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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February 25, 2014

VIA UPS

Rae Ramsdell, Director
Bureau of Health Professions
Michigan Board of Pharmacy
611 W. Ottawa, 1st Floor,
P.O. Box 30670
Lansing, MI 48909-8170

Dear Ms Ramsdell:

The purpose of this letter is to refer to the Michigan Board of Pharmacy (BOP) 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 the Michigan BOP, Portage Pharmacy Inc., located at 7966 Lovers Lane, Portage, MI 49002.

FDA inspected the firm from March 4, 2013 to March 6, 2013. FDA's investigators were accompanied by a Michigan State BOP inspector for one day 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 Portage Pharmacy and determined, based on this sample, that this firm appears to obtain valid prescriptions for individually-identified patients for drug products that it compounds and dispenses.

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. Among other observations noted in the Form FDA 483, the firm did not adequately verify the effectiveness of its sterilization method to ensure that Hydroxyprogesterone Caproate 250 mg/ml prepared from non-sterile ingredients is sterile. For example, the firm did not (b) (4) before sterilization for subsequent evaluation to determine whether the sterilization method was effective. In addition, the (b) (4) specified during the October 2011 (b) (4) of the (b) (4) was (b) more than the (b) (4) routinely used to sterilize Hydroxyprogesterone Caproate 250 mg/ml.

The firm claims that the sterilizer is qualified to maintain the (b) (4) in the batch records for Hydroxyprogesterone Caproate 250 mg/ml. However, the firm has not provided any written documentation which demonstrates that the sterilizer is adequately

[redacted], nor do they discuss the use of a [redacted]
Hydroxyprogesterone Caproate 250 mg/ml.

In its March 28, 2013, response to the Form FDA-483, Portage Pharmacy committed to FDA to correct some of the deviations.

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. In addition, the deviations identified appear to be readily correctable and the firm has agreed in writing to correct some of the deviations. Therefore, FDA believes that the corrective actions can be appropriately overseen by the State and FDA is referring this matter to the Michigan BOP 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,

Glenn T. Bass
District Director
Detroit District Office