DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
19701 Fairchild Irvine, CA 92612-2445 (949)608-2900 Fax:(949)608-4417	4/25/2016-4/29/2016
	FEI NUMBER 3011830726

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED

Steven A Levin , President

FIRM NAME	STREET ADDRESS
Algunas Inc., dba Woodland Hills Compounding Pharmacy	20631 Ventura Blvd, Suite 305
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Woodland Hills, CA 91364-2382	manufacturer

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM I OBSERVED:

OBSERVATION 1

Procedures describing the handling of written and oral complaints related to drug products are deficiently written or followed.

Specifically,

A. The firm's SOP titled "Handling Medication Events for Compounded Preparations" does not require the firm to review and maintain complaint files and adverse drug reports (ADE) for the drugs produced at this facility. For example, after receiving a complaint about the BTT 12.5% gel drug product, the firm did not document the complaint or maintain a log of their communication with the medical provider who reported the problem.

B. The firm's training SOPs do not require employees to report ADEs to the firm's management or document conversations with medical providers or patients.

OBSERVATION 2

There is a failure to thoroughly review any unexplained discrepancy and the failure of a batch or any of its components to meet any of its specifications whether or not the batch has been already distributed.

Specifically,

A. The firm does not have a procedure requiring investigation into failed or rejected batches that do not meet specification. In addition, the firm does not maintain a log of failed or rejected batches and did not always conduct a root-cause analysis of the cause of the failures. Per the firm's President the firm had failed and/or rejected batches in the past two years but did not maintain records.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Roger F Zabinski, Investigator	Roger F. Zabinski	DATE ISSUED 4/29/2016

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B. The firm uses non-validated test methods from a third party contract lab to perform potency testing for the release of drug products such as Amphotericin-B 0.06% Irrigation Solution lot # 06102015@10, Amphotericin-B 0.25% Nasal Spray lot # 06282015@2a and Baddest Topical in Town BTT 12.5Gel lot #09252015@23.

OBSERVATION 3

Routine calibration of electronic equipment is not performed according to a written program designed to assure proper performance.

Specifically,

The (b) (4) pH meter is calibrated at the time of use, but has not been independently calibrated. This pH meter does not have automatic temperature correction and the firm does not have other controls in place to prevent temperature variations that may affect pH measurement. The pH calibrations are not recorded in a log to monitor for trend deviations. The pH (b) (4) standard used by the firm had expired six months prior ((b) (4) lot (b) (4), expiry Oct 2015).

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Roger F Zabinski, Investigator	Roger F. Zabinski	4/29/2016