FDA Adverse Event Reporting System (FAERS)

FOIA Batch Printing Report for Cases

Date - T me: 4-Sep-2023 :2 :23 EDT

Run by: KIA BAZEMORE@FDA HHS GOV

Disclaimer:

Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distr butor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

Data provided in the Quarterly Data Extract (QDE) or a FAERS FOIA report are a snapshot of FAERS at a given time. There are several reasons that a case captured in this snapshot can be marked as inactive and not show up in subsequent reports. Manufacturers are allowed to electronically delete reports they submitted if they have a valid reason for deletion. FDA may merge cases that are found to describe a single event, marking one of the duplicate reports as inactive. The data marked as inactive are not lost but may not be available under the original case number.

The cover page will display all Case ID(s) included in the Batch Printing Report and FOIA case report information may include both Electronic Submissions (Esubs) and MedWatch Reports (Non-Esubs).

Cover page Case ID(s) with an asterisk ('*') indicate an invalid status and are not captured in the body of the report.

Cover page Case ID(s) with an asterisk ('**') indicate an failed status and are not captured in the body of the report.

Case ID(s) Printed:

22255819	22279615	22350139	22359564
22370050	22372901	22518701	22533945
22632639	22638742	22638777	22651073

Total Cases: 12

Total number of Inactive cases: *0

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22255819

Case Information:

Case Type : Direct **eSub:** N **HP:** N **Country:** US **Event Date:** 15-Apr-2023 **Outcomes:** RI **Application Type:**

FDA Rcvd Date: 26-Apr-2023 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2023-31081 **Application #:**

Patient Information:

Age: 26 YR **Sex:** Female **Weight:** 117 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozepmic		1 Dosage Form / 999	Subcutaneous	1 INJECTION WEEKLY SUBCUTANEOUS	insulin resistance and help her loose weight		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozepmic		No	Yes				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Anxiety	Yes
Suicidal ideation	Yes

Event/Problem Narrative:

Ozempic was injected then within couple of hours the patient felt extremely anxious and then starting having suicidal thoughts and these thoughts existed for about 2 days. then towards the end of the week the feelings subsided. Then then next dose dose was given and the the same anxious thoughts and suicidal thoughts are occurring.

Relevant Medical History:

List known medical conditions : anxiety; Please list all allergies : tetracycline, sulfa drugs; List any other important information about the person : none

Disease/Surgical Procedure	Start Date	End Date	Continuing?

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22255819

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	vitamin d	/						
2	b12	/						
3	magnesium	/						

Reporter Source:

Study report?: No **Sender organization:** FDA-CTU **503B Compounding Outsourcing Facility?:**

Literature Text:

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	26-Apr-2023	CTU Received Date	26-Apr-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	15-Apr-2023
	Serious	No
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☑ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Ozempic was injected then within couple of hours the patient felt extremely anxious and then starting having suicidal thoughts and these thoughts existed for about 2 days. then towards the end of the week the feelings subsided. Then then next dose dose was given and the the same anxious thoughts and suicidal thoughts are occurring.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	No

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about			
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Ozepmic		
Name of the company that makes (or compounds) the product	Novo Nordisc		
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength	0.25 mg mg milligram(s)	If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No		
Did the problem return if the person started taking or using the product again?	Yes		

Drug Therapy 1 of 1

Expiration date			
Lot number			
Dosage Form			
Quantity	Other	If Other	1 Injection(s)
Frequency	Other	If Other	weekly
How was it taken or used	Subcutaneous	If Other	
Date the person first started taking or using the product			
Date the person stopped taking or using the product			
Date the person reduced dose of the product			

Give best estimate of duration	14 Day	
Is therapy still on-going?		

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

insulin resistance and help her loose weight

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	Unspecified
Sex	Female
Gender	Decline to answer
Please Specify Other Gender	
Age (specify unit of time for age)	26 Year(s)
Date of Birth	
Weight	117 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)
anxiety

Please list all allergies (such as to drugs, foods, pollen or others)
tetracycline, sulfa drugs

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)
none

List all current prescription medications and medical devices being used.
none

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.
vitamin d, b12, magnesium

Section F - About the Person Filling Out This Form	1 of 1
Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	(b) (6)
Number/Street	
City	
State/Province	--
Country	UNITED STATES
ZIP or Postal code	
Telephone number	(b) (6)
Email address	(b) (6)
Fax	
Reporter Organization	

	Department		
	Reporter Speciality		
	Today's date	26-Apr-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22279615

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** N **Country:** US **Event Date:** 24-Apr-2023 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 03-May-2023 **Mfr Rcvd Date:** 24-Apr-2023 **Mfr Control #:** US-ELI_LILLY_AND_COMPANY-US202304012891 **Application #:** 215866

Patient Information:

Age: 48 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Mounjaro 2.5mg		2.5 Mg Milligram(S) /	Subcutaneous	2.5 mg, unknown	10057097		
2	Mounjaro 5mg		5 Mg Milligram(S) /	Subcutaneous	5 mg, unknown	10057097		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Mounjaro 2.5mg		Unknown	Unknown	D552772C			ELI LILLY AND CO	
2	Mounjaro 5mg		Unknown	NA	D563883D			ELI LILLY AND CO	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Depression	
Depressed mood	
Sleep deficit	
Disturbance in attention	
Hypopnoea	
Hypophagia	

Case ID: 22279615

Hypersomnia

Fatigue

Event/Problem Narrative:

