



113 W. Victoria St.
Long Beach, CA, 90805-2162
562-595-7548

VIA EMAIL AND FEDEX

Friday, March 31, 2017
Mr. Steven Porter
Director
Los Angeles District
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

RE: Hartley Medical Center Pharmacy Inc. Response to FDA Form 483 Issued March 24, 2017

Dear Mr. Porter,

On behalf of Hartley Medical Center 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 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: Hartley Medical Center Pharmacy Inc. letter dated 03/31/2017 excluding attachments/tables, which responds to FDA's Form 483 dated 03/24/2017.

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 Hartley Medical Center Pharmacy Inc. and my full name, title, address, telephone number, and facsimile number is set out below for verification.

Sincerely,

William A. Stuart, RPh

President

Hartley Medical Center Pharmacy, Inc.
113 West Victoria St
Long Beach, CA 90805
Telephone: (562) 595-7548
Facsimile: (562) 595-9855

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Friday, March 31, 2017
Mr. Steven Porter
Director
Los Angeles District
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

RE: Hartley Medical Center Pharmacy Inc. Response to FDA Form 483 Issued March 24, 2017

Dear Mr. Porter,

This letter is in response to the FDA Observation Form FDA-483 issued on March 24, 2017 regarding the inspection of our facility located at 113 W. Victoria St., Long Beach, CA 90805. The inspection was conducted between March 20, 2017 through March 24, 2017. After this inspection, a FDA Form 483 was issued which includes two (2) Observations.

The following are the responses to the FDA's Observations. We respectfully request that this response, excluding any attachments, be posted on the FDA's website as well as every time a copy of Hartley Medical Center Pharmacy's FDA Form 483 is provided to an entity outside of the FDA. This response is to entail all of Hartley Medical Center Pharmacy's responses and remediation to all the Observations made on the FDA Form 483 issued March 24, 2017.

We look forward to working together with the FDA to supply patients with highest quality products as we continue to accommodate patient needs. Hartley Medical Center Pharmacy has always demonstrated a high standard of quality in patient care and we welcome this opportunity to take our facility to the next level of excellence. If there are any questions or concerns in regards to our response, please contact as soon as possible.

Sincerely,



William A. Stuart, RPh
President
Hartley Medical Center Pharmacy, Inc.
113 West Victoria St
Long Beach, CA 90805
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Detailed Response to the Form 483 Letter Dated March 24, 2017

NOTE: FDA Form 483 text is represented in ***Bold, Italic*** text.

OBSERVATION 1

Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically,

The repeater pump used to dispense drug stocks into smaller unit vials is wheeled from the ISO-7 Ante room to the ISO-6 IV Clean Room when needed and wheeled back to the Ante room when not needed.

Response 1:

Hartley Medical Center Pharmacy Inc. agrees with the FDA's observation. The repeater pump is affixed to a stand with wheels that is occasionally moved from the ISO-6 and ISO-7 cleanroom areas. The repeater pump and stand will strictly stay in the ISO-6 buffer room and will not be removed unless repairs are needed or its use is discontinued. If the repeater pump is removed from the ISO-6 area, it will be cleaned appropriately with sterile 70% isopropyl alcohol upon its return. Regardless, the repeater pump and stand will be cleaned on a weekly basis and before each use. These changes will be reflected in an updated SOP #1.05 (Attachment 1) as well as the cleaning log (Attachment 3). Staff have been trained and notified on the revision of SOP #1.05. (Attachment 2).

OBSERVATION 2

The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically,

I observed that gaps in the emergency exit double doors from the ISO-6 IV room are sealed with tape, but there were some areas where the tape had been worn or was not fully maintaining the seal, thus possibly compromising the integrity of the ISO-6 room.

Response 2:

Hartley Medical Center Pharmacy Inc. agrees with the FDA's observation. The tape that is mentioned in Observation 2 is located on the exterior of the cleanroom, which is not an ISO-classified area. The tape is used to prevent any particles, vermin, and / or debris from entering the ISO-6 area. The tape will be changed on a routine basis from now on. The frequency of this will be monthly unless a significant amount of wear and tear is visibly seen on the tape. This policy will be reflected in an updated SOP #1.00 (Attachment 3). Staff have been trained and notified on the revision of SOP #1.00. (Attachment 2).