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.

Olympia Pharmacy Issues Voluntary Nationwide Recall of Seven Compounded Products Due to Being Out-of-Specification

Olympia Pharmacy has issued a voluntary nationwide recall of seven compounded products due to being out-of-specification. The voluntary recall is for 11 specific lots of Trimix Formulas F-9, T-105, SB-4, Sermorelin, Sincalide, Hydroxocobalamin, and NAD, compounded injectables to the consumer level.

Risk Statement: Administration of subpotent Hydroxocobalamin in infants, pregnant/breastfeeding women, and elderly populations are at risk for vitamin B12 deficiency and there is a reasonable probability they could experience adverse events including muscle weakness, neurological peripheral neuropathic numbness or pain, vision loss, and psychiatric disorders (depression, memory loss). Additionally, injectable compounded products, found to contain more or less drug product than the labeled strength or which reconstitute at a different rate than intended, may result in either too much or too little medication being administered. This could result in lower-than-expected effectiveness of the drug or unintended adverse side effects.

Olympia Pharmacy has not received any reports or concerns from patients relating to the safety of the recalled sterile compounded products, and no patients have reported any adverse events attributed to any of the recalled sterile compounded products.

The compounded products being recalled are typically prescribed by medical professionals for age management, erectile dysfunction, vitamin deficiencies, and for diagnostic imaging of the gallbladder. The affected lots include the following lot numbers and expiration dates listed below. The product can be identified by reading the lot number in the black strike zone of the label and was distributed to patients and health clinics.

Drug	Vial Size	Lot	Best Use Date
NAD	500mg vial	C41008	3/8/22
NAD	500mg vial	D24005	4/5/22
Sincalide	5 mcg vial	D24001	4/1/22
Trimix Formula F9	10 ml vial	D41C19	4/19/22
Sermorelin Acetate 9 mg	9 mg vial	D44026	4/26/22
Sermorelin Acetate 9 mg	9 mg vial	F42104	6/4/22
Trimix T-105,	5 ml vial	E41F10	5/10/22
Trimix T-105,	10 ml vial	E41G10	5/10/22

Drug	Vial Size	Lot	Best Use Date
Trimix SB-4	5 ml vial	E41C18	5/18/22
Trimix SB-4	10 ml vial	E41D18	5/18/22
Hydroxocobalamin 1mg/ml	30 ml vial	E47025	5/21/22

Olympia Pharmacy is notifying its customers by mail and is arranging for return and replacement of all recalled compounded products. Patients and health clinics that have any of the listed compounded products which are being recalled should stop using and return to Olympia Pharmacy.

Consumers with questions regarding this recall can contact Olympia Pharmacy by phone at 407-250-4000 or e-mail clientservices@olympiapharmacy.com Monday through Friday from 9 am to 6 pm Eastern Standard Time.

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

This recall is being conducted with the knowledge of the U.S. Food and Drug Administration.

Although compounded drugs can serve an important medical need for certain patients, they also present a risk to patients. FDA's compounding program aims to protect patients from unsafe, ineffective and poor quality compounded drugs, while preserving access to lawfully-marketed compounded drugs for patients who have a medical need for them.

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