This spontaneous case, reported by consumer, who contacted the company to report adverse events, concerned a 47-year-old male patient of an unknown origin. Medical history and concomitant medication were not provided. The patient received tirzepatide (Mounjaro) via a pre-filled pen, 2.5 mg, via subcutaneous route, unknown frequency, for treatment of unknown indication, started on an unknown date. On an unknown, while on tirzepatide therapy, he was feeling blah, not depressed but not happy as normal. He was expecting impact on appetite and was looking for side effect of nausea, but nothing was happening, so he went up to 5 mg tirzepatide dose and still nothing was happening. On 24-Apr-2023, after, second dose of 5 mg tirzepatide dose, he was not eating, wreck, was sleeping on and off, had sleep deprivation and have not been able to focus. While working, four hours had passed, that is when he realized that he had been just staring at the computer screen. He had lot of fatigue, slept 12-14 hours a day and had massive amount problem in focusing. He also noticed shallow breathing episodes. In addition, he had depression, have the blues before, but literally have never had suicidal ideation before. He was known it was related to the treatment. He had thoughts saying he should kill himself, and then think back. He have unique experience with suicidal ideation because he worked in jail before, but others may not be that aware like he does, and it was due to medication. He does not need a wellness check. The event of suicidal thoughts was considered as serious by the company due to medically significant reason. Information regarding corrective treatment, outcome of the events and status of tirzepatide treatment was not provided. The initial reporting consumer did not provide the relatedness assessment of event feeling abnormal to 2.5 mg tirzepatide treatment while did not associate the remaining events to tirzepatide 5 mg. The initial reporting consumer related the event of suicidal ideation and depression however did not provide the relatedness assessment of remaing events to tirzepatide 5 mg.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22279615

Reporter Source:

Study report?: No

Sender organization: ELI LILLY AND CO

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22350139

Case Information:

Case Type : Direct **eSub:** N **HP:** **Country:** US **Event Date:** 13-May-2023 **Outcomes:** RI **Application Type:**

FDA Rcvd Date: 19-May-2023 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2023-37843 **Application #:**

Patient Information:

Age: 23 YR **Sex:** Male **Weight:** 189.9 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	OZEMPIC (SEMAFLUTIDE INJECTION)		1 Dosage Form / QW	Subcutaneous	OTHER QUANTITY : 1 Injection(s); Frequency : Weekly;	PRE DIABETES	13-May-2023	13-May-2023

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	OZEMPIC (SEMAFLUTIDE INJECTION)		No	Yes	NZF4S74	31-Oct-2024	0169-4181-13	NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Loss of personal independence in daily activities	Yes
Fatigue	Yes
Impaired work ability	Yes
Impaired driving ability	Yes
Unhealthy lifestyle	Yes
Disturbance in attention	Yes
Depression	Yes

Anxiety	Yes
Emotional distress	Yes
Feeling of despair	Yes
Suicidal ideation	Yes
Vision blurred	Yes
Eye pain	Yes
Photophobia	Yes
Frustration tolerance decreased	Yes
Quality of life decreased	Yes
Therapy cessation	Yes

Event/Problem Narrative:

Severe Side Effects from Ozempic (semaglutide) ? Request for Urgent Attention Dear FDA Office of Drug Safety, I am writing to bring to your attention my personal experience with the medication Ozempic (semaglutide) and the severe adverse effects I have been enduring. I believe it is crucial to report these side effects in order to protect the well-being of other patients who may be prescribed this medication. On May 13, 2023, I began taking Ozempic as prescribed by my healthcare provider for the prevention of prediabetes, as I was at high risk of developing type 2 diabetes. Unfortunately, shortly after initiating the treatment, I started experiencing a range of distressing side effects that have significantly impacted my daily life. First and foremost, I have been plagued with extreme fatigue, to the point where carrying out even the simplest tasks has become overwhelming. This persistent and debilitating exhaustion has severely hindered my ability to perform my regular activities, including work, driving, and maintaining a healthy lifestyle. I find myself unable to concentrate or focus on essential tasks due to the overwhelming fatigue induced by the medication. Furthermore, I have been experiencing extreme depression and anxiety, which I had never encountered prior to starting Ozempic. These mental health conditions have taken a toll on my overall well-being, causing emotional distress, feelings of hopelessness, and difficulty in coping with daily life. The depressive symptoms have been so severe that, for the first time in my life, I have experienced suicidal thoughts, which has been a frightening and distressing experience for me and my loved ones. Moreover, since taking Ozempic, I have also encountered troubling issues with my vision. Blurriness, occasional eye pain, and heightened light sensitivity have become regular occurrences. These visual impairments have impacted my ability to work, read, and engage in daily activities, leading to further frustration and diminished quality of life. In light of these severe and debilitating side effects, I have been compelled to discontinue the use of Ozempic under the guidance of my healthcare provider. While I understand that every medication carries some level of risk, the intensity and impact of these side effects have been deeply distressing and completely disrupted my life. I urge the FDA to thoroughly investigate and review the adverse effects associated with Ozempic. It is crucial to assess the risk-benefit profile of this medication and ensure that patients are adequately informed about the potential risks and alternative treatment options. I strongly believe that the safety and well-being of patients should be the utmost priority, and any medication that poses such severe risks should be reevaluated and closely monitored. I would be more than willing to provide any additional information or participate in further discussions to contribute to the evaluation of these adverse effects. Please consider this letter as my official report, and I trust that the FDA will take prompt action to address these concerns and protect the health and safety of patients who may be at risk. Thank you for your attention to this matter.

Relevant Medical History:

List known medical conditions : PRE DIABETES, MORBID OBESITY;

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22350139

Disease/Surgical Procedure	Start Date	End Date	Continuing?

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	MELOXICAM	/						
2	VITAMIN D3	/						

Reporter Source:

Study report?: No **Sender organization:** FDA-CTU **503B Compounding Outsourcing Facility?:**

Literature Text:

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	19-May-2023	CTU Received Date	19-May-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	13-May-2023
Serious	No
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☑ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Severe Side Effects from Ozempic (semaglutide) ? Request for Urgent Attention Dear FDA Office of Drug Safety, I am writing to bring to your attention my personal experience with the medication Ozempic (semaglutide) and the severe adverse effects I have been enduring. I believe it is crucial to report these side effects in order to protect the well-being of other patients who may be prescribed this medication. On May 13, 2023, I began taking Ozempic as prescribed by my healthcare provider for the prevention of prediabetes, as I was at high risk of developing type 2 diabetes. Unfortunately, shortly after initiating the treatment, I started experiencing a range of distressing side effects that have significantly impacted my daily life. First and foremost, I have been plagued with extreme fatigue, to the point where carrying out even the simplest tasks has become overwhelming. This persistent and debilitating exhaustion has severely hindered my ability to perform my regular activities, including work, driving, and maintaining a healthy lifestyle. I find myself unable to concentrate or focus on essential tasks due to the overwhelming fatigue induced by the medication. Furthermore, I have been experiencing extreme depression and anxiety, which I had never encountered prior to starting Ozempic. These mental health conditions have taken a toll on my overall well-being, causing emotional distress, feelings of hopelessness, and difficulty in coping with daily life. The depressive symptoms have been so severe that, for the first time in my life, I have experienced suicidal thoughts, which has been a frightening and distressing experience for me and my loved ones. Moreover, since taking Ozempic, I have also encountered troubling issues with my vision. Blurriness, occasional eye pain, and heightened light sensitivity have become

