented on every report that the investigator reviewed during his inspection of the pharmacy.** (See enclosed copies of most recent testing.)

Regarding dynamic conditions: There is never more than one person present in any room during normal sterile compounding operations. The independent testing company has at least one person present (sometimes two) in the room as it is being tested. They also bring more equipment into the room than would be present during compounding. Therefore, testing conditions exceed those of normal compounding.

\*\*\*\*

Riverpoint asserts that since it opened its doors in 2003, it has consistently strived to provide high quality and safe medications to its patients. The Pharmacy has also maintained high practice standards, consistent with applicable state requirements and FDCA Section 503A. Riverpoint looks forward to cooperating with FDA if FDA needs further information or has questions concerning the pharmacy's Response to FDA's Observations.

Best regards,



Catherine M. Hudek, RPh, NCMP  
Director of Pharmacy  
Riverpoint Pharmacy

Attachments