Sample Class: Normal Everyday Sample
Sample Origin: Domestic
Sample Basis: Surveillance
Sample Flag: Official
Collecting District: ORAHQ
Orig C/R and Records To: ORAHQ
Collection PACs: 63001A

Product Name: Human Growth Hormone (Hormone); Human - Non/Rx Combination Ingredient; NonSterile Ointment
Product Description: NEWULIFE SOMADERM Transdermal Homeopathic HGH 3.5 oz
Collection Reason: For identification and quantification of human growth hormone and testosterone.

Lab: FCC
Split Num: 0
Date Received: 09/12/2018
Date Out of Lab: 01/25/2019

District Conclusion:
District Conclusion Made By:
Disposition Reason:
Disposition Authorized By:

Performing Org PAC LID PAF Compliance No Lab Class Description Laboratory Status
FCC-ORG 63001A NAR 4 - No Classification Required Completed

Lab Conclusion
Sample summary report emailed to CAPT Jason Humbert (Branch Chief, ORA-Health Fraud), Nicole Kornspan (CSO, ORA-Health Fraud), and ORA OEIO ENFORCEMENT Health Fraud Branch on 01/28/19.

Lab Conclusion Date Lab Conclusion Made By
01/25/2019 Gamble, Bryan M

Date: 07/31/2019
Date: January 23, 2019

From: Lianji Jin, Ph. D.
Chemist, Organic Laboratory Branch

Subject: Results of Analysis, FACTS #: 1026141

To: CAPT Jason Humbert, Branch Chief
Health Fraud, Division of Enforcement, ORAHQ, U.S. FDA

Through: Cheryl L. Fluref, Ph.D.
Director, Organic Laboratory Branch

I. Description of Samples Received for Analysis
The sample was received via UPS on 09/12/2018 and contained a white plastic pump bottle labeled, in part, “NEW ULIFE™ ... SOMADERM® Gel TRANSDERMAL ... MAXIMUM STRENGTH HOMEOPATHIC HUMAN GROWTH HORMONE ... 3.5 oz (100 g) ... NDC# 61877-0005-1 ... Active Ingredients GLANDULA SUPRARENALIS SUIS 6X THYROIDINUM 8X SOMATROPIN 30X ... (b) (7)(A)”, containing a gel-like material.

II. Analytical Tests Performed on Samples
Per the Collection Report and communication with CAPT Humbert, the contents of the bottle were analyzed for the presence of human growth hormone (hGH) using liquid chromatography-mass spectrometry (LC-MS). The contents were also screened for the presence of any active pharmaceutical ingredients (APIs) using LC-MS and for drugs or poisons using gas chromatography-mass spectrometry (GC-MS).

III. Results and Conclusions
There was no evidence for the presence of hGH at a level greater than approximately 7 micrograms per gram in the contents of the bottle based on comparison to a corresponding standard using LC-MS.

Analysis was inconclusive for the presence of any APIs in the duplicate portions due to the matrix interference from PEG (polyethylene glycol) like materials using LC-MS. However, there was no evidence for the presence of liothyronine (T3) at a level greater than approximately 15 micrograms per gram in the contents of the bottle.

There was no evidence for the presence of any drugs or poisons in the bottle contents using GC-MS.

IV. Sample Retention/Disposition/Feedback Information
This sample will be retained by the Forensic Chemistry Center pending instructions from your office for disposition. If you have any questions, concerns or a need for additional information, please do not hesitate to contact me at (513) 679-2700 Ext 2713, or Bryan M. Gamble, Ph.D. at (513) 679-2700 Ext 2266.

Lianji Jin, Ph.D.

Cc: Nicole Kornspan, CSO, Health Fraud, Division of Enforcement, ORAHQ

Section Authors Concurrency

Sections 1, 731, 731A, 731B:

Lianji Jin, Ph.D.

Reviewer:

Bryan M. Gamble, Ph.D.