May 17, 2022

From: Kansas Department of Health and Environment – Division of Public Health

To: Local health departments, health care facilities, home health agency, hospice, hospitals, KDHE, long term care facilities, health care providers, pharmacies, primary care clinics, epidemiologist

RE: FDA Alerts Customers to Voluntary Recall of Compounded Drugs Due to Sterility Issues

The U.S. Food and Drug Administration (FDA) is alerting patients and health care professionals not to use certain compounded products produced and distributed by Drug Depot, LLC, doing business as APS Pharmacy intended to be sterile, due to lack of sterility assurance. Administration of non-sterile products intended to be sterile may result in serious and potentially life-threatening infections or death.

The recalled drugs include "gonadorelin acetate," "testosterone cypionate in grapeseed oil," "testosterone cypionate/anastrozole in grapeseed oil," "testosterone cypionate/DHEA in grapeseed oil," and "testosterone cypionate/propionate in sesame seed oil" for human use, and "cyclosporin" and "tacrolimus" for animal ophthalmic use. These products were compounded between December 21, 2021, and March 7, 2022. The recalled drugs, lot numbers, and do-not-use beyond date - the date when the compounded drug should no longer be used - are listed here.

Since the company initiated the recall and began contacting patients using the recalled drugs, FDA has received adverse event reports from APS Pharmacy regarding injection site reactions, such as pain, redness, swelling and abscesses requiring medical treatment; and systemic reactions, which include fever, chills, and rash. To date, FDA has received two reports of adverse events occurring in animals following use of the recalled animal ophthalmic products.

RECOMMENDATIONS:

- Health care professionals and veterinarians should immediately check their medical supplies, quarantine any recalled drugs from APS Pharmacy, and not administer or provide them to patients or animals.
- Patients should not use, and animal owners/caretakers should not administer, the recalled drugs from APS Pharmacy. If they are not sure if they have a recalled drug, they should contact APS Pharmacy to confirm.

- Patients and animal owners/caretakers who have received these recalled drugs from APS Pharmacy should contact their healthcare professional/veterinarian as appropriate.

- FDA urges healthcare professionals and consumers who obtained recalled drugs to make alternative arrangements to obtain medications from sources that meet applicable quality standards.

Health professionals and patients are encouraged to report adverse events or side effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

- Complete and submit the report online at www.fda.gov/medwatch/report.htm; or

- Download form or call 1-800-332-1088 to request a reporting from, then complete and return to the address on form, or submit by fax to 1-800-FDA-0178.

Veterinarians and animal owners/caretakers should report adverse events or side effects in animals related to the use of these products to FDA's Center for Veterinary Medicine. Please visit How to Report Animal Drug and Device Side Effects and Product Problems for more information.

For more information about this FDA alert, click here.