United States Food and Drug Administration
Consumer Complaint / Injury Report

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

COMPLAINT # 155581

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
11/08/2018	DAL-DO	KAN-DO	Email	Other, identify in Remarks	Tate,Leon P	Closed

Complainant Identification

Name	Address	
(b) (6)	Not provided	Not provided (b) (6)

Phone (W)	Phone (H)	Source POC Name	Source Phone
	Not provided		

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
Complainant believes the product is a scam and the website is misleading. Complainant state he is a (b) (6) He is routinely asked about the validity of Somaderm "HGH" Gel. He has researched the product and believes the promoters and manufacturers are lying about the product. He indicates the company's website is misleading and misrepresent their FDA status by promoting the NDC with their product "which gives it power." Complainant believes the product is a scam because a 3-ounce (travel-sized) bottle sells for $169.99 and the results attributed to their product is impossible to attain. He states they have various YouTube videos and Facebook pages promoting the product while admitting it has virtually no HGH in the ingredients; 1 HGH to 1,000,000,000,000,000,000,000,000,000,000 dilutions.	None		

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
No		N/A	N/A	N/A	Not Report to Other Source	N/A

Remarks

(b) (6) .

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks

Health Care Professional

Provider Name	Address	Phone	Occupation

Hospital Information

Hospital Name	Address	Phone	Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
New U Life	SOMADERM GEL	60V-99	Anterior Pituitary Suppressor N.E.C.	56R801	n/a

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
3.5 Ounces Other, identify in Label Remarks	N/A	N/A	N/A	No	N/A

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
N/A	N/A	N/A	No	United States	NDC : 61877-0005-1 ***Tube ****The generic name of Hgh is glandula suprarenalis suis, thyroidinum (bovine), hgh. ... Glandula Suprarenalis Suis 6X, Thyroidinum (Bovine) 8X, HGH 30X.

Retail

Name	Address
N/A	

Problem Ingredient Group

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
(b) (4)			Manufacturer
3014692168	New U Life Corporation 2623 Pleasant Hill Rd Pleasant Hill California United States 94523	SAN-DO	Distributor

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Fraud	website is misleading
Defective	product does not work

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Referred to Other FDA District	Tate,Leon P	11/28/2018

Initial Disposition Remarks

Manufacturer location provided to the DAL-DO in an email dated 30 November 2018 from (b) (4) (b) (4) . XYGENYX has an associated website xygenyx.com that sells SOMADERM Gel and Testall Gel.****ACTIVE INGREDIENTS: Glandula Suprarenalis Suis 6X, Thyroidinum (Bovine) 8X, HGH 30X INACTIVE: Purified Water, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, Sodium Hydroxide, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Peg-33, Peg-8 Dimethicone, Peg-14, Aloe Barbadensis Leaf Juice, Aloe Vera (Leaf)*, Green Tea (Leaf)*, Licorice (Root)*, Chaste Tree (Fruit)*, Epimedium (Leaf)*, Ginkgo (Leaf)*, Velvet Bean (Seed)*, Wild Yam (Root)*, Ascorbic Acid (Vitamin C), Tocopherols (Soy), Edetate Disodium, Natural Plant Extract, Potassium Sorbate. *Extract

Referrals

Org Name	HHS Mail Code
KAN-DO	HFR-SW300

There are no Cosmetics details for this Complaint.

There are no Adverse Event details for this Complaint.

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date

There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
No	(b) (4)			Manufacturer

Follow-Up Disposition	Disposition Made By	Disposition Date
Surveillance Information for Next EI	Johnson,Teresa S	02/25/2019

Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code

United States Food and Drug Administration
Consumer Complaint / Injury Report

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

COMPLAINT	# 155782

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
12/03/2018	DET-DO	KAN-DO	Telephone	(b) (6)	Becker,Keith A	Closed

Complainant Identification

Name	Address
(b) (6)	(b) (6)

Phone (W)	Phone (H)	Source POC Name	Source Phone
	(b) (6)		

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
New U Life - Soma Derma Gel Complainant is a (b) (6) former consumer whom used the product. In her own experience of using this product she had increase weight gain, breast enlargement and abnormal menses. In speaking with other consumers, she noted that in addition to the problems that she experienced others had Tachycardia and even some have developed cancer. She spoke with (b) (6) concerning these problems and was told that some of the in-active ingredients were powerful herbs. (b) (6) She is concerned that since she (b) (6) (b) (6) they may be using real HGH. In her experience, she has never seen anyone have the symptoms that she and other consumers are experiencing.	Non-Life Threatening Injury/Illness - No Adverse Event Reporting	unk	Other - identify in Remarks

