January 8 2021

VIA FEDERAL EXPRESS AND ELECTRONIC MAIL

Ms. Diana Amador-Toro, Program Division Director/District Director
Office of Pharmaceutical Quality Operations
Division I/New Jersey District
10 Waterview Blvd.
3rd Floor
Parsippany, NJ 07054

RE: Life Science Pharmacy FDA Untitled Letter Response for Life Science Pharmacy issued 12/9/2020.
Herein referred to as "Life Science" or Life Science Pharmacy, Inc, Harriman, NY

Dear Director Diana Amador-Toro:

Life Science Pharmacy, Inc. Harriman, NY would like to take this opportunity to respond to the recent letter issued by the New Jersey District Office on December 9, 2020 ("Untitled Letter") to provide the Food and Drug Administration ("FDA") with further assurance that Life Science is committed to providing the safest and highest quality compounded preparations prepared in compliance with all applicable standards and that, as demonstrated herein, we take our professional responsibilities very seriously.

To that end, patient safety and wellbeing are our primary concerns, and we strive to and do provide the highest quality preparations and services. Our quality assurance and standard operating procedures ("SOPs") follow demonstrated pharmacy best practices and are designed to produce high-quality compounded preparations. We do this to ensure that we continue to meet recognized State pharmacy requirements and other standards applicable to compounding pharmacies, and so that our patients can continue to access high-quality compounded medications to meet their individual medical needs

Life Science takes FDA's observations and its professional responsibilities very seriously. Patient safety and well-being are the primary concerns of Life Science. Life Science strives to and does provide the highest quality preparations and services.

Further, and in response to FDA's observations, Life Science implemented several immediate corrections to certain compounding practices and procedures. Those corrections included updating various other procedural aspects of Life Science operations. Life Science retrained all staff engaged in the cleaning process on the importance of cleaning and documentation of the cleaning. Life Science took these, and the other steps set forth herein to ensure that it continues to meet recognized standards applicable to NY State Board of Pharmacy Board of Pharmacy Regulation pursuant to the guidelines set forth by the New York State Board of Pharmacy and the United States Pharmacopeia ("USP"), which are the recognized standards for New York-based compounding pharmacies and that, where appropriate, comply with Section 503A of the Federal Food, Drug, and Cosmetic Act ("Section 503A"). Moreover, Life Science has an impeccable safety record concerning the compounded medications that it prepares according to the applicable standards. Currently, Life Science is a community pharmacy compounding non-sterile drugs.

Please note that this Response to FDA's Untitled Letter does not constitute an admission or agreement by Life Science to the alleged deficiencies or conclusions set forth in FDA's Letter. None of the actions that may be taken by Life Science pursuant to its response should be considered an admission that an Observation existed or that additional

measures should have been in place at the time of the inspection. Without conceding that any of the Observations are applicable, set forth below are FDA's Observations, followed by Life Science response thereto.

Life Science respectfully requests that if FDA posts the Untitled Letter issued to this Pharmacy, then FDA shall post this Response along with it, and provide this Response when FDA provides the Untitled Letter to third parties. Failure to post the response brings into question the seriousness being taken of the FDA Transparency Initiative. Posting actions without a counter letter is presenting the information in a one-sided manner.

Life Science also respectfully requests that FDA post the 483 Response previously sent to the agency.

Life Science also asked that the 483 section labeled "Type of Facility Inspected" from "Producer of Sterile and Non-Sterile Drug Products" to "Pharmacy" as Life Science is not and has never been a "producer" of any drug product. As previously stated, "Producer of Sterile and Non-Sterile Drug Products" - is not a category recognized in any statute, rule, or guidance. Similarly, FDA also has not published any regulations or even non-binding agency guidance that would provide inspection standards. Congress passed Section 503A, which, along with its exemption from cGMP, applies to this Pharmacy. Further Life Science has never engaged in producing sterile and non-sterile drug products. Life Science compounds and dispenses preparations.

As such, Life Science provides the following response to the Untitled Letter:

Clarifications of Corrective Actions –

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) .

Response:

As stated in the 483 Response, "We acknowledge your observation but disagree with your conclusion. Life Science uses USP <795> for compounding non-parenteral preparations. USP <795> references USP <1231> to determine the type of (b) (4) to be used. The update to USP <795> has rectal preparations as Compounded Non-Sterile Preparations (CNSPs). This would require (b) (4) to be used for the suspensions and the enema. (b) (4) is not required to be sterile. Life Science was using (b) (4) as the (b) (4) source."

"However, in the spirit of continuous quality improvement, Life Science has switched to (b) (4) for (b) (4) instead of (b) (4) for all CNSPs."

Attached are representative invoices for the purchased (b) (4) for (b) (4) . See: Attachment 1 (b) (4) for (b) (4) Invoices.pdf

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.

Response:

As stated in the 483 Response, "We acknowledge your observation but disagree with your conclusion. This Pharmacy is a registered pharmacy practicing under the authority of the NYBOP, complying with both NYBOP and USP General Chapter <797> guidance for Environmental Quality and Control of our cleanrooms."

"The testing of our compounding areas is consistent with current <797> guidance and NYBOP regulation and is consistent with CETA guidance included within USP General Chapter <797>, we believe this also to be consistent as a pharmacy "best practice" and consistent with the prevailing standard of care for pharmacies."

"We do agree that the report's language is somewhat deficient in fully describing the actual dynamic conditions under which this testing is being carried out. There use of the terminology "guidelines" in their summary section can be better expressed. In consultation with our certifier, we have requested that they clarify and amend our certification document, now and going forward to include the specific standards being applied to alleviate any confusion. This notwithstanding please be assured that our certifications are always reviewed, and results were verified by Supervising Pharmacist (SP) as part of his supervisory duties under NY Pharmacy regulations. See Attachment: "(b) (4) Revised.pdf""[2]

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.

Response:

Please see the attached completed media fill documentation. Attachments here.

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.

Response:

As stated in the 483 response, "We acknowledge your observation. All staff engaged in the cleaning process have been re-trained on the importance of cleaning and documentation of the cleaning. This retraining has been documented and is available upon request."

Please see the attached training documents.

Life Science emphasizes that it takes patient safety and its professional responsibilities very seriously. Life Science shares FDA's goal of ensuring that patients in need of custom compounded medications receive quality preparations. To that end, and although it is not required to do so, Life Science has voluntarily taken corrective measures identified herein.

Additionally, we would like to acknowledge the agency's counsel regarding any resumption of sterile compounding services conducted by Life Science. We would not attempt any service constitution without the assistance of a competent and qualified third-party consultant.

In conclusion, Life Science appreciates the professional interactions it has had with FDA and looks forward to continuing them. To that end, if you have any questions regarding the responses we are providing to the Letter, Life Science welcomes additional dialogue or a meeting with the District Office to continue to work collaboratively to resolve the observations noted in the Untitled Letter to FDA's satisfaction.

In the interim, please do not hesitate to contact me should you have any questions.

Sincerely,

Scott Berliner

Scott Berliner, RPh, President
Life Science Pharmacy, Inc.