VIA EMAIL CONFIRMED DELIVERY
RETURN RECEIPT REQUESTED

March 15, 2024

Dave Wuest, RPh, Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Suite 206
Reno, NV 89521
Email: dwuest@pharmacy.nv.gov

Ref: CMS # 667723; FEI # 3011888866

State Referral Letter

Dear Mr. Wuest:

The purpose of this letter is to refer to you, the Nevada State Board of Pharmacy (BOP) for appropriate follow up, the U.S. Food and Drug Administration's concerns about poor practices observed during an FDA inspection at a pharmacy you licensed, Barclay, Luke, and Pillai Specialty Pharmacy PLLC, dba Meta Pharmacy Services, located at 8352 W Warm Springs Road, Suite 120, Las Vegas, NV 89113-3629.

The FDA inspected the firm from November 28, 2022, to December 9, 2022. The FDA investigator was accompanied by your state investigators for part of the inspection.

A copy of an amended Form FDA 483 that documents our investigator's observations from the inspection can be found at https://www.fda.gov/media/176470/download with any nonpublic information redacted. In addition, an Untitled Letter was issued by the FDA to the firm, dated September 14, 2023, which can be found at https://www.fda.gov/media/176472/download with any nonpublic information redacted. Because we consider this inspection to be "closed" under 21 CFR 20.64(d)(3), you may request a copy of the Establishment Inspection Report (EIR) that the FDA will provide to the firm, which contains additional information about our inspection. If your state agency has entered into a 21 CFR 20.88 information sharing agreement, you may be able to receive a copy of the Form FDA 483 and/or the EIR that includes certain nonpublic information. You may also choose to request such documentation directly from the firm.

During the inspection, the FDA investigator reviewed a small sample of records for drug products compounded by Barclay, Luke, and Pillai Specialty Pharmacy PLLC, dba Meta Pharmacy Services, and the FDA does not intend to take further actions at this time related to conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

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During the inspection, the FDA investigator observed deviations from appropriate practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Barclay, Luke, and Pillai Specialty Pharmacy PLLC, dba Meta Pharmacy Services, committed to the FDA in its responses to the Form FDA 483, received January 3, 2023, March 6, 2023, and March 8, 2023, and in its responses to the Untitled Letter received November 13, 2023, and December 5, 2023, to correct the deviations in the Form FDA 483 and Untitled Letter and provided documentation in support of those corrective actions. In addition, the deviations identified appear to be readily correctable.

After review of the records, the FDA does not intend to take further action at this time with regard to the findings of this inspection. The FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, the FDA is referring this matter to you for follow up to ensure appropriate corrective action has been taken. We believe you, the state, are in the best position to conduct follow-up and routine regulatory activities at this firm to ensure the ongoing quality of drug products they produce. Please notify us if you become aware of any adverse events or product quality concerns associated with human or animal drug products made at this facility, or if you observe any practices at this facility that concern you or that could be violations of federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Compliance Officer LCDR Rumany Penn, by email at Rumany.Penn@fda.hhs.gov. Please use the reference numbers cited in the heading of the document.

Sincerely,

CDR Steven E. Porter
Director, Office of Pharmaceutical Quality Operations Division IV

SP:rp

Cc:
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