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	02/25/2019					

Remarks
(b) (6), see symptoms section

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Change in menstrual pattern	RENAL/URINARY			
Change in breast size or tenderness	RENAL/URINARY			
Change in body weight	METABOLIC			

Health Care Professional

Provider Name	Address	Phone	Occupation

Hospital Information

Hospital Name	Address	Phone	Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
New U Life	Soma Derm Gel	60V-99	Anterior Pituitary Suppressor N.E.C.	56R801	

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
				No	

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
			No	United States	

Retail

Name	Address
N/A	

Problem Ingredient Group

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
(b) (4)			Manufacturer
3014692168	New U Life Corporation 2623 Pleasant Hill Rd Pleasant Hill California United States 94523	SAN-DO	Corporate Headquarters

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Other, identify in Details	Increase in Medical Conditions
Reaction	Abnormal medical reactions

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Referred to Other FDA District	Becker,Keith A	12/03/2018

Initial Disposition Remarks

Manufacturer and Corporate Headquarters determined by CC 155581 for same product

Referrals

Org Name	HHS Mail Code
KAN-DO	HFR-SW300
HAFW2	HAFW2

There are no Cosmetics details for this Complaint.
There are no Adverse Event details for this Complaint.

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date

There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
No	(b) (4)			Manufacturer

Follow-Up Disposition	Disposition Made By	Disposition Date
Surveillance Information for Next EI	Johnson,Teresa S	02/25/2019

Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code

United States Food and Drug Administration
Consumer Complaint / Injury Report

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

COMPLAINT # 156381

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
02/12/2019	DAL-DO	KAN-DO	Telephone	Consumer	Tate,Leon P	Closed

Complainant Identification

Name	Address
(b) (6)	(b) (6)

Phone (W)	Phone (H)	Source POC Name	Source Phone
	(b) (6)		

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
Complainant states she has experienced an adverse reaction from the use of Somaderm gel. She (b) (6) user of the product. Promotional claims state the human growth hormone product was FDA registered and approved with health benefits as improved skin, weight loss, and overall wellness. She used the product and began noticing redness of her skin at the application sites on her body. Her skin redness evolved to constant itching and scratching that developed into a rash. She experienced weight gain and jitters of the nerve. Complainant is (b) (6). She contacted (b) (6) was told to continue using the product that the redness on her skin would soon vanish. Complainant stated she used the product for several months, her adverse reactions did not subside until she terminated use of the product.	Non-Life Threatening Injury/Illness - No Adverse Event Reporting	01.21.19	Other - identify in Remarks

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	02/12/2019	No	No	No	Reported to Manufacturer	No

Remarks

Similar FACTS Consumer Compliant 155581. Rash, itching, weight gain. ****Complainant state (b) (6) (b) (6) adverse reactions to the product.

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Itching (pruritis)	SKIN	Weeks	Persists	Wrist, inside forearm, and top of feet.
Tingling	SKIN	Weeks	Persists	jitters
Rash	SKIN	Weeks	Persists	
Change in body weight	METABOLIC	Immediate	Persists	
Discoloration	SKIN	Immediate	Persists	redness

Health Care Professional

Provider Name	Address	Phone	Occupation

Hospital Information

Hospital Name	Address	Phone	Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
NewULife	Somaderm Gel	60V-99	Anterior Pituitary Suppressor N.E.C.	56R801	N / A

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
3.5 Ounces Bottle	(b) (6)	(b) (6)	(b) (6)	Yes	2 bottles

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
Aug 2018	01/21/20119	2 unopened bottles	No	United States	NDC: 61877-0005-1 (b) (6) . She purchased (b) (6) bottles; she have 2 nopened bottles ****Bottle retails 169.00 (b) (6) (b) (6)

Retail

Name	Address
n/a	

Problem Ingredient Group

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
(b) (4)			Manufacturer
3014692168	New U Life Corporation 2623 Pleasant Hill Rd Pleasant Hill California United States 94523	SAN-DO	Distributor

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Allergic Reaction	Redness, itching and jitters
Fraud	1). FDA Approved & Health claim. 2) Cost 169.00; does not work.3). Company refuses to give refund

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Referred to Other FDA District	Tate,Leon P	02/21/2019

