FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS

VIA UPS SIGNATURE DELIVERY CONFIRMATION

July 13, 2022

David Wuest
Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, STE 206
Reno, NV 89521

Ref: [CMS #347797, FEI #3015134033]

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 sterile practices observed during an FDA inspection at a pharmacy licensed by the Nevada BOP, ACRX Specialty Pharmacy Inc., located at 3200 Soaring Gulls Drive, Suite 101, Las Vegas, Nevada. (Pharmacy License Number PHC03673; expiration October 31, 2022).

The FDA inspected the firm from July 12, 2021 to July 23, 2021. FDA investigators were accompanied by your Nevada State BOP investigators throughout the six-day inspection. A copy of a Form FDA 483 that documents our investigator's observations from the inspection can be found at: https://www.fda.gov/media/153655/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 FDA will provide to the firm, which contains additional information about our inspection. If you are a commissioned official or 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 ACRX Specialty Pharmacy Inc., and 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).

Division of Pharmaceutical Quality Operations IV
19701 Fairchild Road, Irvine CA 92612-2506
Telephone: 949-608-2900
Fax: 949-608-4417
www.fda.gov

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. Examples of deviations observed during our inspection include:

1. The firm produced drug products with materials that had not been verified to assure that they did not contribute to endotoxin contamination that may be objectionable given the product's intended use. Specifically, the firm used non-pharmaceutical grade glutathione labeled for dietary supplement.
2. Dynamic smoke studies were not representative of production.
3. Personnel conducted aseptic manipulations and placed equipment/supplies in an area that blocked the movement of first pass air around an open unit before or after it was filled with sterile product.

ACRX Specialty Pharmacy committed to the FDA in its response to the Form FDA 483, received August 13, 2021, to correct the deviations in the Form FDA 483. The response was deemed inadequate, and the FDA held a regulatory meeting with ACRX Specialty Pharmacy on May 5, 2022, to address these deviations. ACRX Specialty Pharmacy committed to the FDA in its response to the regulatory meeting invite, received April 21, 2022, and to the regulatory meeting, received May 26, 2022, 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 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 LCDR Rumany Penn, compliance officer, at 949-608-4409 or 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, Jr.
Director, Division of Pharmaceutical Quality Operations IV

Cc: Eghomware J. Igbinovia
Pharmacist-in-Charge/Owner
ACRX Specialty Pharmacy Inc.
3200 Soaring Gulls Dr Ste 101
Las Vegas, NV 89129-2198
jerry@acrxpharmacy.com