U.S. FOOD & DRUG ADMINISTRATION

VIA EMAIL CONFIRMED DELIVERY

April 6, 2023

Anne Sodegren, Executive Officer
California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Anne.Sodergren@dca.ca.gov

Ref: CMS 459269, FEI 3011893599

State Referral Letter

Dear Ms. Sodegren:

The purpose of this letter is to refer to you, the California 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, Auro Pharmacies Inc., located at 520 W. La Habra Blvd., La Habra, CA 90631.

The FDA inspected the firm from August 4, 2022, to August 12, 2022. You were informed of the inspection but did not accompany the FDA investigator during the 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/162963/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 Auro Pharmacies 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).

U.S. Food & Drug Administration
Office of Regulatory Affairs
Office of Pharmaceutical Quality Operations, Division IV
19701 Fairchild Road
Irvine, California 92612
Telephone (949) 608-2900
www.fda.gov

Additionally, 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 hazardous drugs without providing adequate containment or cleaning of work surfaces to prevent cross-contamination. For example, accumulation of white powder was observed in hoods such as the area under the HEPA filters and the bolts on the front shield of two hoods.
2. Non-microbial contaminants were observed in the production areas where non-hazardous drug products were produced. For example, accumulation of white powder was observed in hoods such as the area under the HEPA filters and the bolts on the front shield of two hoods.

Auro Pharmacies, Inc. committed to the FDA in its response to the Form FDA 483 dated August 31, 2022, to correct the deviations in the Form FDA 483 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. 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 Compliance Officer Mariza Jafary, at (949) 608-2977, or email at Mariza.Jafary@fda.hhs.gov. Please use the reference numbers cited in the heading of the document.

Sincerely,

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

SP: mj

Cc: Nayan Patel, Pharm.D. and CEO
Auro Pharmacies, Inc.
520 W La Habra Blvd
La Habra, CA 90631
nayan@centaldrugsrx.com