DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
New England District Office
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March 25, 2015

William J. Summa
Chair
Department of Consumer Protection
Commission of Pharmacy
165 Capital Ave., Room 147
Hartford, CT 06106

Dear Mr. Summa:

The purpose of this letter is to refer to the Connecticut Commission of Pharmacy for appropriate follow-up, the U.S. Food and Drug Administration's (FDA) concerns about a pharmacy licensed by the Connecticut Commission of Pharmacy, Yeung Business Solutions, LLC dba Reliant Pharmacy, 200 Main Street, Southbury, CT 06488-4250.

FDA inspected the firm on October 30, 2013, after receiving a Medwatch report concerning adverse events associated with liothyronine capsules compounded by Reliant Pharmacy. Attached is a redacted copy of the Med Watch report. FDA investigators were accompanied by a Drug Control Agent from Compliance and Enforcement of the State of Connecticut Department of Consumer Protection.

During this limited inspection focused on the issues described in the Med Watch report, FDA did not observe objectionable conditions in Reliant' s compounding operations and did not issue a Form FDA 483 at the conclusion of the inspection. In addition, during the inspection, the FDA investigator reviewed a sample of records for products produced by the firm 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. The FDA investigator also collected samples of liothyronine capsules made by Reliant during the inspection and separately from a patient who experienced adverse events. Upon subsequent testing by an FDA laboratory, some of the samples were found to be super-potent, and other samples were found to

be sub-potent. FDA provided a copy of our sample worksheet to the State of Connecticut, Compliance and Enforcement, Department of Consumer Protection on November 21, 2013.

At this time, FDA does not intend to take further action regarding 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 the Connecticut Commission of Pharmacy 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 Karen Archdeacon, Compliance Officer, at 781-587-7491, or by email at karen.archdeacon@fda.hhs.gov.

Sincerely,

Mutahar Shamsi
District Director
New England District

Attachment

cc: John Gadea, Director
Department of Consumer Protection
Drug Control -Compliance and Enforcement
165 Capitol Avenue
Hartford, CT 06106-1630