CIVIC CENTER PHARMACY

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January 27, 2017

Mariza M. Jafary,

On behalf of Civic Center Pharmacy, I authorize the United States Food and Drug Administration (FDA) to publicly disclose the information described below on FDA's web site. 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, 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: Civic Center Pharmacy FDA 483 response letter dated 10/10/2014 and Civic Center Pharmacy Warning Letter response letter 09/17/2015 dated excluding attachments/exhibits, which responds to FDA's Form 483 dated 10/09/2014.

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

Sincerely,

Tenille Davis, PharmD RPh
Pharmacist-in-charge
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October 10, 2014

Department of Health and Human Services
Food and Drug Administration
19701 Fairchild
Irvine, CA 92612

Attention: Alonza Cruse, District Director

Re: Investigational Observations - Civic Center Pharmacy
Date(s) of Inspection: September 10th, 11th, & October 9th, 2014

Civic Center Pharmacy does not compound sterile prescriptions for office use and, therefore, is not subject to Section 503B of the Federal Food, Drug and Cosmetic Act. Rather, Civic Center Pharmacy is a retail, community compounding pharmacy (a Section 503A pharmacy) and is required to follow laws and rules put forth by the Arizona State Board of Pharmacy and, as applicable, the Boards of Pharmacy in non-resident states in which the pharmacy is licensed. Civic Center Pharmacy is also required to follow USP <795> and USP <797> guidelines as they relate to compounding. However, Civic Center Pharmacy is not legally required to follow cGMP because it is not a manufacturer nor is it registered with the FDA as a 503B Outsourcing Facility. Some of the investigator's observations and/or recommendations made during the FDA inspection ignore the laws and regulations that Civic Center Pharmacy is required to follow and assume that it must follow laws and regulations to which it is not subject. We have respectfully responded to each observation in turn below.

Observation 1

a. Viable particulate air monitoring in the ISO 5 hoods is only conducted every 6 months by an outside contractor.

    i. Per USP <797>, every 6 months is all that is required. Employees simulate actual working conditions during the semi-annual testing done by Controlled Environment Management to reflect changes in turbulence, air flow, etc. that would be encountered during actual

aseptic processing. Actual aseptic processing during viable particulate air monitoring is not required per USP <797>.

b. Viable particulate air monitoring in the ISO 7 cleanroom is only conducted every 6 months by an outside contractor.

    i. Per USP <797>, every 6 months is all that is required. Employees simulate actual working conditions during the semi-annual testing done by Controlled Environment Management to reflect changes in turbulence, air flow, etc. that would be encountered during actual aseptic processing. Actual aseptic processing during viable particulate air monitoring is not required per USP <797>.

c. Non-viable particulate air monitoring in the ISO 5 hoods is only conducted every 6 months by an outside contractor.

    i. Per USP <797>, every 6 months is all that is required. Employees simulate actual working conditions during the semi-annual testing done by Controlled Environment Management to reflect changes in turbulence, air flow, etc. that would be encountered during actual aseptic processing. Actual aseptic processing during non-viable particulate air monitoring is not required per USP <797>.

d. Non-viable particulate air monitoring in the ISO 7 cleanroom is only conducted every 6 months by an outside contractor.

    i. Per USP <797>, every 6 months is all that is required. Employees simulate actual working conditions during the semi-annual testing done by Controlled Environment Management to reflect changes in turbulence, air flow, etc. that would be encountered during actual aseptic processing. Actual aseptic processing during non-viable particulate air monitoring is not required per USP <797>.

e. Cleanroom pressure differentials are not actively monitored during aseptic processing of drug products. Differential pressures are manually read and recorded daily.

    i. This is all that is required by USP <797>, although the pharmacy agrees that continuous pressure monitoring would be preferable so staff could be alerted if pressures fell during aseptic processing to halt compounding or sterilization. Employees will look into the pharmacy's pressure monitoring system and see if it is capable of importing data into Simpifi 797 or printing a receipt of pressures. The pharmacy will turn on the audible alarm for the pressure system, so if there is a change in pressure during compounding or sterilizing, the staff will be

alerted to halt processing and find out the reason for the pressure change.

f. There is not adequate surface environmental monitoring that represents actual conditions.

    i. Staff of Civic Center Pharmacy will change the day/time of surface sampling to Friday afternoons to adequately reflect when the compounding and sterile rooms will be the "dirtiest" and give the most accurate surface sampling reports.

g. Routine personnel monitoring is not conducted.

h. Personnel monitoring (i.e. fingertip tests) are performed and recorded monthly. Per USP <797>, it is only required to be done by each sterile compounding employee twice per year for high-risk sterile compounding (after an initial 3 tests performed during sterile training). Civic Center Pharmacy is currently exceeding the recommended frequency of fingertip testing.

2. Observation 2 - Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

    a. The process for handling sterilized vials has not been well established or designed to prevent microbiological contamination.

        i. There are written procedures to prevent microbiological contamination of drug products purporting to be sterile. However, the process by which the pharmacy sterilizes vials could be improved. The pharmacy will change our autoclave sterilization of vials and stoppers to heat depyrogenization/sterilization of vials and autoclaving stoppers. Trays will be triple wrapped in aluminum foil so they can be wiped down and a foil layer removed each time the tray is moved to a cleaner area (ISO 8 to ISO 7, then ISO 7 to ISO 5, etc).

    b. The process for aseptically filling and stoppering vials has not been well designed to prevent microbiological contamination.

        i. Manual stoppering of vials is acceptable per USP <797>, but the pharmacy agrees that leaving upstoppered vials and stoppers in the ISO 5 hood for long periods of time poses a greater risk than leaving them for shorter times. The pharmacy will consider, for large batches especially, sending two technicians into the sterile room at a time, so one technician can decant the sterilized solution into vials and the other technician can stopper the vials so the process is quicker.

c. Articles entering the ISO 5 environment are not always disinfected before introduction.

    i. Double bagging autoclave bags of stoppers will become a standard of practice, so sterile compounding technicians can remove the outer bag when the bag is transferred from ISO 7 room to ISO 5 hood, thereby helping to ensure sterility of the final product.

d. Cleanroom certification of ISO 5 hoods does not include performing smoke studies.

    i. Smoke studies will be conducted during the next environmental testing under dynamic conditions.

Please include this response letter on the FDA website and anytime you provide the record of the pharmacy's inspection per public request.

Sincerely,

Tenille Davis, PharmD RPh
Pharmacy Manger, Civic Center Pharmacy