regular occurrences. These visual impairments have impacted my ability to work, read, and engage in daily activities, leading to further frustration and diminished quality of life. In light of these severe and debilitating side effects, I have been compelled to discontinue the use of Ozempic under the guidance of my healthcare provider. While I understand that every medication carries some level of risk, the intensity and impact of these side effects have been deeply distressing and completely disrupted my life. I urge the FDA to thoroughly investigate and review the adverse effects associated with Ozempic. It is crucial to assess the risk-benefit profile of this medication and ensure that patients are adequately informed about the potential risks and alternative treatment options. I strongly believe that the safety and well-being of patients should be the utmost priority, and any medication that poses such severe risks should be reevaluated and closely monitored. I would be more than willing to provide any additional information or participate in further discussions to contribute to the evaluation of these adverse effects. Please consider this letter as my official report, and I trust that the FDA will take prompt action to address these concerns and protect the health and safety of patients who may be at risk. Thank you for your attention to this matter.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	
Low Test Range		High Test Range	
More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Food/Medical food		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	OZEMPIC (SEMAFLUTIDE INJECTION)		
Name of the company that makes (or compounds) the product	NOVO NORDISK		
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength	0.25/0.5 ml millilitre(s)	If Other	
NDC number	0169-4181-13		
Did the problem stop after the person reduced the dose or	No		

stopped taking or using the product?		
Did the problem return if the person started taking or using the product again?	Yes	

Drug Therapy 1 of 1

Expiration date	31-Oct-2024		
Lot number	NZF4S74		
Dosage Form			
Quantity	Other	If Other	1 Injection(s)
Frequency	Other	If Other	ONCE WEEKLY
How was it taken or used	Subcutaneous	If Other	
Date the person first started taking or using the product	13-May-2023		
Date the person stopped taking or using the product	13-May-2023		
Date the person reduced dose of the product			
Give best estimate of duration			
Is therapy still on-going?			

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

PRE DIABETES

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Age (specify unit of time for age)	23 Year(s)
Date of Birth	
Weight	189.9 kg
Ethnicity (Choose only one)	Hispanic/Latino
Race (Check all that apply)	☑ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

PRE DIABETES, MORBID OBESITY

Please list all allergies (such as to drugs, foods, pollen or others)

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

MELOXICAM (AS NEEDED FOR JOINT PAIN)

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

VITAMIN D3

Section F - About the Person Filling Out This Form 1 of 1

	Primary?	Yes
	Reporter is Patient?	
	Title	
	Last name	(b) (6)
	Middle Name	
	First name	
	Number/Street	
	City	
	State/Province	
	Country	
	ZIP or Postal code	
	Telephone number	
	Email address	
	Fax	
	Reporter Organization	
	Department	
	Reporter Speciality	
	Today's date	19-May-2023
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No

0.25 mg

0.5 mg

OZEMPIC®

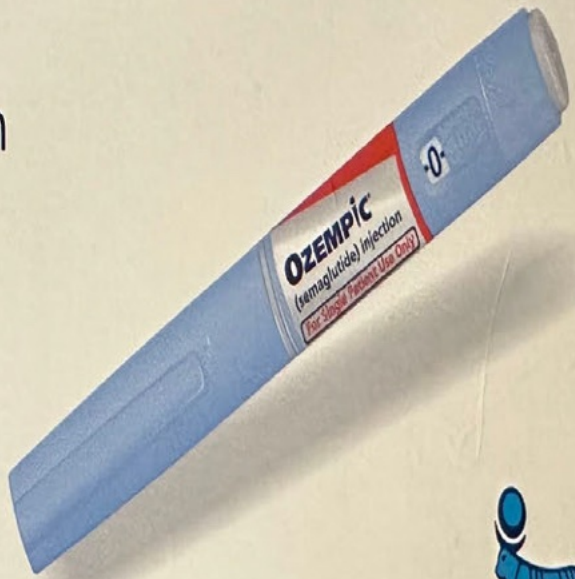
(semaglutide) injection

NDC 0169-4181-13 List 418113

For Single Patient Use Only

2 mg/3 mL (0.68 mg/mL) Prefilled pen

Pen delivers doses in 0.25 mg or 0.5 mg increments only



For subcutaneous use only

Use OZEMPIC once weekly

Contains: 1 OZEMPIC pen, 6 NovoFine® Plus 32G needles, Product Literature.

Dispense the enclosed Medication Guide to each patient.

novo nordisk®

Open here

Use as directed by your healthcare professional.
Dosage: See prescribing information.
Subcutaneous use only
Sterile
Rx only

Each prefilled pen contains 2 mg semaglutide in 3 mL and will deliver 4 doses of 0.25 mg and 2 doses of 0.5mg or 4 doses of 0.5 mg.

REFRIGERATE – DO NOT FREEZE.
After first use, store at a temperature below 86°F (30°C).

Discard pen 56 days after first use.

