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FDA Works to Improve Adverse Event Reporting for Compounded Drugs September 11, 2019

In a September 9, 2019, statement FDA reported that during an inspection of one of its outsourcing facilities that markets compounded bioidentical hormone replacement therapy (in this case, progesterone and testosterone pellets), investigators uncovered information about 4,202 adverse events (AEs) that had never been reported to FDA. This facility was not registered with FDA as an outsourcing facility. Outsourcing facilities, such as those that produced these products, are required to report certain AEs to FDA and are subject to regulatory and enforcement action if they do not appropriately label their drugs with AE-reporting information. Although the outsourcing facility had an online portal to collect AE data from its customers, it never reported that information to FDA nor did it provide this information to the manufacturing outsourcing facilities.

The AE information suggests that the compounded hormone pellets were possibly associated with endometrial cancer, prostate cancer, strokes, heart attacks, deep vein thrombosis, cellulitis, and pellet extrusion. However, because the reports lacked certain critical information, FDA was able to attribute only a small percentage of the AEs (61 reports) to the use of compounded hormone pellets containing testosterone. The company that collected the AEs did not report them during the 5 years they occurred between 2013 and 2018. In light of this discovery, FDA intends to take appropriate action if outsourcing facilities do not comply with the AE reporting requirements.

This action by FDA is a critical step in providing improvement in AE reporting by compounding facilities. In addition, FDA is partnering with the National Academy of Sciences, Engineering, and Medicine to study the risks associated with compounded hormone products. NAMS continues to advise against the use of compounded bioidentical hormone therapy, given the availability of multiple formulations and doses of FDA-approved bioidentical hormones, specifically estradiol and progesterone.