U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
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EMAIL DELIVERY
RETURN RECEIPT REQUESTED

December 9, 2020

Scott Berliner, R.Ph., President
Life Science Pharmacy, Inc.
144 Route 17m, Suite 4
Harriman, NY 10926-3321

Dear Mr. Berliner:

From November 6, 2019 to November 20, 2019, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Life Science Pharmacy, Inc., located at 144 Route 17m, Suite 4, Harriman, NY 10926. During the inspection, the investigator noted deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on November 20, 2019. FDA acknowledges receipt of your facility's response, dated December 11, 2019. We also acknowledge that your firm ceased compounding sterile products effective November 7, 2019. 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] Receipt of valid prescriptions for individually-identified patients is one of the conditions for the exemptions under section 503A.

Specific violations are described below.

[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.

B. Violations of the FDCA

Adulterated Drug Products

The FDA investigator noted that drug products intended or expected to be sterile and non-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 non-USP grade (b) (4) was used to compound oral suspensions and enemas from bulk drug substances to include chloral hydrate(g) suspension 500mg/5ml, nystatin oral suspension (raspberry) 100,000U/ml, and butyrate enemas (100mM/L). The investigator observed that only a static smoke study was performed in your ISO 5 (b) (4) flow biological safety cabinet and not for the ISO 5 (b) (4) laminar flow hood. The investigator observed that there had been no successful media fills completed in the year prior to the inspection. Additionally, the investigator observed that (b) (4) cleaning of the ISO 5 and ISO 7 areas in July 2019 did not include a sterile sporicidal agent.

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(s) being adulterated.

Corrective Actions

We have reviewed your firm's response to the Form FDA 483. We acknowledge that "effective November 7, 2019, Life Science Pharmacy [ceased] all sterile compounding." If you should resume sterile compounding, your corrective actions pertaining to sterile compounding will be evaluated at the next inspection at your facility.

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

1. You state that you have switched to (b) (4) for (b) (4) for all compounded non-sterile preparations, but you did not provide any supporting documentation to include invoices or source of the (b) (4) for (b) (4).

2. You state that the terminology guidelines in the report summary for the certification of the ISO-5 classified areas has been updated. You provide a revised report for certification of the ISO-5 classified areas, but it does not address that certification occurred under dynamic conditions. Additionally, the revised report lacks information regarding the air flow pattern for the ISO 5 (b) (4) Laminar Flow Hood.

3. You state that media fills were performed prior to the last inspection. You provide a copy of the media fills for personnel who compound sterile products, but these are the same copies which were collected during the inspection. They do not demonstrate completion of successful media fills.

4. You state that your pharmacy staff was retrained on the importance of cleaning and documentation of cleaning, but did not provide the training record.

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.

FDA strongly recommends that if you decide to resume production of sterile drugs, your management first undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations. A third-party consultant with relevant sterile drug manufacturing expertise should assist you in conducting this comprehensive evaluation.

C. 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 the violations identified above 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 if you have taken any specific steps to correct the violations cited in this letter, or you may inform us that you do not intend to resume production of sterile drugs. If you intend to resume production of sterile drugs in the future, please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe that the products discussed above violated the FDCA, include your reasoning and any supporting information for our consideration. In addition to taking appropriate corrective actions, you should notify this office fifteen (15) days prior to resuming production of any sterile drugs in the future.

Please address your electronic response to ORAPHARM1_RESPONSES@fda.hhs.gov. Your written notification should refer to Case Number 610357.

If you have questions regarding the contents of this letter, please contact Nancy Scheraga at 973-331-4910, or by email at Nancy.Scheraga@fda.hhs.gov.

Sincerely,

Diana Amador-toro -S

Digitally signed by Diana Amador-toro -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=1300011579, cn=Diana Amador-toro -S
Date: 2020.12.09 13:33:39 -05'00'

Diana Amador-Toro
Program Division Director/District Director
Office of Pharmaceutical Quality Operations
Division I