U.S. FOOD & DRUG ADMINISTRATION

December 5, 2016

Andrea Faley, Program Director
Colorado State Board of Pharmacy
1560 Broadway, Suite 1350
Denver, CO 80202

Dear Ms. Faley,

The purpose of this letter is to notify the Colorado State Board of Pharmacy (BOP) that the U.S. Food and Drug Administration does not intend to take further action with regard to an inspection of a pharmacy licensed by the Colorado BOP, Belmar Pharmacy, located at 12860 W. Cedar Drive, Suite 210, Lakewood, CO 80228 (License #: PDO.0730000018).

FDA inspected the firm from June 10, 2015, to June 18, 2015, after we became aware that Belmar Pharmacy was producing testosterone implants. The Colorado BOP was informed of the inspection but did not accompany FDA investigators during the inspection. A redacted copy of a Form FDA 483 that documents our investigators' observations from the inspection can be found at http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofGlobalRegulatoryOperationsandPolicy/ORA/ORAElectronicReadingRoom/UCM454185.pdf

During the inspection, the FDA investigators reviewed a small sample of records for products compounded by Belmar Pharmacy 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 which is consistent with traditional pharmacy practice. After review of the records and the firm's response to the Form FDA 483, FDA does not intend to take further action with regard to the findings of this inspection at this time and believes that the firm's pharmacy practice can be appropriately overseen by the State. 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 Matthew R. Dionne, Compliance Officer, at (303) 236-3064.

Sincerely,

LaTonya M. Mitchell

LaTonya M. Mitchell
District Director
Denver District

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