Compounded Drugs – 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 – Recall Alert

Date of Notice: April 26, 2022

Brief Description of Recall Alert

The US FDA is alerting patients and health care professionals 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. APS Pharmacy initiated the voluntary nationwide recall via a recall letter dated March 15, 2022. The company has sent recall letters to all patients 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 were compounded between December 21, 2021, and March 7, 2022.

Administration of a non-sterile drug intended to be sterile may result in serious and potentially life-threatening infections. Since the company initiated the recall and began contacting patients, 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.

Affected Products

Drug Name & Strength	Lot	Expiration Date
gonadorelin acetate (4 mL), 0.2 mg/mL	749842	7/13/2022
	749568	7/12/2022
	752053	7/23/2022
	752817	7/25/2022
	757404	8/21/2022
	757915	8/23/2022
	757321	8/20/2022
	753718	7/30/2022
gonadorelin acetate (5 mL), 0.2 mg/mL	745708	6/21/2022
	753364	7/27/2022
	752508	7/24/2022

	750313	7/16/2022
	753020	7/26/2022
	747712	7/4/2022
	747974	7/5/2022
	754802	8/3/2022
	751158	7/19/2022
	756837	8/16/2022
	748939	7/10/2022
	750842	7/18/2022
	755742	8/8/2022
	758691	8/28/2022
	758432	8/27/2022
	758975	8/29/2022
	756643	8/15/2022
testosterone cypionate in grapeseed oil (2 mL), 80 mg/mL	746269	6/27/2022
testosterone cypionate in grapeseed oil, 200 mg/mL	754381	8/1/2022
testosterone cypionate/ anastrozole grapeseed oil (4 mL), 200 mg/0.5 mg/mL	750851	7/18/2022
testosterone cypionate/ anastrozole grapeseed oil (10 mL), 200 mg/0.5 mg/mL	754549	8/2/2022
testosterone cypionate/ anastrozole grapeseed oil (4 mL), 200 mg/1 mg/mL	745383	6/20/2022
	759295	8/30/2022
testosterone cypionate/ anastrozole grapeseed oil (10 mL), 200 mg/1 mg/mL	745749	6/21/2022
testosterone cypionate/ anastrozole grapeseed oil (10 mL), 200 mg/1 mg/mL (RM)	746272	6/27/2022
testosterone cypionate/ dhea grapeseed oil (5 mL), 200 mg/10 mg/mL	746000	6/26/2022
testosterone cypionate/ dhea grapeseed oil (10 mL), 200 mg/10 mg/mL	751472	7/20/2022
testosterone cypionate/ propionate seseme seed oil (10 mL), 160 mg/20 mg/mL	759312	8/30/2022

Prescriber Information

Health care professionals should immediately check their medical supplies, quarantine any recalled drugs from APS Pharmacy, and not administer or provide them to patients.

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.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report Online
- Regular Mail or Fax: Download form or call 1- 800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178

Member Information

Members should contact their doctor or healthcare provider if they have any questions related to this recall or have experienced any problems that may be related to taking or using this drug product.

Members 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.

RxAdvance Response

Members should continue taking their medication until a doctor or pharmacist provides replacement drug (if needed) or a different treatment option is given. RxAdvance is in the process of contacting members and prescribers to advise them of this recall.