DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
6000 Metro Drive, Suite 101 Baltimore, MD 21215 (410) 779-5455 Industry Information: www.fda.gov/oc/industry	07/25-27/2016, 08/10/2016
	FEI NUMBER 3012590153

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Bassem Grigis, Owner and Pharmacist

FIRM NAME	STREET ADDRESS
Akina Pharmacy	4080 Lafayette Center Drive, Suite 270
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Chantilly, VA 20151	Producer of Sterile and Non-Sterile Drug Products

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DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

Quality System

Observation 1

Testing and release of drug products for distribution do not include appropriate laboratory determination of satisfactory conformance to final specifications of identity and strength of each active ingredient prior to release.

Specifically,

(a) Identity and potency tests are not conducted prior to the release of sterile drug products. (b) (4) is conducted as a training and assessment tool for (b) (4) for sterile drug products.

(b) Batches of sterile drug products when formulated according to (b) (4) Beyond Use Dates (BUD) are not consistently sterility tested. According to the pharmacist, only (b) (4) are tested for sterility.

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
		Tajah L. Blackburn, Consumer Safety Officer	08/10/2016

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Observation 2

Cleaning procedures have not been validated for effectiveness.

Specifically, (b) (4) is used a the disinfectant/sporicide for ISO 5 and ISO 7 areas within the clean room. According to the "Clean Room Monthly Checklist" and the stated practices employed by the pharmacist, there is (b) (4). Further, the firm has not conducted any disinfectant effectiveness tests to demonstrate that the (b) (4) solution, as used, is effective.

Observation 3

The responsibilities and procedures applicable to the quality control unit are fully followed.

Specifically, according to the "Clean Room Monthly Checklist" the expiration dates of all sterile chemicals is (b) (4). The chemicals are stored in the ante area of the clean room. During a walk-through of this area on July 25, 2016, I observed (1) a container of sodium chloride USP (b) (4) with no legible date for when it was opened or an expiration date; and (2) a container of ascorbic acid without a date for when it was opened or an expiration date.

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Observation 4

Written procedures are not followed for cleaning and maintenance of equipment, including utensils, used in the manufacture, processing, packing or holding of a drug product.

Specifically, according to SOP No. 6.013, titled (b) (4) are to (b) (4) During the production of TriMix on July 26, 2016, I observed a spatula, retrieved from a storage cart in the ante area of the clean room,being (b) (4) Papaverine (Lot (b) (4)) and Phentolamine (Lot # (b) (4)). I was told that the spatula was clean, but I did not observe the spatula being (b) (4) to demonstrate that it had been depyrogenated. There were other unwrapped stainless steel spatulas designated as ready for use in the same area.

Observation 5

Firm lacks procedures and written documentation for investigations into complaints and failures.

Specifically, a Complaint No. 051601, filed May 13, 2016, was issued for pain following TriMix injection. The "Patient Complaint and Grievance Form" included that no investigation was required, and another batch was made. However, no additional information was provided regarding patient outcome on the "Patient Complaint and Grievance Form". A sterility failure was documented for TriMix Injectable Solution (Alprostadil, Papaverine, Phentolamine 10 mcg/30 mg/1mg/ml injection) for lot# 04282016@19 produced on April 28, 2016. No additional information or investigation was conducted to identify the contaminant or source of contamination.

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