The Board of Pharmacy has received notice of the following product recall. The Board strongly encourages pharmacies to immediately review their quality assurance and recall policies and procedures to determine if any corrective action is required.

FDA alerts customers to voluntary recall of compounded drugs due to sterility issues by Drug Depot, LLC, dba APS Pharmacy

[4/26/2022] FDA is alerting patients, health care professionals, veterinarians, and animal owners/caretakers about a voluntary recall by Drug Depot, LLC, doing business as APS Pharmacy, of certain unexpired compounded drugs due to a lack of sterility assurance. Administration of a non-sterile drug intended to be sterile may result in serious and potentially life-threatening infections.

APS Pharmacy, located in Palm Harbor, Florida, which compounds drugs intended for human use and drugs intended for animal (veterinary) use, initiated the voluntary nationwide recall via a recall letter dated March 15, 2022. The company has sent recall letters to all patients and animal owners who received the recalled drugs, and they are contacting all customers via telephone calls and emails as part of their recall strategy.

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.

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 who have received these recalled drugs from APS Pharmacy should contact their health care professional. Animal owners/caretakers should contact their veterinarian as appropriate.

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.

FDA urges health care professionals and consumers who obtained recalled drugs from this company to make alternative arrangements to obtain medications from sources that meet applicable quality standards.

Health care professionals and consumers should report adverse events or side effects related to the use of products from APS Pharmacy to 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 form, 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.

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