

MOONEY'S PHARMACY

11/22/2016

U.S. Food and Drug Administration
404 BNA Drive, Building 200, Suite 500
Nashville, TN 37217-2565
Attn: Rebecca Asente, Compliance Officer

RECEIVED

NOV 28 2016

NOL-DO Compliance Branch

Re: FDA Disclosure of 483 Response

Dear Compliance Officer,

On behalf of Mooney's Pharmacy Inc., I authorize the United States Food and Drug Administration (FDA) to publicly disclose the information described below on FDA's website. I understand that the information that is disclosed may contain confidential commercial or financial information or trade secrets within the meaning of 18 U.S.C. § 1905, 21 U.S.C. § 331 (0), and 5 U.S.C. § 552(b)(4) that is exempt from public disclosure under those statutory provisions and/or relevant FDA regulations. I agree to hold FDA harmless for any injury caused by FDA's sharing the information with the public.

Information to be disclosed: Mooney's Pharmacy Inc. letter dated 09/10/2016 excluding attachments/exhibits, which responds to FDA's Form 483 dated 09/02/2016.

Authorization is given to FDA to disclose the above-mentioned information which may include confidential commercial or financial or trade secret information. As indicated by my signature, I am authorized to provide this consent on behalf of Mooney's Pharmacy Inc. and my full name, title, address, telephone number, and facsimile number is set out below for verification.

X 
Thomas Rouse Mooney
Owner/RPH

1107 North Roan Street
Johnson City, TN 37601
Phone (423) 926-7333
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Attn: Rebecca Asente, Compliance Officer

Re: Response to FDA 483 Issued Sept. 09/02/2016 to Mooney's Pharmacy Inc.

Dear Compliance Officer,

The Food and Drug Administration ("FDA") conducted an inspection of Mooney's Pharmacy Inc., a pharmacy located at 1107 North Roan Street, Johnson City, TN 37601, in September, 2016. Upon the conclusion of its inspection, the FDA provided Mooney's Pharmacy Inc. with an FDA Form 483. This letter is Mooney's Pharmacy Inc. response to the FDA Form 483 observations. We respectfully request that this response, excluding the attachments, be posted on the FDA's website with the Form 483 and be included every time the FDA provides a copy of the Mooney's Pharmacy Inc. FDA Form 483 to anyone outside the FDA.

Mooney's Pharmacy Inc.

Date(s) of Inspection: 08/29/16-08/30/16, 09/02/16

FEI Number: 3012066153

Observation 1:

Beta-lactam drugs were produced without 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 multiuse compounding room which is not equipped with a powder hood.

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Response 1:

Mooney's Pharmacy Inc. agrees with the FDA on the possibility of cross contamination with regard to certain drug classes like beta-lactams. Mooney's being a 503a regulated pharmacy not a 503b facility nor a manufacturer of API or finished products would have no knowledge of guidance for the manufacturing industry. We have reviewed the "Guidance for Industry" and Current Good Manufacturing Practices published in April 2013 and have implemented policies to prevent any future actions that may raise concern. It is our policy to avoid manipulation of all beta-lactam containing medications/APIs even though we are now equipped with a powder hood. See attached exhibits for policy regarding beta-lactams and pictures of 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.

Response 2:

Mooney's Pharmacy Inc. agrees with the FDA on the possibility of cross contamination with regard to Fluorouracil even with the use of disposable compounding supplies. Mooney's Pharmacy Inc. now has the policy that we will not compound any class 1 hazardous chemicals and has ceased all compounding of Fluorouracil even though we are now equipped with a powder hood. See attached exhibits for the policy regarding medications/APIs listed as class 1 hazardous chemicals. Mooney's Pharmacy Inc. is currently working on preparation for USP 800 to further address issues with medications determined by USP and NIOSH as hazardous with the intention to avoid all class 1 listed chemicals.

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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 textured popcorn coated drywall.

B) On 08/29/2016, black and brown stains were observed on the ceiling in the compounding room directly above the work bench and API storage cabinet. Additionally, scattered stains were observed on the carpet in the compounding room.

Response 3:

Mooney's Pharmacy Inc. agrees with the FDA that the materials used are not easily cleaned. Mooney's Pharmacy Inc. would like to mention that medication preparation surfaces including counter top and equipment used are cleaned regularly at the start and end of each shift and in between compounds. With regard to the ceiling, floors and walls we are replacing these materials with ones that can be easily maintained and will not stain from solvents or spills. The improvements include removing all cabinets and commercial carpeting and using a solid sheet of thick laminate to cover the floor. The walls and ceiling will also be covered with a laminate type product with all seams caulked or covered by molding as well as the addition of a clean room approved light fixture and stainless steel work stations. Mooney's Pharmacy Inc. gladly makes these upgrades to improve environmental controls with regard to the compounding room. Please see the attached policies regarding proper cleaning of the compounding areas as well as pictures of the improvements.

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