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

VIA SIGNATURE CONFIRMED DELIVERY

April 18, 2018

Steve Saxe, RPh, FACHE
Executive Director
Washington State Department of Health
PO Box 47852
Olympia, WA 98501

Reference: FEI 3013401760

Dear Mr. Saxe :

The purpose of this letter is to refer to the Washington State Department of Health for appropriate follow up, the U.S. Food and Drug Administration's (FDA) concerns about poor non-sterile practices observed during an FDA inspection at a pharmacy licensed by the Washington State Department of Health, Shiraz Specialty Pharmacy, Inc. dba Axis Pharmacy Northwest, located at 6007 244th Street SW Suite A2, Mountlake Terrace, WA 98043. (Pharmacy license Numbers #PHAR.CF.60691335 and #PHAR.CF.60691845).

FDA inspected the firm from May 30, 2017, to June 15, 2017. Washington State Department of Health was informed of the inspection but did not accompany FDA investigators during the inspection. A redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at: https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-afda-orgs/documents/document/ucm564003.pdf 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 or the EIR that includes certain nonpublic information. Alternatively, you may also choose to request a copy of the EIR directly from the firm.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Shiraz Specialty Pharmacy, Inc. dba Axis Pharmacy Northwest and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and distributes.

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During the inspection, the FDA investigators observed deviations from appropriate non-sterile 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 both highly potent and beta-lactam containing drugs without providing adequate containment, segregation and/or cleaning of work surfaces, utensils and/or personnel to prevent cross-contamination.
2. Non-pharmaceutical grade components are used in the production of non-sterile drug products.

Shiraz Specialty Pharmacy, Inc. dba Axis Pharmacy Northwest committed to FDA in its response to the Form FDA 483, dated June 21, 2017, request for additional information (RAI) response dated October 5, 2017, and teleconference response dated December 15, 2017, 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, FDA does not intend to take further action at this time with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients before distributing its compounded drugs, as required by section 503A(a) of the Federal Food, Drug and Cosmetic Act, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to the Washington State Department of Health for follow up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs 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 Maria Kelly-Doggett, Compliance Officer, at 425-302-0427, or by email at MariaKelly-Doggett@fda.hhs.gov.

Sincerely,

Steven E. Porter Jr -S

Digitally signed by Steven E. Porter Jr -S
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Date: 2018.04.20 14:22:37 -07'00'

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

SP: mpk

Cc: Axis Pharmacy Northwest
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