Ingredients: Each 1 mL of OZEMPIC contains 0.68 mg of semaglutide and the following inactive ingredients: disodium
dihydrate, 1.42 mg; pr
glycol, 14.0 mg; pheno
and water for injectio

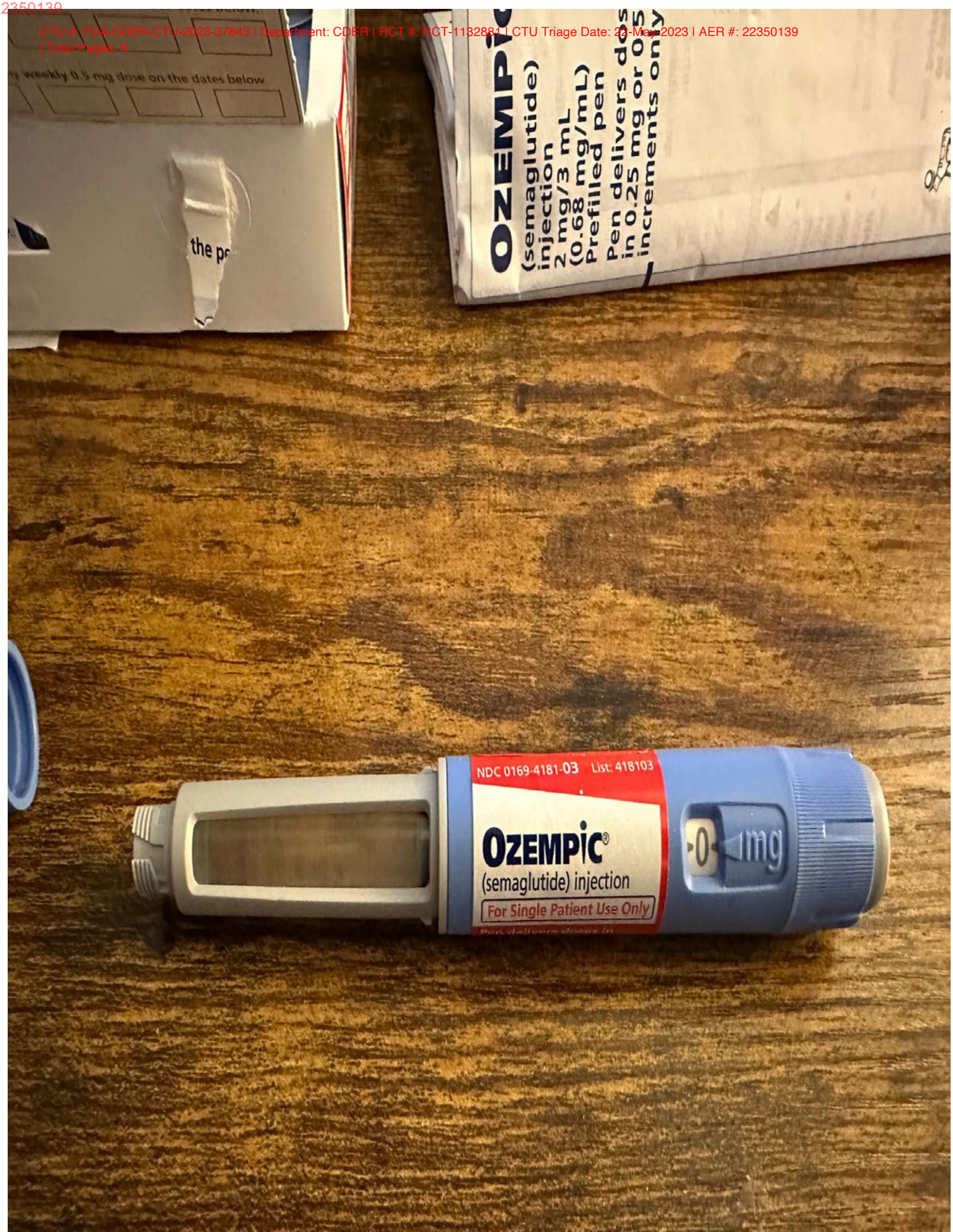
Each prefilled pen con
solution of OZEMPIC e
2 mg semaglutide.

Not a child resistant co
If the seal is broken be
contact your pharmaci

PATENT Information:
https://www.novonord
products/product-pate

OZEMPIC® and NovoFi
registered trademarks
Novo Nordisk A/S.

(b) (6)



FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22359564

Case Information:

Case Type : Direct **eSub:** N **HP:** **Country:** US **Event Date:** 28-Apr-2023 **Outcomes:** LT , RI **Application Type:** COMP

FDA Rcvd Date: 23-May-2023 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2023-38607 **Application #:** 99

Patient Information:

Age: 65 YR **Sex:** Male **Weight:** 85.5 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic (semaglutide) injection	Y	/	Other	OTHER ROUTE : injected into stomach area;	lower sugar levels	10-Jan-2022	05-Jun-2022

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic (semaglutide) injection		Yes	Yes	LX40189	31-Oct-2026			

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Depressed mood	Yes
Suicidal ideation	Yes
Merycism	Yes
Judgement impaired	Yes
Anosognosia	Yes
Disturbance in attention	Yes
Abulia	Yes
Paranoia	Yes

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22359564

Event/Problem Narrative:

Tell us what happened and how it happened : I was prescribed Ozempic by my endocrinologist(b)(6)********** in January of 2022. The doctor prescribed me this medication to keep my sugar levels under control. After taking Ozempic my symptoms included depressed mood, suicidal thinking, paranoid thinking, intense ruminations, loss of judgment and insight, inability to judge what was real and what was not, poor concentration. I lacked capacity to make decisions during that time and started to feel extremely paranoid and depressed, After noticing a change in my mood and my life, i decided to go see a Psychiatrist - who prescribed psychotropic medications - but towards the end had believed my symptoms were secondary to a medical drug i had been prescribed. After severe damage to my life, my health and my mental state, i finally realized that Ozempic was the reason i was feeling ill and decided to cut out the medication completely - within 6 weeks of not taking the medication i was able to come back to my senses and gain my life back - but not soon enough to stop some of the damage the side effects had caused.;

Relevant Medical History:

List known medical conditions : diabetes, high blood pressure; Please list all allergies : no allergies; List any other important information about the person : N/A

Disease/Surgical Procedure	Start Date	End Date	Continuing?

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study report?: No **Sender organization:** FDA-CTU **503B Compounding Outsourcing Facility?:**

Literature Text:

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	High		
Override Auto Calculation Rule	No		
FDA Received Date	23-May-2023	CTU Received Date	23-May-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	28-Apr-2023
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☑ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☑ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

I was prescribed Ozempic by my endocrinologist (b) (6) in January of 2022. The doctor prescribed me this medication to keep my sugar levels under control. After taking Ozempic my symptoms included depressed mood, suicidal thinking, paranoid thinking, intense ruminations, loss of judgment and insight, inability to judge what was real and what was not, poor concentration. I lacked capacity to make decisions during that time and started to feel extremely paranoid and depressed, After noticing a change in my mood and my life, i decided to go see a Psychiatrist - who prescribed psychotropic medications - but towards the end had believed my symptoms were secondary to a medical drug i had been prescribed. After severe damage to my life, my health and my mental state, i finally realized that Ozempic was the reason i was feeling ill and decided to cut out the medication completely - within 6 weeks of not taking the medication i was able to come back to my senses and gain my life back - but not soon enough to stop some of the damage the side effects had caused.

