June 30, 2023

Case #: 641286

VIA Electronic Mail
Return Confirmation Requested

Aaron M. Schneider, R.Ph.
Co-Owner/Director of Operations
Revive Rx, LLC, dba Revive Rx Pharmacy
3831 Golf Drive, Suite A
Houston, TX 77018-5218

Dear Mr. Schneider:

From April 12, 2022, to May 4, 2022, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Revive Rx, LLC dba Revive Rx Pharmacy, located at 3831 Golf Drive, Suite A, Houston, TX, 77018. During the inspection, the investigator noted deficiencies in your practices for producing drug products intended or expected to be sterile, which put patients at risk.

FDA issued a Form FDA 483 to your firm on May 4, 2022. FDA acknowledges receipt of your facility's response, dated May 24, 2022. Based on this inspection, it appears that you produced drug products that violate the Federal Food, Drug, and Cosmetic Act (FDCA).

A. Compounded Drug Products Under the FDCA

Section 503A of the FDCA describes the conditions under which human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practice (CGMP) (section 501(a)(2)(B)); labeling with adequate directions for use (section 502(f)(1)); and FDA approval prior to marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)].[1]

[1] We remind you that there are conditions other than those discussed in this letter that must be satisfied to qualify for the exemptions in section 503A of the FDCA.

U.S. Food and Drug Administration
Office of Pharmaceutical Quality Operations, Division II
1201 Main Street, Suite 7200
Dallas, Texas 75202
www.fda.gov

B. Violations of the FDCA

Adulterated Drug Products

The FDA investigator noted that drug products intended or expected to be sterile were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example, the investigator observed that:

1. An operator blocked first air to critical in-process operations and conducted aseptic processing without changing or sanitizing gloves after transferring components into and trash out of the ISO 5 area.

2. An operator reached over the top of open filled vials of filtered sterile drug while placing rubber stoppers on top of each filled vial in the ISO 5 area.

3. A filter intended to render final product sterile was not pharmaceutical grade.

4. Operators failed to conduct post-use filter-integrity testing on filters used to sterilize drug products.

5. Smoke studies were not performed under dynamic conditions to demonstrate unidirectional airflow within the ISO areas.

6. Sterilized depyrogenated glassware used in the processing of sterile drug product was exposed to less than ISO 5 air quality. Additionally, a beaker containing non-sterile bulk drug product was observed to be transferred uncovered from your ISO 7 Hazardous Drug Ante Room through the ISO 7 Ante Room and into the ISO 7 Cleanroom.

Under section 301(a) of the FDCA [21 U.S.C. § 331(a)], the introduction or delivery for introduction into interstate commerce of any drug that is adulterated is a prohibited act. Further, it is a prohibited act under section 301(k) of the FDCA [21 U.S.C. § 331(k)] to do any act with respect to a drug if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being adulterated.

Unapproved New Drug Product

You do not have any FDA-approved applications on file for human chorionic gonadotrophin (HCG) that you manufacture. This product is an unapproved new drug under section 505 of the FDCA [21 U.S.C. § 355(a)]. Your HCG product is also a biological product under section 351 of the Public Health Service Act (PHS Act) [42 U.S.C. § 262]. In order to lawfully market a drug that is also a biological product, a valid biologics license application (BLA) must be in effect under the PHS Act. Your HCG

product is not the subject of an approved BLA. The introduction or delivery for introduction of this product into interstate commerce is prohibited under section 301(d) of the FDCA [21 U.S.C. § 331(d)].[2]

Misbranded Drug Product

The HCG product that you manufacture is intended for conditions not amenable to self-diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layman can use this product safely for their intended uses. Consequently, its labeling fails to bear adequate directions for its intended use causing it to be misbranded under section 502(f)(1) of the FDCA [21 U.S.C. § 352(f)(1)].[3] The introduction or delivery for introduction into interstate commerce of this product therefore violates section 301(a) of the FDCA. Further, it is also a prohibited act under section 301(k) of the FDCA to do any act with respect to a drug if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.

C. Corrective Actions

We have reviewed your firm's response to the Form FDA 483.

Regarding your response related to the insanitary conditions, some of your corrective actions appear adequate; however, we cannot fully evaluate whether the following corrective actions described in your response appear to be adequate because you did not include sufficient information or supporting documentation:

1. You state in your response that you conducted a retrospective assessment of your operations to evaluate whether our observations relating to your operator's poor aseptic practices might have affected drug product quality over time. However, your response provided a general summary of your retrospective assessment. Quantitative data specifically describing your investigative process and findings was not provided. Given the nature of the observations, we would need to observe aseptic practices to verify the adequacy of your firm's corrective actions during a future inspection.

2. You state that you purchased pharmaceutical grade filters to replace the use of the Minisart RC filter, which is not a pharmaceutical grade filter. However, we are unable to evaluate the adequacy of the corrective action because

[2] Biological products subject to licensure under section 351 of the PHS Act are not eligible for the exemptions for compounded drugs under sections 503A and 503B of the FDCA. For additional information, you may wish to review FDA's 2018 guidance document, "Mixing, Diluting, or Repackaging Biological Products Outside the Scope of an Approved Biologics License Application."

[3] Your HCG product is not exempted from the requirements of section 502(f)(1) of the FDCA by regulations issued by the FDA (see, e.g., 21 CFR § 201.115).

documentation of the purchase of the replacement pharmaceutical grade filters was not provided in your response.

3. You state that you purchased a LabLogic Bubble Point Filter Integrity Tester. However, we are unable to evaluate the adequacy of this corrective action because you did not provide documentation of this purchase or of the operator training in your response.

4. We are unable to assess whether unidirectional airflow within the ISO areas is adequate under dynamic conditions is adequate to ensure your products intended to be sterile are produced in an environment that provides adequate protection against the risk of contamination because documentation was not provided.

5. In your response you state that you have begun to cover beakers with sterile foil during the filtration step and you are exploring other options. The practice of covering beakers with sterile foil, or other option employed, would need to be observed and evaluated to verify the adequacy of your firm's corrective action during a future inspection.

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A.

Furthermore, the FDA investigator noted that your facility produced biological products, including HCG and Thymosin-Beta 4. FDA acknowledges your statement that Revive RX, LLC has voluntarily discontinued producing Thymosin-Beta 4.

D. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of any violations and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

Within thirty (30) working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to address any violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. This letter notifies you of our concerns and provides you an opportunity to address them. If you believe your products are not in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot completely address this matter within thirty (30) working days, state the reason for the delay and the time in which you will do so.

Your written notification should refer to case # **641286**.

Please electronically submit your reply, on company letterhead, to Rebecca Asente, Compliance Officer, at ORAPHARM2_RESPONSES@fda.hhs.gov, and copy Ronda Loyd-Jones, Director, Compliance Branch, at ronda.loyd-jones@fda.hhs.gov.

If you have questions regarding the contents of this letter, you may contact Rebecca Asente via (504) 846-6104 or Rebecca.asente@fda.hhs.gov.

Sincerely,

Ronda R. Loyd-jones -S

Digitally signed by Ronda R. Loyd-jones -S
Date: 2023.06.30 10:38:33

Ronda Loyd-Jones
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II