

Food and Drug Administration Office of Regulatory Affairs

Summary Report

For Sample Number: 1026141

TD Sample Number:

Import Sample Number

This is an accurate reproduction of the original electronic record as of 07/31/2019

Sample Class: Normal Everyday Sample

Sample Origin: Domestic

Sample Basis: Surveillance

Sample Flag:

Sample Type: Official

Collecting District: ORAHQ

Home District:

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 GHG 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:

District Conclusion Date:

Disposition Reason:

Disposition Authorized By:

Disposition Authorized Date:

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



Case/Sample Summary Report

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. Flurer
Cheryl L. Flurer, 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 U LIFE™ ... 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.

Jin Lianji
Lianji Jin, Ph.D.

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

Section Authors Concurrences

Sections 1, 731, 731A, 731B: Jin Lianji
Lianji Jin, Ph.D.

Reviewer: Bryan M. Gamble
Bryan M. Gamble, Ph.D.