Initial Disposition Remarks

Manufacturer location provided to the DAL-DO CCC in a previous email dated 30 November 2018 from (b) (4) (b) (4) . *****XYGENYX has an associated website xygenyx.com that sells SOMADERM Gel and Testall Gel.****ACTIVE INGREDIENTS: Glandula Suprarenalis Suis 6X, Thyroidinum (Bovine) 8X, HGH 30X INACTIVE: Purified Water, Phenoxyethanol, Caprylyl Glycol, Sorbic Acid, Sodium Hydroxide, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Peg-33, Peg-8 Dimethicone, Peg-14, Aloe Barbadensis Leaf Juice, Aloe Vera (Leaf)*, Green Tea (Leaf)*, Licorice (Root)*, Chaste Tree (Fruit)*, Epimedium (Leaf)*, Ginkgo (Leaf)*, Velvet Bean (Seed)*, Wild Yam (Root)*, Ascorbic Acid (Vitamin C), Tocopherols (Soy), Edetate Disodium, Natural Plant Extract, Potassium Sorbate. *Extract

Referrals

Org Name	HHS Mail Code
KAN-DO	HFR-SW300

There are no Cosmetics details for this Complaint.

There are no Adverse Event details for this Complaint.

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date

There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type
No	(b) (4)			Manufacturer

Follow-Up Disposition	Disposition Made By	Disposition Date
Surveillance Information for Next EI	Johnson,Teresa S	02/25/2019

Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code

United States Food and Drug Administration
Consumer Complaint / Injury Report

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

COMPLAINT # 156620

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
03/04/2019	NWE-DO	KAN-DO	Telephone	Consumer	Squire,Maura A	Pending at Branch

Complainant Identification

Name	Address
(b) (6)	(b) (6)

Phone (W)	Phone (H)	Source POC Name	Source Phone
	(b) (6)		

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
Product: New U Life Somaderm Transdermal Gel Maximum Strength Homeopathic Human Growth Hormone (OTC) - A (b) (6) y/o woman, with no prediagnosed conditions and not breastfeeding, experienced a very bloated abdomen, and little pieces of bloody tissue being frequently passed in 06/2018. She had an ultrasound and CAT Scan at (b) (6) (b) (6). She was diagnosed by (b) (6) and (b) (6) with three types of cancer: (1) endometrial; (2) ovarium of the left ovary; and (3) ovarium of the right ovary after they found 2 large masses on her ovaries. The physicians advised her that this was unusual as these cancers don't grow together. On (b) (6), she had a full hysterectomy at (b) (6), and was treated with chemotherapy. The symptom of little pieces of bloody tissue being frequently passed subsided within 3 months but the bloated abdomen has persisted, although it is much smaller. The Complainant believes that this HGH product caused her symptoms. She stated that she obtained this product during the time she (b) (6) (b) (6). She started using the product on or about 02/25/18, 1 bottle per month, according to instructions: 1 pump in the morning and 1 pump in the evening, 5 days on and 2 days off, applying the gel on one wrist and rubbing both wrists togehter and in creases of her arms. She used the gel for 6 months and discontinued in 06/2018. She had heard from other sources, including a homeopathic doctor, (b) (6), and read online that that people had used this product and had gotten symptoms, cancer and/or had died.	Non-Life Threatening Injury/Illness - No Adverse Event Reporting	06/2018	Other - identify in Remarks

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	03/04/2019	Yes	Yes	No	Not Reported to Manufacturer	Yes

Remarks

Complainant is not reporting Anonymously, but does not wish her name and contact information to be shared with company.

INJURY/ILLNESS: very bloated abdomen, and little pieces of bloody tissue being frequently passed.

CONTINUED FROM LABEL REMARKS, PAGE 2: WARNING: KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away. If pregnant or breast-feeding, ask a health professional before use. FOR EXTERNAL USE ONLY. Sealed for your protection. Do not use if seal has been broken or tampered with.

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Abdominal swelling	BLOOD OR LYMPHATIC	4 Months	Persists	very bloated abdomen, which now is slightly bloated
Other Urogenital	RENAL/URINARY	4 Months	3 Months	little pieces of bloody tissue being passed

Health Care Professional

Provider Name	Address	Phone	Occupation
(b) (6)			Medical Doctor (MD)

Hospital Information

Hospital Name	Address	Phone	Dates of Stay
(b) (6)			

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
New U Life	Somaderm Transdermal Gel Maximum Strength Homeopathic Human Growth Hormone (OTC)	64RBY18	Human Growth Hormone (Hormone);Human - Non/Rx Combination Ingredient;NEC	56R801	783583190473

