DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Denver Federal Center - Building 20 6th Avenue and Kipling Street PO Box 25087 Denver, CO 80225 Phone: 303-236-3000 Industry Information: www.fda.gov/oc/industry	11/13/2018-11/16/2018
	FEI NUMBER 3014597508

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Martha J. Carter, Owner

FIRM NAME	STREET ADDRESS
Prescription Alternatives, Inc.	610 East Main Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Frisco, CO 80443	Producer of Sterile and Non-Sterile Drug Products

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) (WE) OBSERVED:

Observations 1-5 are applicable to ophthalmic drug products for animals produced by your pharmacy.

These products are required to be sterile.

They include the following:
Cyclosporine Suspension 1% Ophthalmic Drops
Tacrolimus Suspension 0.02% Ophthalmic Drops
Tacrolimus Suspension 0.03% Ophthalmic Drops

OBSERVATION 1
Separate or defined areas to prevent contamination or mix-ups are deficient regarding operations related to aseptic processing of drug products.

Specifically,
All manipulations performed in the production of animal drug products required to be sterile are conducted in a non-classified, uncontrolled environment on the main pharmacy counter top.

OBSERVATION 2
Protective apparel is not worn as necessary to protect drug products from contamination.

Add Continuation Page

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
	Zachary L. Stamm -S Digitally signed by Zachary L. Stamm -S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, 0.9.2342.19200300.100.1.1=2000500894, cn=Zachary L. Stamm -S Date: 2018.11.16 13:11:22 -0700'	Zachary L. Stamm, Investigator	11/16/2018

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Denver Federal Center - Building 20 6th Avenue and Kipling Street PO Box 25087 Denver, CO 80225 Phone: 303-236-3000 Industry Information: www.fda.gov/oc/industry	11/13/2018-11/16/2018
	FEI NUMBER 3014597508

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Martha J. Carter, Owner

FIRM NAME	STREET ADDRESS
Prescription Alternatives, Inc.	610 East Main Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Frisco, CO 80443	Producer of Sterile and Non-Sterile Drug Products

Specifically,
Employees performing manipulations in the production of animal drug products required to be sterile do not wear sterile garb (gowns, hairnets, or sterile gloves) during production.

OBSERVATION 3
Procedures designed to prevent microbiological contamination of drug products required to be sterile are not established.

Specifically,
You have not established any written procedures regarding the production of animal drug products required to be sterile.

OBSERVATION 4
The final containers/closures used for drug product required to be sterile were not sterile or pyrogen free.

Specifically,
The final container/closure for animal drugs required to be sterile are not purchased sterile or pyrogen free and are not sterilized or depyrogentated prior to use.

OBSERVATION 5
There is no written testing program designed to assess the stability characteristics of drug products.

Add Continuation Page

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
SEE REVERSE OF THIS PAGE		Zachary L. Stamm, Investigator	11/16/2018

DISTRICT OFFICE ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
Denver Federal Center - Building 20 6th Avenue and Kipling Street PO Box 25087 Denver, CO 80225 Phone: 303-236-3000 Industry Information: www.fda.gov/oc/industry	11/13/2018-11/16/2018
	FEI NUMBER 3014597508

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED

TO: Martha J. Carter, Owner

FIRM NAME	STREET ADDRESS
Prescription Alternatives, Inc.	610 East Main Street
CITY, STATE AND ZIP CODE	TYPE OF ESTABLISHMENT INSPECTED
Frisco, CO 80443	Producer of Sterile and Non-Sterile Drug Products

Specifically,
The 180 day beyond use dates (BUD) that you apply to drug products required to be sterile is not supported by a written stability study or sterility data.

OBSERVATION 6
You used a non-pharmaceutical grade component in the formulation of a drug product.

Specifically,
You firm does not use a pharmaceutical grade water to compound human drug products; including but not limited to oral suspensions and solutions such as:
Nystatin 100,000 U/mL Suspension
Lansoprazole Suspension 7.5 mg/mL
Omeprazole Suspension 15 mg/mL
Zinc Sulfate Solution 10 mg/mL

Add Continuation Page

	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (*Print or Type*)	DATE ISSUED
SEE REVERSE OF THIS PAGE		Zachary L. Stamm, Investigator	11/16/2018