

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 Recall of 11 lots of compounded products Due to Out of Specification Potency and Reconstitution Time Testing Results

Company Contact:

Recall Coordinator

407-250-4000 or clientservices@olympiapharmacy.com

Open M-F 9AM-6PM EST

March 7, 2022 – Orlando, FL, Olympia Pharmacy is voluntarily recalling 11 specific lots of Trimix Formulas F-9, T-105, SB-4, Sermorelin, Sincalide, Hydroxocobalamin, and NAD, injectables to the consumer level. The products have been found to have potency or reconstitution time testing results that are out of specification.

Risk Statement: This potentially could result in too little or too much medication. Olympia Pharmacy has not received any reports of adverse events.

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. Other lot numbers are not affected.

NAD, Lot C41008, BUD 3/8/22, failed reconstitution time limit of 60 seconds

Sincalide Lot D24001, BUD 4/1/22, correct potency range is 90%-110%, testing shows this product is 110.4%

NAD, Lot D24005, BUD 4/5/22, correct potency range is 90%-110%, testing shows this product is 85.6%

Trimix Formula F9, Lot D41C19, BUD 4/19/22, correct potency range is 90%-115%, testing shows this product is 85% for phentolamine, all other ingredients are in spec

Sermorelin Acetate 9 mg vial, Lot D44026, BUD 4/26/22, correct potency range is 90%-110%, testing shows this product is 79.7%

Trimix T-105, Lot E41F10, BUD 5/10/22, correct potency range is 90%-115%, testing shows this product is 115.4% for alprostadil, all other ingredients are in spec

Trimix T-105, Lot E41G10, BUD 5/10/22, correct potency range is 90%-115%, testing shows this product is 115.4% for alprostadil, all other ingredients are in spec

Trimix SB-4, Lot E41C18, BUD 5/18/22, correct potency range is 90%-115%, testing shows this product is 89.2% for alprostadil, all other ingredients are in spec

Trimix SB-4, Lot E41D18, BUD 5/18/22, correct potency range is 90%-115%, testing shows this product is 89.2% for alprostadil, all other ingredients are in spec

Hydroxocobalamin 1mg/ml, Lot E47025, BUD 5/21/22, correct potency range is 95%-105%, testing shows this product is 92.7%

Sermorelin Acetate 9 mg Vial, Lot F42104, BUD 6/4/22, correct potency range is 90%-110%, testing shows this product is 80%

Olympia Pharmacy is notifying its customers by mail and is arranging for return and replacement etc. of all recalled products. Consumers and clinics that have any of the listed products which is 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: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm 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.

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