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
3.5 Fluid ounces Bottle	(b) (6)	none on bottle	(b) (6)	Yes	all

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
est 02/25/18	08/02/2018none	has (b) (6) emaining bottles	No	United States	INGREDIENTS - ACTIVE: Glandula Suprarenalis Suis 6X, Thyroidinum 8X, Somatropin, 30X, INACTIVE: Purified Water, Aloe Vera Leaf, Green Tea (Leaf), Licorice (Root), Chaste Tree (Fruit), Epimedium (Leaf), Ginkgo (Leaf), Velvet Bean (Seed), Wild Yam (Root), Ascorbic Acid (Vitamin C), Phenoxyethanol (and) Caprylyl Glycol (and) Sorbic Acid, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Peg-33 (and) Peg-8 Dimethicone, (and) Peg-14, Aloe Barbadensis Leaf Juice, Tocopherols (Soy), Disodium EDTA, Natural Plant Extract, Sodium Hydroxide and Potassium Sorbate. DIRECTIONS: Apply 1 full pump in the morning and 1 full pump in the evening: 5 days on, 2 days off. For intensive use, apply 2 full pumps in the morning, 2 full pumps in the evening. Gel should always be applied to the thin areas of skin, wherever veins are visible. You may apply the gel to your underarms, forearms, wrists and behind the knees. Applied locations should be rotated. WARNINGS: Continued in Remarks

Retail

Name	Address
thru New U Life	2623 Pleasant Hill Rd Pleasant Hill CA 94523

Problem Ingredient Group

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
(b) (4)			Manufacturer
3014692168	New U Life Corporation 2623 Pleasant Hill Rd Pleasant Hill California United States 94523	SAN-DO	Corporate Headquarters

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Reaction	very bloated abdomen, and small pieces of bloody tissue frequently passed
Other, identify in Details	DX'd with 3 types of cancer: endometrial; (2) ovarian of left ovary; and (3) ovarian of right ovary

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Referred to Other FDA District	Squire,Maura A	03/04/2019

Initial Disposition Remarks

NWE-DO CCC verified manufacturer via Complainant and FMS.

The last EI for manufacturer concluded on (b) (4). There have been 2 CCs since last EI: CC 155581 (reported on 11/08/18 that this product is a scam and CC 155782 (reported on 12/03/18 by (b) (6)).

Transferred to KAN-DO.

Referrals

Org Name	HHS Mail Code
KAN-DO	HFR-SW300

There are no Cosmetics details for this Complaint.
There are no Adverse Event details for this Complaint.

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date

There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type

Follow-Up Disposition	Disposition Made By	Disposition Date

Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code

United States Food and Drug Administration
Consumer Complaint / Injury Report

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

COMPLAINT # **156627**

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
03/04/2019	NWE-DO	KAN-DO	Telephone	Consumer	Squire,Maura A	Pending at Branch

Complainant Identification

Name	Address
(b) (6)	(b) (6)

Phone (W)	Phone (H)	Source POC Name	Source Phone
	(b) (6)		

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
Product: New U Life Somaderm Transdermal Gel Maximum Strength Homeopathic Human Growth Hormone (OTC) - A (b) (6) y/o woman, with no pre-diagnosed conditions, and not breastfeeding, experienced menses increasing from every 4 weeks to every 2 weeks, gray hair reverting to original shade of brown, hands falling asleep, and lack of coordination starting in 10/2018. She did not seek healthcare, discontinued the product in 11/2018 and her symptoms subsided by 12/2018.	Death	10/2018 for both individuals	Other - identify in Remarks

The Complainant believes that this product caused her symptoms. She stated that she (b) (6) (b) (6) . She began taking it as directed: 1 pump in the morning, 1 pump in the evening, 5 days on and 2 days off, applying the gel on the wrists. She stated that her symptoms began in 2 months following first use. She read on an online site that hands falling asleep was a problem with other people and stopped putting the gel on her wrists, and started using it on other parts of her body where the skin was thin.

She stated that she discontinued the product due to the death of (b) (6) , who had been using the product since (b) (6) called the Complainant in mid-10/2018 and told her that she was having severe stomach cramps and was asking the Complainant questions about this. The Complainant advised (b) (6) to go to see a physician. (b) (6) visited an Onocologist at (b) (6) who administered a series of tests which resulted in her being diagnosed with Stage 4 Liver and Lung cancer. She went to the (b) (6) where she got a second opinion, which confirmed the first diagnosis by (b) (6) . The Complainant advised that the (b) (6) physician stated that, according to this HGH product label, it is a "placebo" and it couldn't cause anyone good or bad side effects. (b) (6) passed away in (b) (6) .