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	

Low Test Range		High Test Range		
More Information Available?				

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	Yes

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Other		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Ozempic (semaglutide) injection		
Name of the company that makes (or compounds) the product			
Product Type(check all that apply)	☐ Over-the-Counter ☑ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☑ Biosimilar		
Strength	2mg/1.5 ml (1.34 mg/ml) prefilled mg milligram(s)	If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Yes		

Drug Therapy 1 of 1

Expiration date	31-Oct-2026		
Lot number	LX40189		
Dosage Form			
Quantity		If Other	
Frequency		If Other	
How was it taken or used	Other	If Other	injected into stomach area

	Date the person first started taking or using the product	10-Jan-2022
	Date the person stopped taking or using the product	05-Jun-2022
	Date the person reduced dose of the product	
	Give best estimate of duration	
	Is therapy still on-going?	

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

	lower sugar levels

	Returned to Manufacturer On	

Section D - About the Medical Device

	Name of medical device	
	Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

	Model Number	
	Catalog Number	
	Lot Number	
	Serial Number	
	UDDI Number	
	Expiration date	
	Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

	Person's Initials	(b) (6)
	Sex	Male
	Gender	Cisgender man/boy
	Please Specify Other Gender	
	Age (specify unit of time for age)	
	Date of Birth	(b) (6)
	Weight	85.5 kg
	Ethnicity (Choose only one)	Not Hispanic/Latino

Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

diabetes, high blood pressure

Please list all allergies (such as to drugs, foods, pollen or others)

no allergies

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

N/A

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	
Number/Street	
City	
State/Province	
Country	
ZIP or Postal code	

	Telephone number	(b) (6)	
	Email address		
	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	23-May-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

(b) (6)

OZEMPIC®
(semaglutide) injection

For Single Patient Use Only

2 mg/1.5 mL (1.34 mg/mL) Prefilled pen

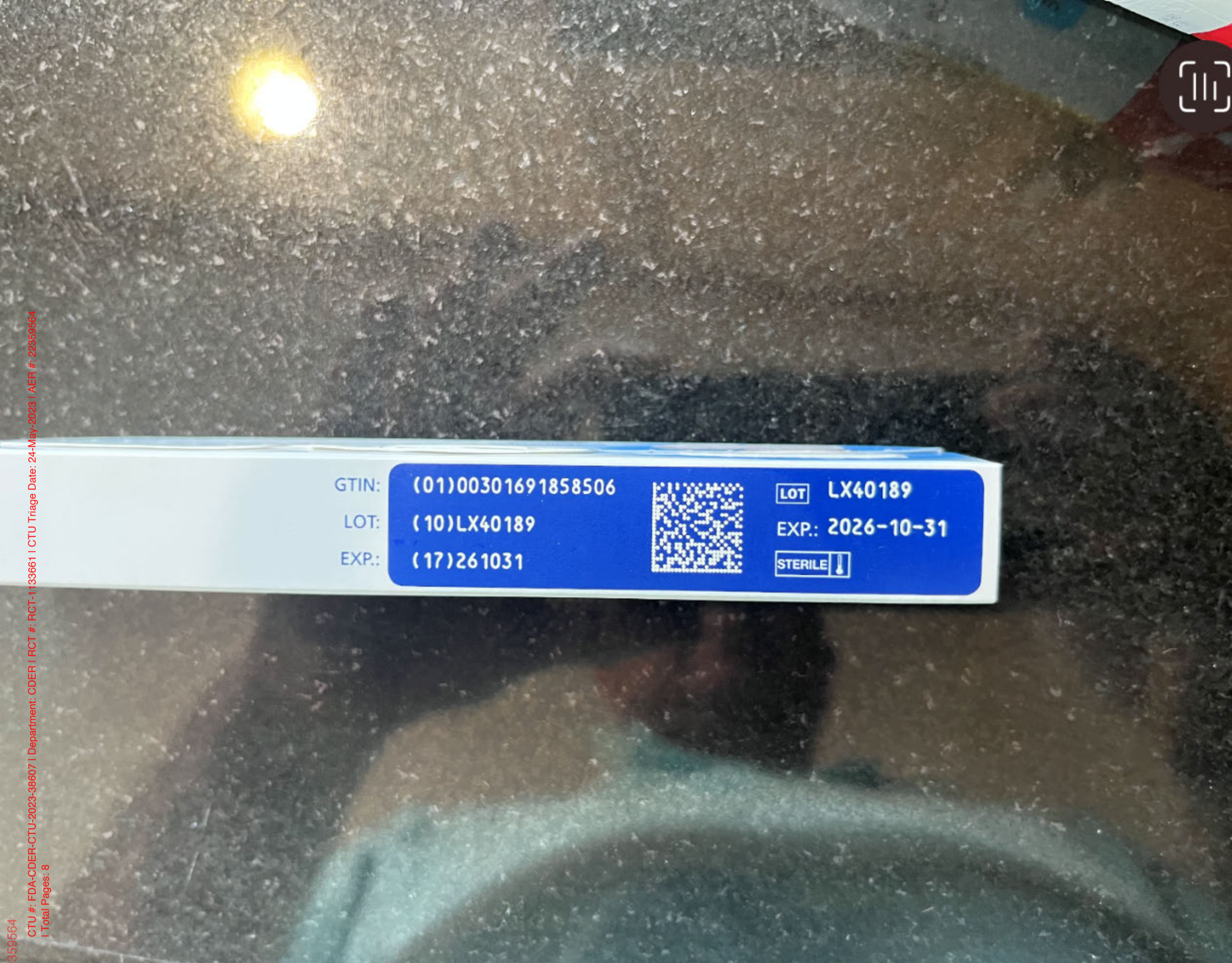
Pen delivers doses in 0.25 mg or 0.5 mg increments only

For subcutaneous use only

Use OZEMPIC once weekly

Contains: 1 OZEMPIC pen, 6 NovoFine® Plus 32G needles

Dispense the enclosed Medication Guide to each patient



(b) (6)

