



Clifton Health Department Food Recall Notification



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Food/Drug/Pet Recall: Innoveix Pharmaceuticals, Inc.

Innoveix Pharmaceuticals, Inc. is voluntarily recalling all sterile compounded drug products, within expiry, to the consumer level. 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.

The affected products are injectable Human Chorionic Gonadotropin (HCG) and injectable Sermorelin w/GHRP2. The products can be used for various indications as prescribed. The products can be identified by an Innoveix Pharmaceuticals, Inc. label. Products were distributed 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

HCG 11,000 IUs Lot # INX 530: Exp: 11/9/18 to 11/6/19 Lot # INX 535: Exp: 11/21/18 to 11/15/19 Lot # INX 540: Exp: 2/20/19 to 2/1/20 Lot # INX 555: Exp: 4/9/19 to 3/26/20 Lot # INX 550: Exp: 3/22/19 to 3/9/20 Lot # INX 555: Exp: 4/9/19 to 3/26/20 Lot # INX 560: Exp: 5/9/19 to 5/3/20 Lot # INX 565: Exp: 6/12/19 to 5/18/20 Lot # INX 570: Exp: 6/28/19 to 6/28/20 Lot # INX 575: Exp: 7/26/19 to 7/18/20

HCG 5,000 IU's Lot # INX 910: Exp: 2/20/19 to 2/7/20 Lot # INX 915: Exp: 3/22/19 to 3/12/20

HCG 5,500 IU's Lot # INX 50: Exp: 5/9/19 to 5/1/20

Sermorelin w/GHRP2 3mg Lot # SER 925: Exp: 11/19/18 to 11/4/19 Lot # SER 930: Exp: 2/22/19 to 11/18/19 Lot # SER 935: Exp: 3/5/19 to 2/21/20 Lot # SER 400: Exp: 4/29/19 to 4/1/20 Lot # SER 405: Exp: 6/3/19 to 5/11/20

Lot # SER 410: Exp: 7/23/19 to 7/15/20

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. 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.



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- . 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.

No action is required of local health departments at this time for any of these recalls. If any requests for assistance are received from either FDA or USDA, the Public Health and Food Protection Program will contact you. For additional information regarding warnings and recalls, please click on the weblink below.

For all recalls - <http://www.recalls.gov/recent.html>