

## COMPANY ANNOUNCEMENT

# Innoveix Pharmaceuticals, Inc. Issues Voluntary Recall of All Sterile Compounded Drug Products Due to A Lack of Sterility Assurance

When a company announces a recall, market withdrawal, or safety alert, the FDA posts the company's announcement as a public service. FDA does not endorse either the product or the company.

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## Summary

**Company Announcement Date:**

July 12, 2021

**FDA Publish Date:**

July 13, 2021

**Product Type:**

Drugs

**Reason for Announcement:**

Potential lack of sterility assurance

**Company Name:**

Innoveix Pharmaceuticals, Inc.

**Brand Name:**

Innoveix Pharmaceuticals, Inc.

**Product Description:**

Injectable Semorelin / Ipamorelin 3mg and injectable AOD-9604 3mg

## Company Announcement

Innoveix Pharmaceuticals, Inc. is voluntarily recalling the following lots of sterile compounded drug products, within expiry. The products are being recalled due to a lack of assurance of sterility. These concerns arose following a routine inspection of the pharmacy by FDA.

Administration of a drug product intended to be sterile, that is not sterile, could result in serious infections which may be life-threatening. To date, Innoveix Pharmaceuticals, Inc. has not received any reports of adverse events related to this recall. This voluntary recall is being

conducted out of an abundance of caution and to promote patient safety, which is the pharmacy's highest priority.



The affected products are injectable Semorelin / Ipamorelin 3mg and injectable AOD-9604 3mg. The products can be used for various indications as prescribed. The products can be identified by an Innoveix Pharmaceuticals, Inc. label. The products were distributed in glass vials contained in a small 3 inch by 3 inch white box. Products were distributed nationwide to both customers and/or medical facilities. A full list of the affected products with the applicable lot numbers and expiration dates is as follows:

Product	Lot/Expiry
Semorelin / Ipamorelin 3mg	Lot# SIP210; Exp: 12/15/2021 Lot# SIP215; Exp: 01/14/2022 Lot# SIP220; Exp: 01/23/2022
AOD-9604 3mg	Lot# AOD205; Exp: 11/09/2021 Lot# AOD210; Exp: 11/18/2021 Lot# AOD 215; Exp: 12/15/2021 Lot# AOD202; Exp: 11/09/2021

The pharmacy has notified potentially affected customers of the voluntary recall via U.S. Mail and direct outreach. Customers who have received sterile compounded products subject to the voluntary recall should not use them and return the product to the pharmacy for a full refund.

Consumers with questions regarding this recall can contact Innoveix Pharmaceuticals, Inc. by phone 800-370-1910 or [innoveix@gmail.com](mailto:innoveix@gmail.com) (<mailto:innoveix@gmail.com>). We are available Monday through Friday from 9 AM to 4:30 PM CST. Consumers should contact their physician or healthcare provider if they have experienced any problems that may be related to taking or using these drug products.

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 \(file:///C:/node/360543\)](file:///C:/node/360543)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>)
- Regular Mail or Fax: [Download form \(file:///C:/node/360547\)](file:///C:/node/360547)  (<http://www.fda.gov/about-fda/website-policies/website-disclaimer>) 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.

# Company Contact Information

## Consumers:

Innoveix

☎ 800-370-1910

✉ [innoveix@gmail.com](mailto:innoveix@gmail.com) (<mailto:innoveix@gmail.com>)

## Media:

Kevin Hogan

☎ 214-390-3371

# Product Photos

Compounded Lyophilized  
Sermorelin/Ipamorelin 3mg

For subcutaneous or intramuscular  
injection

Lot # [REDACTED] Exp. [REDACTED]



Innoveix

Rx Only

Store at controlled room  
Temperature 15°-30°C  
(58°-86°F) After reconstitu-  
tion store under refrigeration  
2°-8°C (36°-46°F) for up  
to 28 days. Do not freeze.  
Compounded by:  
Innoveix  
Addison, TX 75001  
800-370-1910

Compounded Lyophilized  
AOD-9604 3mg

For subcutaneous or intramuscular  
injection

Lot # [REDACTED] Exp. [REDACTED]



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➡ More Recalls, Market  
Withdrawals, &  
Safety Alerts (</safety/recalls-market-withdrawals-safety-alerts>)