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	03/06/2019	Yes	Yes	No	Reported to Manufacturer	Yes

Remarks

Complainant has given permission to share her personal information with the company. She notified New U Life and has gotten no answers and feels as though she has been blackballed by the firm.

CONTINUED FROM LABEL REMARKS, PAGE 2: WARNING: KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away. If pregnant or breast-feeding, ask a health professional before use. FOR EXTERNAL USE ONLY. Sealed for your protection. Do not use if seal has been broken or tampered with.

INJURY/ILLNESS:
of Complainant: experienced menses increasing from every 4 weeks to every 2 weeks, gray hair reverting back to original shade of brown, hands falling asleep, and lack of coordination.

of (b) (6) experienced severe abdominal cramps and was diagnosed with Stage 4 Liver and Kidney Cancer and passed away in (b) (6).

Complainant has 4 bottles remaining: 1 partial (1 belongs to her boyfriend and the 2nd is her own, Lot code (b) (6) (b) (6), No Exp Date, UPC: 783583190473); and 3 closed (1 belonged to her boyfriend, 1 belonged to (b) (6) and 1 is her own)

(b) (6), previous address: (b) (6)

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Change in menstrual pattern	RENAL/URINARY	2 Months	2 Months	Complainant: menses increasing from every 4 weeks to every 2 weeks; Friend: unk symptoms of Stage 4
Dizziness or problems with balance	NERVOUS	2 Months	2 Months	Complainant: lack of coordination
Change in sensation (numbness, tingling)	NERVOUS	2 Months	2 Months	Complainant: hands falling asleep
Other Change in hair or nails, not listed	SKIN	2 Months	2 Months	Complainant: gray hair reverting to original
Abdominal cramps	GASTROINTESTINAL	2 Months		(b) (6) passed away on (b) (6)

Health Care Professional

Provider Name	Address	Phone	Occupation
(b) (6)			Medical Doctor (MD)

Hospital Information

Hospital Name	Address	Phone	Dates of Stay
(b) (6)			

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
New U Life	Somaderm Transdermal Gel Maximum	64RBY18	Human Growth Hormone (Hormone);Human - Non/Rx Combination Ingredient;NEC	56R801	783583190473

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
3.5 Fluid ounces Bottle	(b) (6)	None on bottle	(b) (6)	Yes	3 bottles/has 1/2 bottle

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
mid 08/2018	11/2018	3	No	United States	INGREDIENTS - ACTIVE: Glandula Suprarenalis Suis 6X, Thyroidinum 8X, Somatropin, 30X, INACTIVE: Purified Water, Aloe Vera Leaf, Green Tea (Leaf), Licorice (Root), Chaste Tree (Fruit), Epimedium (Leaf), Ginkgo (Leaf), Velvet Bean (Seed), Wild Yam (Root), Ascorbic Acid (Vitamin C), Phenoxyethanol (and) Caprylyl Glycol (and) Sorbic Acid, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Peg-33 (and) Peg-8 Dimethicone, (and) Peg-14, Aloe Barbadensis Leaf Juice, Tocopherols (Soy), Disodium EDTA, Natural Plant Extract, Sodium Hydroxide and Potassium Sorbate. DIRECTIONS: Apply 1 full pump in the morning and 1 full pump in the evening: 5 days on, 2 days off. For intensive use, apply 2 full pumps in the morning, 2 full pumps in the evening. Gel should always be applied to the thin areas of skin, wherever veins are visible. You may apply the gel to your underarms, forearms, wrists and behind the knees. Applied locations should be rotated. WARNINGS: Continued in Remarks on page 1.

Retail

Name	Address
thru New U Life	2623 Pleasant Hill Rd Pleasant Hill CA 94523

Problem Ingredient Group

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
(b) (4)			Manufacturer
3014692168	New U Life Corporation 2623 Pleasant Hill Rd Pleasant Hill California United States 94523	SAN-DO	Corporate Headquarters

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Other, identify in Details	(b) (6) , experienced severe abdominal cramps
Reaction	Complainant: menses 4 to 2 wks; gray hair to original brown; hands falling asleep; lack of coord.
Death	death of (b) (6) , from this product from Stage 4 Liver and Kidney Cancer on (b) (6) .

