

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER 19701 Fairchild Irvine, CA 92612-2445 (949) 608-2900 Fax: (949) 608-4417	DATE(S) OF INSPECTION 10/4/2018-10/11/2018* FEI NUMBER 3011830726
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NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Steven A. Levin, Pharmacist-In-Charge / Owner / CEO

FIRM NAME Algunas Inc., dba Woodland Hills Compounding Pharmacy	STREET ADDRESS 20631 Ventura Blvd Ste 305
CITY, STATE, ZIP CODE, COUNTRY Woodland Hills, CA 91364-2352	TYPE ESTABLISHMENT INSPECTED Producer of Non-Sterile Drugs

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

You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,

Since 2017, rather than using USP grade (b) (4), your firm has been using a (b) (4) brand (b) (4) system which you do not routinely test to assure its production quality and contamination risks in the preparation of the following of your non-sterile drug products:

Topical Facial Pads
Clear Face Pads (Salicylic Acid 2%, Sulfacetamide 5%, Clindamycin 0.5%)
Daily Facial Peel (Pads) (Glycolic Acid 1%, Salicylic Acid 1%, Lactic Acid 3%)
Skin Lightening Pads (Hydroquinone 4%, Kojic Acid 4%, Lactic Acid 7%)
Ultra Complexion Pads (Glycolic Acid 10%, Salicylic Acid 5%)
Topical Facial Solutions
Glycolic Acid Soln
Retinoic Acid Soln
Trichloroacetic Acid Soln
Tranexamic Acid 4.8% Soln
Topical Dental Gels and Rinse
BTT 12.5 Gel ((Lidocaine 12.5%, Tetracaine 12.5%, Prilocaine 3%, Phenylephrine 3%)
Chlorhexidine 2% Gel

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Rumany C Penn, Investigator	Rumany C Penn Investigator Signed By: 2001146009 Date Signed: 10-11-2018 09:37:47 X	DATE ISSUED 10/11/2018

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Minocycline 2% Kit (in the gel)
Dyclonine 1% Rinse
Profound Gel (Lidocaine 10%, Prilocaine 10%, Tetracaine 4%)
TAC 20 ALT Gel (Lidocaine 20%, Tetracaine 4%, Phenylephrine 2%)
Enema
Short Chain Fatty Acid Enema
Sod Butyrate 100 mm/L Enema

***DATES OF INSPECTION**

10/04/2018(Thu), 10/05/2018(Fri), 10/09/2018(Tue), 10/10/2018(Wed), 10/11/2018(Thu)

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