DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Detroit District
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Detroit, MI 48207
Telephone: 313-393-8100
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May 21, 2015

Ms. Ann Ward-Fuchs, Administrative Law Specialist
Department of Licensing and Regulatory Affairs
Health Investigation Division
Bureau of Health Care Services
611 W. Ottawa Street
Lansing, MI 48933

Dear Ms. Ward-Fuchs,

The purpose of this letter is to refer to the State of Michigan , Licensing and Regulatory Affairs (LARA), for appropriate follow-up, the U.S. Food and Drug Administration's (FDA) concerns about poor sterile practices observed during an FDA inspection at a pharmacy licensed by LARA; Health Dimensions, Inc., 39303 Country Club Drive, Suite A26, Farmington Hills, Michigan, 48331-3482 (Pharmacy license number 5301006453).

FDA inspected the firm from July 31, 2014, through August 8, 2014. The FDA investigator was accompanied by Michigan state investigators for three days of the inspection. Attached is a redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection.

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Health Dimensions, Inc. and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for the drug products that it compounds and dispenses. In the response to the Form FDA 483, received August 28, 2014, the firm advised FDA that it "is committed to compliance with all requirements of pharmacy compounding under Section 503A of the Federal Food, Drug, and Cosmetic Act."[1]

During the inspection, the FDA investigators observed deviations from appropriate sterile practice standards that, if not corrected, could lead to contamination of drugs, potentially putting patients at risk. Examples of deviations observed during our inspection include:

1. The firm's program to ensure that each process used is able to produce sterile product without contamination and to evaluate the competency of all personnel who engage in these operations is inadequate. For example, personnel do not perform media fills under conditions that closely simulate the most challenging or stressful conditions encountered during routine aseptic operations.

[1] See attached response letter received August 28, 2014, from Health Dimensions, Inc. to Jeffrey D. Meng, Investigator, Detroit District Office.

2. The aseptic practices employed by personnel at the firm are inadequate and increase the risk of microbial contamination of the product. The investigator observed that personnel:
    - Exposed their bare hands within the ISO 5 area when changing out their gloves.
    - Failed to sanitize materials transferred from the ISO 7 to the ISO 5 work area.

3. The firm's viable environmental monitoring program for the ISO 5 and 7 areas is inadequate. For example, the firm does not use microbial growth media that contains disinfectant neutralizers when performing viable surface and fingertip sampling.

Health Dimensions, Inc. committed to FDA in its response, received August 28, 2014, to correct all deviations on the Form FDA 483. In addition, the deviations identified appear to be readily correctible.

After review of the record, at this time FDA does not intend to take further action with regard to the findings of this inspection. This firm apparently obtains prescriptions for identified individual patients, consistent with traditional pharmacy practice, and FDA believes that the corrective actions can be appropriately overseen by the State. Therefore, FDA is referring this matter to LARA for follow-up to ensure appropriate corrective action is taken. Please notify us if you become aware of any adverse events or product quality concerns associated with drugs made at this facility, or if you observe any practices at this facility that concern you or that could be violations of Federal law.

We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Tina Pawlowski, Compliance Officer, at 313-393-8217, or by email at tina.pawlowski@fda.hhs.gov.

Sincerely,

Art O. Czabaniuk
District Director
U.S. Food and Drug Administration
Detroit District Office

Enclosures