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Referred to Other FDA District	Squire,Maura A	03/12/2019

Initial Disposition Remarks

NWE-DO CCC verified manufacturer via Complainant and FMS in CC 156620, reported to NWE-DO on 03/04/19, and FMS.

The last EI for manufacturer concluded on (b) (4) . There have been 3 CCs since last EI: CC 155581 (reported on 11/08/18 that this product is a scam and CC 155782 (reported on 12/03/18 by (b) (6)), and CC 156620.

(b) (5) .

Transferred to KAN-DO.

Referrals

Org Name	HHS Mail Code
KAN-DO	HFR-SW300

There are no Cosmetics details for this Complaint.

There are no Adverse Event details for this Complaint.

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date

There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type

Follow-Up Disposition	Disposition Made By	Disposition Date

Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code

United States Food and Drug Administration
Consumer Complaint / Injury Report

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

COMPLAINT # **156677**

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
03/06/2019	NWE-DO	KAN-DO	Telephone	Consumer	Squire,Maura A	Pending at Branch

Complainant Identification

Name	Address
(b) (6)	(b) (6)

Phone (W)	Phone (H)	Source POC Name	Source Phone
	(b) (6)		

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
Product: New U Life Somaderm Transdermal Gel Maximum Strength Homeopathic Human Growth Hormone (OTC) - A (b) (6) y/o woman, with a pre-diagnosed medical condition, experienced heart palpitations, insomnia, severe headaches, and pain when opening and closing hands in mid-06/2018. She discontinued use of this product in mid-07/2018, and her symptoms subsided by mid-08/2018. Pre-diagnosed medical condition: diagnosed with Hyperthyroidism at age (b) (6) y/o (estimated), by an MD. The Complainant (woman) believes that this product caused her symptoms. She stated that she is (b) (6) (b) (6) obtained this product from the firm in the beginning of (b) (6). She began using the product in mid-06/2018 as directed on the label: 1 pump in the morning, 1 pump in the evening, 5 days on and 2 days off, applying the gel on the wrists. She began experiencing the symptoms within 2 weeks and cut down her dosage to 1/2 pump, 2x a day, on the wrist, 5 days on and 2 days off. She discontinued it altogether at end of 07/2019 and her symptoms subsided in about 2 weeks by mid-08/2019. She asked New U Life, Inc., Customer Service questions many timse regarding this product as she was very concerned and did not receive any answers. She is aware of (b) (6) having issues with this product as well. She discarded remaining 1.5 bottles and has not product information available.	Non-Life Threatening Injury/Illness - No Adverse Event Reporting	mid-06/2018	Other - identify in Remarks

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	03/07/2019	No	No	No	Reported to Manufacturer	Yes

Remarks

CONTINUED FROM LABEL REMARKS, PAGE 2: WARNING: KEEP OUT OF REACH OF CHILDREN. If swallowed, get medical help or contact a Poison Control Center right away. If pregnant or breast-feeding, ask a health professional before use. FOR EXTERNAL USE ONLY. Sealed for your protection. Do not use if seal has been broken or tampered with.

INJURY/ILLNESS: heart palpitations, severe headaches, insomnia, and pain when opening and closing hands.

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Change in heart rate, pulse; palpitations, fibrillation	CARDIOVASCULAR	2 Weeks	2 Weeks	heart palpitations
Sleep problems	NERVOUS	2 Weeks	2 Months	insomnia
Headache	CARDIOVASCULAR	2 Weeks	2 Months	severe
Other extremity pain	MUSCULO-SKELETAL	2 Weeks	2 Months	pain when opening and closing hands

Health Care Professional

Provider Name	Address	Phone	Occupation

Hospital Information

Hospital Name	Address	Phone	Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
New U Life	Somaderm Transdermal Gel Maximum	64RBY18	Human Growth Hormone (Hormone);Human - Non/Rx Combination Ingredient;NEC	56R801	783583190473

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
3.5 Fluid ounces Bottle	not available	not available	(b) (6)	Yes	est 1.5 bottles

