

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

DISTRICT OFFICE ADDRESS AND PHONE NUMBER 404 BNA Dr., BLDG 200, Ste. 500 Nashville, TN 37217 (615) 366 -7801 Industry Information: www.fda.gov/oc/industry	DATE(S) OF INSPECTION 08/29/2016-08/30/2016, 09/02/2016
	FEI NUMBER 3012066153

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT IS ISSUED
TO: Thomas R. Mooney, Owner

FIRM NAME Mooney's Pharmacy, Inc.	STREET ADDRESS 1107 N Roan St
CITY, STATE AND ZIP CODE Johnson City, TN 37601	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:
Q - Beth 09/02/2016

Observation 1:

Beta-lactam 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 prepared an amoxicillin/clavulanic acid solution by crushing Augmentin tablets in a multi-use compounding room which is not equipped with a powder hood.

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 prepared Fluorouracil 5.25% cream, using bulk Fluorouracil USP powder, in a multi-use compounding room which is not equipped with a powder hood.


Observation 3:

The production areas have difficult to clean, particle-generating, and visibly dirty surfaces.

Specifically,

A) The ceiling and floors in the compounding room are not constructed of readily cleanable materials. The floor in the room is carpeted and the ceiling is constructed of a textured popcorn coated drywall.

B) On 08/29/2016, black and brown stains were observed on the ceiling in the compounding room directly above

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE 	EMPLOYEE(S) NAME AND TITLE (Print or Type) Brandon C. Heitmeier, Investigator	DATE ISSUED 09/02/2016
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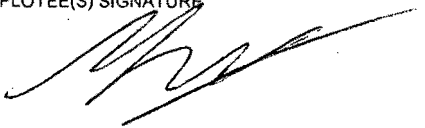
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the work bench and API storage cabinet. Additionally, scattered stains were observed on the carpet in the compounding room.

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