



Randy Davis, D.Ph.
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On behalf of the Wellness Center Pharmacy, Inc. dba Designer Drugs, 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: Designer Drugs' letter dated 12/27/2017 excluding attachments/exhibits, which responds to FDA's Form 483 dated 12/22/2017.

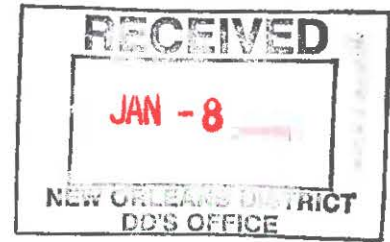
Authorization is given to FDA to disclose the above-mentioned information which may include confidential commercial or financial or trade secret information. As indicated by my signature, I am authorized to provide this consent on behalf of Designer Drugs and my full name, title, address, telephone number,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

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December 27, 2017

Brandon C. Heitmeier
Investigator
Department of Health and Human Services
Food and Drug Administration
404 BNA Drive, building 200, Suite 500
Nashville, TN 37217-2597

*Via Fax 615-366-7802
and Via Overnight Delivery*

Re: Response to FDA Form 483 Issued December 22, 2017,
to The Wellness Center Pharmacy, Inc, dba Designer Drugs

Dear Mr. Heitmeier:

The Food and Drug Administration conducted an inspection of The Wellness Center Pharmacy, Inc. dba Designer Drugs, a pharmacy located at 7304 Jarnigan Road, Chattanooga, Tennessee, between December 12 and December 22, 2017. Upon the conclusion of its inspection, the FDA provided Designer Drugs with an FDA Form 483. This letter is Designer Drugs' response to the FDA Form 483 observations, including corrective actions taken. 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 Designer Drugs' FDA Form 483 to anyone outside the FDA.

Our response is as follows.

Observation 1:

Non-Microbial contamination was observed in your productions area.

Specifically, on 12/12/2017, rust-like stains were observed on the clean room (non-hazardous buffer room ISO 7) floor adjacent to the Laminar Air Flow Hood (ISO 5 area). Additionally, rust-like stains were observed on the seat of a metal stool located in the clean room (non-hazardous buffer room). This stool was used during aseptic processing on 12/12/17.

Response: We acknowledge that there were stains on the buffer room floor located directly under the legs of our shelving unit. While the shelf is stainless steel, the leveling bolts at the bottom are not. There are two sporicidal agents we use in our cleaning that could have caused either rust or staining to occur. We use a daily bleach solution on the floors which can be corrosive to metal surfaces. We also use a monthly fogging solution (4% hydrogen peroxide/0.5% silver nitrate), which can cause staining if the fogging time

is too long (the silver nitrate can cause a rusty looking stain if it condenses). Either of these chemicals may have caused the staining on the floor.

The metal stool in the buffer room has discoloration on the seat where the seat was originally welded to the base. It is not a stain, and it is not rusted.

Corrective Action: The stain on the floor has been removed to the best of our ability, and there is no rust or contamination on the floor. To prevent new stains and to promote easier cleaning in the future, the leveling bolts have been replaced with castors. We have amended SOP 3.020 to include checking for rust or signs of wear as a part of the monthly cleaning process and added a column on the monthly cleaning log to validate this has been completed. A copy of the amended SOP 3.020 is provided as Attachment A. Additionally, a 'Read and Understand' memo has been circulated to the pharmacists and technicians regarding the new cleaning procedures. A copy of the Read and Understand memo is provided as Attachment B.

The metal stool's surface, while not rusted, is worn due to age, and in the interest of preventing future concerns, we have ordered a new cleanroom stool. A copy of the order form is provided as Attachment C.

Observation 2:

Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, your firms' large batch media fill consists of 25 test vials, however your firm routinely produces a sterile ophthalmic product (Cataractive3) with a batch volume of 10 liters which is packaged in 2,000 individual units.

Response: The two media fills that we currently perform are representative of our most challenging conditions for injectables. The media fill for our large batch does, in fact, replicate the filling process of our ophthalmic preparation. It uses many of the same devices and equipment for filling the vials. However, the quantity and type of containers does not match our largest ophthalmic preparation.

Corrective Action: We acknowledge the need to add a media fill that matches our largest ophthalmic preparation. We have amended SOP 9.100 to include a new ophthalmic media fill procedure that matches the preparation. We have also created a media fill validation form to record the results. An amended copy of SOP 9.100 is provided as Attachment D. A 'Read and Understand' memo has been circulated to the pharmacists and technicians regarding the new procedure. A copy of this memo is provided as Attachment E.

Clear sterile droptainers have been ordered, and upon their receipt, the ophthalmic media fill will be completed. A copy of the droptainer order is provided as Attachment F. Expected arrival date of the droptainers is 6-8 weeks. The results of the media fill will be submitted to Mr. Heitmeier.

Observation 3:

The ISO classified aseptic processing areas contained dust-collecting overhangs without adequate and frequent cleaning.

Specifically, on 12/12/17, I observed the cleaning of the Laminar Air Flow Hood (ISO 5 area) by your Lab Coordinator prior to aseptic processing. During the cleaning of the hood canopy the plastic cover

became dislodged exposing the inner housing of canopy/light fixture. The inner housing of canopy/light fixture and overhang is not included in your firm's cleaning procedures.

Response: Our Laminar Air Flow Hood (ISO 5 area) has a plastic lighting cover, which rests on an overhang. This cover is removable if a lightbulb needs to be changed, and is not fixed in place on the overhang. When cleaning the interior canopy of the hood, the upper cover does move slightly within the boundaries of the overhang, but it does not expose the light housing area. Cleaning of the overhang or of the inner housing has not before been implemented in our cleaning SOP.

Corrective Action: We acknowledge that we need to include cleaning of the overhang in our SOP, and have updated SOP 3.020 with the proper procedure. An amended copy of SOP 3.020 is provided as Attachment A. Additionally, a 'Read and Understand' memo has been circulated to the pharmacists and technicians regarding the new cleaning procedures. A copy of the Read and Understand memo is provided as Attachment B.

Conclusion

With this response, Designer Drugs has sought to address all the FDA inspectors' observations and concerns. If the FDA requires any additional information or communication from Designer Drugs, please contact me at (423)954-2585.

Sincerely,

A handwritten signature in black ink, appearing to read "Randy Davis". The signature is fluid and cursive, with the first name "Randy" and last name "Davis" clearly distinguishable.

Randy Davis, Owner