

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration Southwest Region Kansas City District 8050 Marshall Drive Suite 205 Lenexa, Kansas 66214-1524 913-495-5100

UPS OVERNIGHT MAIL

February 18, 2015

Kimberly Grinston Executive Secretary Missouri Board of Pharmacy 3605 Missouri Boulevard P.O. Box 625 Jefferson City, MO 65102

Dear Ms. Grinston:

The purpose of this letter is to notify you that the U.S. Food and Drug Administration does not intend to take further action with regard to an inspection at a pharmacy licensed by the Missouri BOP, Med 4 Home Inc. (dba Med 4 Home Pharmacy) located at 10800 N. Congress Ave, Kansas City, MO 64153.

As part of its routine surveillance, FDA inspected the firm on March 18, 2014. FDA had previously inspected the firm in 2003 after the Missouri BOP notified FDA's Kansas City District Office that the firm dispensed an inhalation solution to patients that was contaminated with a microorganism.

During the 2014 inspection, FDA investigators reviewed the product list of drugs and a small sample of records to identify products dispensed by Med 4 Home. Based on the product list and sample of records, FDA determined that the firm is not compounding any drug products. No Form FDA 483 was issued to the firm.

Because this firm has ceased compounding operations, FDA does not intend to take further action with regard to the findings of this inspection. Please notify us if the firm resumes compounding operations and you become aware of any adverse events or product quality concerns associated with drugs compounded and dispensed by this facility, or you observe any compounding practices at this facility that concern you and could be violations of Federal law.

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We look forward to continuing to work with you on the oversight of compounding pharmacies. If you have additional questions, please contact Miguel Hernandez, Director, Compliance Branch at 913-495-5101, or by email at miguel.hernandez@fda.hhs.gov.

Sincerely,

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Cheryl Bigham District Director Kansas City District