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22370050

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** DK **Event Date:** 02-Mar-2023 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 17-Jul-2023 **Mfr Rcvd Date:** 10-Jul-2023 **Mfr Control #:** DK-NOVOPROD-1064502 **Application #:** 215256

Patient Information:

Age: 44 YR **Sex:** Female **Weight:** 83 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Wegovy FlexTouch 0.25 mg		0.25 Mg Milligram(S) / /WK		0.25 mg, qw	Overweight	01-Mar-2023	Mar-2023
2	Wegovy FlexTouch 0.25 mg		0.25 Mg Milligram(S) / /WK		0.25 mg, qw		25-Apr-2023	
3	Wegovy FlexTouch 0.5 mg		0.5 Mg Milligram(S) / / WK		0.5 mg, qw	Overweight	Mar-2023	05-Apr-2023

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Wegovy FlexTouch 0.25 mg	1 Day	NA	NA				NOVO NORDISK	
2	Wegovy FlexTouch 0.25 mg	1 Day	NA	NA				NOVO NORDISK	
3	Wegovy FlexTouch 0.5 mg		Yes	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Restlessness	

Case ID: 22370050

Suicidal ideation

Depression

Anxiety

Event/Problem Narrative:

This serious Spontaneous Regulatory Authority case received via Danish Medicines Agency(DKMA) from DENMARK was reported by a Physician as "Restlessness/stress in the body recovered 17apr2023 but re-emerged 26apr2023 after one injection of 0.25 mg 25apr2023(Restlessness)" beginning on 02-MAR-2023, "suicidal ideation - could be deflected(Suicidal ideation)" beginning on 04-APR-2023, "Depression(Depression)" beginning on 06-APR-2023, "Anxiety(Anxiety)" beginning on 06-APR-2023, and concerned a 44 Years old Female patient who was treated with Wegovy FlexTouch 0.25 mg (SEMAGLUTIDE) from 01-MAR-2023 and ongoing for "Overweight", Wegovy FlexTouch 0.5 mg (SEMAGLUTIDE) from MAR-2023 to 05-APR-2023 for "Overweight". Patient's height: 180 cm Patient's weight: 83 kg Patient's Body mass index (BMI): 25.617284. Dosage Regimens: Wegovy FlexTouch 0.25 mg: 01-MAR-2023 to ??-MAR-2023, 25-APR-2023 to Not Reported (Dosage Regimen Ongoing); Wegovy FlexTouch 0.5 mg: ??-MAR-2023 to 05-APR-2023; Current Condition: Overweight, Hypercholesterolaemia Historical Condition: Anxiety, depression. Concomitant products included - VENLAFAXIN BLUEFISH(VENLAFAXINE HYDROCHLORIDE), SERTRALIN ACCORD(SERTRALINE HYDROCHLORIDE) On 02-MAR-2023, patient experienced Restlessness/stress in the body that recovered 17-APR-2023. On 04-APR-2023, patient experienced 'suicidal ideation - could be deflected' On 06-APR-2023, patient experienced Depression and anxiety On 26-APR-2023 , Restlessness/stress in the body re-emerged after one injection of 0.25 mg 25-APR-2023. On an unknown date, Body mass index (Body mass index) was slightly above 27 (units not reported) Batch Numbers: Wegovy FlexTouch 0.25 mg: was not reported Wegovy FlexTouch 0.5 mg: was not reported Action taken to Wegovy FlexTouch 0.25 mg was reported as No Change. Action taken to Wegovy FlexTouch 0.5 mg was reported as Product discontinued. The outcome for the event "Restlessness/stress in the body recovered 17apr2023 but re-emerged 26apr2023 after one injection of 0.25 mg 25apr2023(Restlessness)" was Not recovered. On 15-APR-2023 the outcome for the event "suicidal ideation - could be deflected(Suicidal ideation)" was Recovered. On 17-APR-2023 the outcome for the event "Depression(Depression)" was Recovered. On 17-APR-2023 the outcome for the event "Anxiety(Anxiety)" was Recovered. Since last submission the case has been updated with the following: General tab updated (hcp reporter added) Event tab updated (Medical Confirmation by HCP was changed to yes) Narrative updated accordingly. Company comment: Restlessness, Suicidal ideation, Depression, and Anxiety are assessed as unlisted according to the Novo Nordisk current CCDS on Wegovy. Medical history of anxiety and depression are assessed as risk factors for the reported events. Limited information as related to family/ social history, circumstances surrounding the events, details of treatment given if any, and diagnostic evaluation precludes detailed medical evaluation. This single case report is not considered to change the current knowledge of the safety profile of Wegovy. No further information available. References included: Reference Type: E2B Report Duplicate Reference ID#: DK-DKMA-ADR 27871487 Reference Notes: DKMA Reference Type: E2B Authority Number Reference ID#: DK-DKMA-WBS-1004511 Reference Notes: Reference Type: E2B Report Duplicate Reference ID#: DK-DKMA-WBS-1004511 Reference Notes: DKMAEFORMS

Relevant Medical History:

Patient informs that she has not experienced symptoms of anxiety or depression for many years due to the prophylactic treatment.

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Overweight			Yes
Hypercholesterolaemia			Yes
Anxiety			

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22370050

Depression

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
BODY MASS INDEX					Y

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	VENLAFAXIN BLUEFISH	/		UNK	Anxiety	01-Aug-2013		3533 Day
2	SERTRALIN ACCORD	/		UNK	Anxiety	01-Mar-2008		5512 Day

Reporter Source:

Study report?: No **Sender organization:** NOVO NORDISK **503B Compounding Outsourcing Facility?:**

Literature Text:

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22372901

Case Information:

Case Type : Direct **eSub:** N **HP:** **Country:** US **Event Date:** 25-May-2023 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 25-May-2023 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2023-39461 **Application #:**

Patient Information:

Age: 32 YR **Sex:** Female **Weight:** 131.85 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	MOUNJARO		/			pcos	01-Mar-2023	25-May-2023

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	MOUNJARO		No	Yes					

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	Yes
Depression	Yes
Personality change	Yes

Event/Problem Narrative:

Tell us what happened and how it happened : suicidal ideation, very bad depression, personality changes/ isolation on Mounjaro;

Relevant Medical History:

List known medical conditions : pcos; Please list all allergies : bactrim;

Disease/Surgical Procedure	Start Date	End Date	Continuing?