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
06/2018 - 08/2018	07/2018	none- discarded	No	United States	INGREDIENTS - ACTIVE: Glandula Suprarenalis Suis 6X, Thyroidinum 8X, Somatropin, 30X, INACTIVE: Purified Water, Aloe Vera Leaf, Green Tea (Leaf), Licorice (Root), Chaste Tree (Fruit), Epimedium (Leaf), Ginkgo (Leaf), Velvet Bean (Seed), Wild Yam (Root), Ascorbic Acid (Vitamin C), Phenoxyethanol (and) Caprylyl Glycol (and) Sorbic Acid, Acrylates/C10-30 Alkyl Acrylate Crosspolymer, Peg-33 (and) Peg-8 Dimethicone, (and) Peg-14, Aloe Barbadensis Leaf Juice, Tocopherols (Soy), Disodium EDTA, Natural Plant Extract, Sodium Hydroxide and Potassium Sorbate. DIRECTIONS: Apply 1 full pump in the morning and 1 full pump in the evening: 5 days on, 2 days off. For intensive use, apply 2 full pumps in the morning, 2 full pumps in the evening. Gel should always be applied to the thin areas of skin, wherever veins are visible. You may apply the gel to your underarms, forearms, wrists and behind the knees. Applied locations should be rotated. WARNINGS: Continued in Remarks on page 1.

Retail

Name	Address
obtained thru New U Life, Inc	

Problem Ingredient Group

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
(b) (4)			Manufacturer
3014692168	New U Life Corporation 2623 Pleasant Hill Rd Pleasant Hill California United States 94523	SAN-DO	Corporate Headquarters

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Reaction	heart palpitations, insomnia, severe headaches, and pain when opening and closing hands

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Referred to Other FDA District	Squire,Maura A	03/12/2019

Initial Disposition Remarks

NWE-DO CCC verified manufacturer via Complainant in CC 156620, reported to NWE-DO on 03/04/19, and FMS.

The last EI for manufacturer concluded on (b) (4). There have been 3 CCs since last EI: CC 155581 (reported on 11/08/18 that this product is a scam and CC 155782 (reported on 12/03/18 by (b) (6)), and CC 156620 and CC 156627.

Transferred to KAN-DO.

Referrals

Org Name	HHS Mail Code
KAN-DO	HFR-SW300

There are no Cosmetics details for this Complaint.
There are no Adverse Event details for this Complaint.

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date

There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type

Follow-Up Disposition	Disposition Made By	Disposition Date

Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code

United States Food and Drug Administration
Consumer Complaint / Injury Report

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

COMPLAINT	# 157391

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
03/05/2019	FLA-DO	KAN-DO	Telephone	(b) (6)	Milan,Stephanie C	Pending at Branch

Complainant Identification

Name	Address
(b) (6)	(b) (6)

Phone (W)	Phone (H)	Source POC Name	Source Phone
N/A	N/A	(b) (6)	N/A

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
On 03/05/19 (b) (6) (b) (6), contacted FLA-DO to report the following concerns: Somaderm Gel, (Glandula Suprarenalis Suis,Thyroidinum (bovine), HGH), has major undeclared side effects which include : rashes, burning of the skin, increased thyroid levels, elevated heart rate, elevated blood pressure, and potential cancer increase after using the product. Please see continuation in "Remarks"			

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
No		N/A	N/A	N/A	Not Report to Other Source	N/A

Remarks

Continuation from "Complainant Description":

Anonymity Statement:

For anonymity the complainant's information has been removed from the following sections: "Complainant Name (Last, First)", "Street Address", "City", "Zip", and "Phone", Federal regulatory officials may obtain this information by contacting FDA, FLA-DO, CC, by phone :407-475-4762, 1-866-337-6272, or e-mail: ORAFLACC@FDA.HHS.GOV .

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks

Health Care Professional

Provider Name	Address	Phone	Occupation

Hospital Information

Hospital Name	Address	Phone	Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
New U Life Corporation,	Somaderm Gel	64RDY18	Human Growth Hormone (Hormone);Human - Rx/Combination Ingredient;NEC	56R801	N/A

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
100 Grams Bottle	N/A	N/A	N/A	No	N/A

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
N/A	N/A	N/A	No	United States	NDC #: 61877-0002, 61877-0003, 61877-0004, 61877-0005, and 61877-0006

Retail

Name	Address
New Life Corporation, website: http://newulife.com ,	2623 Pleasent Hill Road, Pleasent Hill, CA 94523

Problem Ingredient Group

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
(b) (4)			Manufacturer
3014692168	New U Life Corporation 2623 Pleasant Hill Rd Pleasant Hill California United States 94523	SAN-DO	Corporate Headquarters

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Other, identify in Details	Somaderm Gel, has major undeclared side effects.

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Referred to Other FDA District	Milan,Stephanie C	05/08/2019

Initial Disposition Remarks

I located the most responsible firm through FACTS/MARC.

Referrals

Org Name	HHS Mail Code
KAN-DO	HFR-SW300
SAN-DO	HFR-PA100

There are no Cosmetics details for this Complaint.
There are no Adverse Event details for this Complaint.

