

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION**

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 404 BNA Drive, Bldg 200, Suite 500 Nashville, TN 37217 (615)366-3601 Email: ORAPharm2_responses@fda.hhs.gov Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 08/14/2018 - 08/16/2018*
	FEI NUMBER 3005011432

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Mr. Clayton E. Johnson, President

FIRM NAME Quinn Pharmacy dba Northland Discount Drug Inc.	STREET ADDRESS 3160 Audubon Drive
CITY, STATE AND ZIP CODE Laurel, MS 39440	TYPE OF 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) (WE) OBSERVED:

OBSERVATION 1

Non-pharmaceutical grade components are used in the formulation of non-sterile drug products.

Specifically, your firm uses (b) (4) that is (b) (4) through the (b) (4) (b) (4) system for the production of Sodium Bicarbonate and Omeprazole. However, your firm did not provide any documentation supporting the (b) (4) used in production is (b) (4). Your firm does not conduct any microbial testing on any drug products that use this system. In addition, your Pharmacist-in-Charge could not provide supporting documentation cleanings are conducted per the manufacturer's recommendations.

OBSERVATION 2

Hazardous drugs were produced without providing adequate containment, segregation, and/or cleaning of work surfaces, utensils, and/or personnel to prevent cross-contamination.

Specifically, your firm compounds hazardous drugs using non-dedicated equipment and could not provide any documentation supporting cleanings were conducted between production batches of hazardous drugs and non-hazardous drugs.

***DATES OF INSPECTION**

08/14/2018 (Tue), 08/15/2018 (Wed), 08/16/2018 (Thu)

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SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE June P. Page -S	EMPLOYEE(S) NAME AND TITLE (Print or Type) June P. Page, Investigator	DATE ISSUED 08/16/2018
	<small>Digital signed by June P Page S DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People cn=June P Page S, o=234210200300100111-2000405709 Date: 2018.08.16 10:08:55 -0500</small>		