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22372901

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	vitamin d	/						
2	b12	/						
3	iron	/						
4	iron	/						

Reporter Source:

Study report?: No **Sender organization:** FDA-CTU **503B Compounding Outsourcing Facility?:**

Literature Text:

All dates displayed in the report are in EST(GMT-05:00) time zone

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	25-May-2023	CTU Received Date	25-May-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	25-May-2023
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
	Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

suicidal ideation, very bad depression, personality changes/ isolation on Mounjaro

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	

More Information Available?	

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	No

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Other		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	MOUNJARO		
Name of the company that makes (or compounds) the product			
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	No		
Did the problem return if the person started taking or using the product again?	Yes		

Drug Therapy 1 of 1

Expiration date			
Lot number			
Dosage Form			
Quantity		If Other	
Frequency		If Other	
How was it taken or used		If Other	
Date the person first started taking or using the product	01-Mar-2023		
Date the person stopped taking or using the product	25-May-2023		

Date the person reduced dose of the product	
Give best estimate of duration	
Is therapy still on-going?	Yes

Why was the person using the product? (such as what condition was it supposed to treat) 1 of 1

pcos

Returned to Manufacturer On	

Section D - About the Medical Device

Name of medical device	
Name of the company that makes the medical device	

Other identifying information (The model, catalog, lot, serial, or UDI number, and the expiration date, if you can locate them)

Model Number	
Catalog Number	
Lot Number	
Serial Number	
UDDI Number	
Expiration date	
Was someone operating the medical device when the problem occurred?	

For implanted medical devices ONLY (such as pacemakers, breast implants, etc.)

Date the implant was put in		Date the implant was taken out (If relevant)	

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Gender	Cisgender woman/girl
Please Specify Other Gender	
Age (specify unit of time for age)	32 Year(s)
Date of Birth	
Weight	131.85 kg
Ethnicity (Choose only one)	
Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian

	☑ White ☑ Black or African American

List known medical conditions (Such as diabetes, high blood pressure, cancer, heart disease, or others)

pcos

Please list all allergies (such as to drugs, foods, pollen or others)

bactrim

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

List all current prescription medications and medical devices being used.

List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used.

vitamin d, b12, iron

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	
Number/Street	
City	
State/Province	
Country	
ZIP or Postal code	
Telephone number	
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	25-May-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22518701

Case Information:

Case Type : Direct **eSub:** N **HP:** N **Country:** US **Event Date:** 14-May-2023 **Outcomes:** DE **Application Type:**

FDA Rcvd Date: 02-Jun-2023 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2023-41147 **Application #:**

Patient Information:

Age: **Sex:** Male **Weight:** 235 LBS

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	OZEMPIC		/ QW	Subcutaneous	Frequency : Weekly;	to treat his type 2 diabetes and hopefully lose weight		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	OZEMPIC		NA	Not Applicable				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Depression	NA
Suicidal ideation	NA
Weight decreased	NA
Gun shot wound	NA
Completed suicide	NA

Event/Problem Narrative:

Tell us what happened and how it happened : My brother 13 months ago (April of 2022) was diagnosed with new onset clinical depression. He sought treatment and was doing very well. Around sometime in January or February of 2023 he was prescribed Ozempic for his Type 2 diabetes by his family medicine physician dosed with a build-up to 1 mg per week via injection. Ozempic, SEMAGLUTIDE, or We govy SEMAGLUTIDE (stated in section 5.9 of Wegovy's PI) should be avoided in patients with a history of suicidal attempts or active suicidal ideation. Semaglutide, if prescribed, patients should be monitored for the emergence or worsening of depression, suicidal thoughts or behaviors, and / or any unusual changes in mood or behavior. It is well written in literature and a plethora of

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22518701

drug websites that Ozempic can trigger these thoughts, but healthcare providers are not warned and subsequentially patients are not informed. My brother (b)(6)********** had extreme weight-loss of 60lbs in a matter of months on Ozempic and no monitoring. No screening questions asked – healthcare providers are not being properly detailed on this drug – it is being pushed so heavily for the latest miracle-loss drug. There is no black box warning or alert in OZEMPIC prescribing information to alert healthcare providers or patients about suicidal thoughts and it is my belief that many healthcare professionals are not aware of the potential deadly adverse event. Again, Doctors are not being informed properly to screen for this or monitor appropriately. Therefore, this drug is being prescribed to very vulnerable people unaware and triggering suicidal thoughts in some people. On the morning of (b)(6)********** he got up early, made coffee, while his fiancé was in nearby bedroom, and preceded at some point to go outside to their patio pavilion and kill himself by gun-shot wound to the head. He was on medications he had been on for years. He was not on anything new until Ozempic was prescribed. There were no outward reasons or any warning for this to happen. It seemingly was a spur of the moment decision he made. His life was very good. He was getting married in the fall – he said he was the happiest he had ever been. He had a great job, he was financially secure and had 4 beautiful children, and his second grandchild on the way. He had a very loving and close immediately and extended family. My family and I feel this could have caused the suicide or significantly contributed. ;

Relevant Medical History:

List known medical conditions : diabetes, high blood pressure, high triglycerides, hashimoto's disease, depression Allergies: NKA;

Disease/Surgical Procedure	Start Date	End Date	Continuing?