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date

There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type

Follow-Up Disposition	Disposition Made By	Disposition Date

Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code

United States Food and Drug Administration
Consumer Complaint / Injury Report

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

COMPLAINT # 157749

Complaint Date	Receiving Organization	Accomplishing District	How Received	Complaint Source	Complaint Received By	Complaint Status
06/12/2019	NYK-DO	KAN-DO	Telephone	Consumer	Allen,Vera L	Pending at Branch

Complainant Identification

Name	Address
(b) (6)	(b) (6)

Phone (W)	Phone (H)	Source POC Name	Source Phone
	(b) (6)		

Complaint/Injury

Complaint Description	Adverse Event Result	Adverse Event Date	Injury / Illness
(b) (6) year old male complainant with no known allergies and taking no medications began using New U Life Somaderm HGH Gel around Oct 2018. He applied product to his wrist a few times daily. Only other products he used on his skin were shampoos and deordorants. After a month of use he experienced weight gain of 20 pounds. Around April 2019 he began to experience an enlarged thyroid, trouble swallowing food and feeling extremely cold. He discontinued use 05/28/2019 and believes product in question caused his symptoms.	Non-Life Threatening Injury/Illness - No Adverse Event Reporting	04/2019	Other - identify in Remarks

Notify DEIO/EMOPS?	Notification Date	Attended Health Professional?	Required Hospitalization?	Emergency Room / Outpatient Visit?	Reported Complaint To?	Need addnl. FDA Contact?
Yes	06/12/2019	No	No	No	Reported to Manufacturer	

Remarks

See below

Complaint Symptoms

Sympton	System Affected	Onset Time	Duration	Remarks
Change in body weight	METABOLIC	1 Months	Persists	Gained 20 pounds
Change in body temperature	CARDIOVASCULAR	5 Months	Persists	Feels extremely cold
Difficulty swallowing	GASTROINTESTINAL	5 Months	Persists	Trouble swallowing food
Local swelling	BLOOD OR LYMPHATIC	5 Months	Persists	Enlarged thyroid

Health Care Professional

Provider Name	Address	Phone	Occupation

Hospital Information

Hospital Name	Address	Phone	Dates of Stay

Emergency Room/Outpatient Visit

Hospital Name	Address	Phone	ER Date

Product and Labeling

Brand Name	Product Name	Product Code	Product Description	PAC	UPC Code
New U Life	Somaderm HGH Gel	64RBJ18	Human Growth Hormone (Hormone);Human - Non/Rx Combination Ingredient;NonSterile Ointment	56R801	UNK

Qty / Unit / Package	Lot/ Serial #	Exp/Use by Date	Purchase Date	Product Used	Amount Consumed/Used
	UNK	UNK	10/2018	Yes	UNK

Date Used	Date Discontinued	Amount Remained	Imported Product?	Country of Origin	Label Remarks
10/2018 - 05/28/2019	05/28/2019	NONE	No	United States	

Retail

Name	Address
Received products through a friend	

Problem Ingredient Group

Manufacturer/Distributor

FEI	Name & Address	Home District	Firm Type
(b) (4)			Manufacturer
3014692168	New U Life Corporation 2623 Pleasant Hill Rd Pleasant Hill California United States 94523	SAN-DO	Distributor

Initial Evaluation/Initial Disposition

Problem Keyword	Problem Keyword Details
Reaction	Weight gain, difficulty swallowing food, enlarged thyroid, feeling extremely cold

Initial Evaluation	Initial Disposition	Disposition Made By	Disposition Date
FDA Action Indicated	Referred to Other FDA District	Allen,Vera L	06/12/2019

Initial Disposition Remarks

Manu verified via CC 155581 in FACTS

Referrals

Org Name	HHS Mail Code
KAN-DO	HFR-SW300

There are no Cosmetics details for this Complaint.
There are no Adverse Event details for this Complaint.

Complaint #157749

COMPLAINTS FOLLOW - UP

Grouped Follow - Up Operations

Operation Id	Operation Code	Assignment Number	Accomplishing Organization	Performing Organization	Sample Number	PAF	Status	Status Date

There are no Follow Up Operations related to this complaint.

Disposition Summary

Is Consumer Responsible?	Responsible FEI	Address	Name	Firm Type

Follow-Up Disposition	Disposition Made By	Disposition Date

Disposition Remarks

Follow-Up Sent To

Organization Name	HHS Mail Code