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study report?: No **Sender organization:** FDA-CTU **503B Compounding Outsourcing Facility?:**

Literature Text:

MedWatch Voluntary Report

1 2 3 4 5 6

Review & Submit

About Problem

Edit Section

What kind of problem was it?	• Were hurt or had a bad side effect *(including new or w orsening symptoms)*
Did any of the following happen?	• Death *(Date of Death)*: (b) (6)
Date the problem occurred:	05/14/2023

Tell us what happened and how it happened:	My brother 13 months ago (April of 2022) was diagnosed wi th new onset clinical depression. He sought treatment and was doing very well. Around sometime in January or Februa ry of 2023 he was prescribed Ozempic for his Type 2 diabet es by his family medicine physician dosed with a build-up to 1 mg per week via injection. Ozempic, SEMAGLUTIDE, or We govy SEMAGLUTIDE (stated in section 5.9 of Wegovy's PI) s hould be avoided in patients with a history of suicidal attem pts or active suicidal ideation. Semaglutide, if prescribed, p atients should be monitored for the emergence or worsenin g of depression, suicidal thoughts or behaviors, and /or any unusual changes in mood or behavior. It is well written in lit erature and a plethora of drug websites that Ozempic can tri gger these thoughts, but healthcare providers are not warne d and subsequentially patients are not informed. My brother (b) (6) had extreme weight-loss of 60lbs in a m atter of months on Ozempic and no monitoring. No screenin g questions asked - healthcare providers are not being prop erly detailed on this drug - it is being pushed so heavily for t he latest miracle weight- loss drug. There is no black box w arning or alert in OZEMPIC prescribing information to alert h ealthcare providers or patients about suicidal thoughts and it is my belief that many healthcare professionals are not a ware of the potential deadly adverse event. Again, Doctors a re not being informed properly to screen for this or monitor appropriately. Therefore, this drug is being prescribed to ver y vulnerable people unaware and triggering suicidal thought s in some people. On the morning of (b) (6) h e got up early, made coffee, while his fiancé was in nearby b edroom, and preceded at some point to go outside to their p atio pavilion and kill himself by gun-shot wound to the head. He was on medications he had been on for years. He was n ot on anything new until Ozempic was prescribed. There wer e no outward reasons or any warning for this to happen. It s eemingly was a spur of the moment decision he made. His l ife was very good. He was getting married in the fall - he sai d he was the happiest he had ever been. He had a great job, he was financially secure and had 4 beautiful children, and h is second grandchild on the way. He had a very loving and cl

	ose immediate and extended family. My family and I feel thi s could have caused the suicide or significantly contributed.
Relevant Tests/Laboratory Data:	
Additional Comments:	
Please select the cause of the problem that applies below:	• Problem with a product
Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product?	

About Product

Edit Section

Product 1	
This report is about:	Other
Check if therapy is on-going	
Name(s) of the product as it appears on the box, bottle, or package:	OZEMPIC
Name(s) of the company that makes (or compounds) the product:	NOVO NORDISC
Product Type:	
Expiration date:	
Lot number:	
NDC number:	
Strength:	1 MG
Quantity:	1 Injection(s)
Frequency:	weekly

How was it taken or used?	injected into the stomach, thighs or arm
Date the person first started taking or using the product:	
Date the person stopped taking or using the product:	
Date the person reduced dose of product:	
Give best estimate of duration:	3 Month(s)
Why was the person using the product?	to treat his type 2 diabetes and hopefully lose weight
Did the problem stop after the person reduced the dose or stopped taking or using the product?	
Did the problem return if the person started taking or using the product again?	Didn't restart

About Patient

Edit Section

Person's Initials:	Unspecified
Sex:	Male
Gender:	Cisgender man/boy (gender corresponds with birth sex)
Age:	
Date of Birth:	(b) (6)
Weight:	235 lb
Ethnicity:	Not Hispanic/Latino
Race:	White

List known medical conditions:	diabetes, high blood pressure, high triglycerides, hashimoto's disease, depression
Please list all allergies:	NKA
List any other important information about the person:	
List all current prescription medications and medical devices being used:	
List all over-the-counter medications and any vitamins, minerals, supplements, and herbal remedies being used:	

About Reporter

Edit Section

Name:	(b) (6)
Preferred Address:	
Telephone number:	
Email address:	
Did you report this problem to the company that makes the product (the manufacturer/compounder)?	Yes
If you do NOT want your identity disclosed to the manufacturer, place an "X" in this box:	☐

reCAPTCHA *

I'm not a robot

reCAPTCHA

Previous Submit Exit

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22533945

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** US **Event Date:** Apr-2023 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 07-Sep-2023 **Mfr Rcvd Date:** 29-Aug-2023 **Mfr Control #:** US-NOVOPROD-1072596 **Application #:** 209637

Patient Information:

Age: 75 YR **Sex:** Male **Weight:** 85.714 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic 0.25/0.50 mg		/	Subcutaneous	UNK	Type 2 diabetes mellitus	Jan-2023	
2	Ozempic 0.25/0.50 mg		0.5 Mg Milligram(S) / / WK	Subcutaneous	0.5 mg, qw		Apr-2023	30-May-2023
3	DULOXETINE		/	Oral	UNK	Product used for unknown indication		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 0.25/0.50 mg		Yes	NA				NOVO NORDISK	
2	Ozempic 0.25/0.50 mg		Yes	NA				NOVO NORDISK	
3	DULOXETINE		Unknown	NA					

Event Information:

Preferred Term (MedDRA Version: v.26.0) **ReC**

Suicidal ideation

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Physician as "suicidal thoughts(Suicidal ideation)" beginning on APR-2023, and concerned a 75 Years old Male patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from JAN-2023 to 30-MAY-2023 for "Type 2 diabetes mellitus", a non-Novo Nordisk suspect product DULOXETINE (DULOXETINE) from unknown start date for "Drug use for unknown indication". Patient's height:

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22533945

165.1 cm Patient's weight: 85.7 kg Patient's BMI: 31.4. Current Condition: Type 2 diabetes mellitus, Chronic kidney disease 3, Hypertension. A physician reported that a patient receiving therapy with Ozempic 0.5 mg and duloxetine experienced suicidal thoughts in APR-2023. The physician reported the suicidal thoughts started after the Ozempic dosage was changed to 0.5 mg. As a result of the suicidal thoughts, the Ozempic was discontinued, and the patient recovered. The physician felt the suicidal thoughts were probably related to the use of Ozempic. Batch number unavailable. Since last submission of the case, the following has been updated: -Healthcare provider name updated, secondary reporter added -Patient DOB, height/weight added. -Medical history added -Ozempic action taken updated to product discontinued due to AE, start/stop date added. Duloxetine added as co-suspect -Suicidal thoughts start date added, outcome updated to recovered, and HCP causality updated to probable -Narrative updated accordingly Company Comment: Suicidal ideation is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. Concurrent therapy with antidepressant duloxetine has been associated with an increased risk for emergence of suicidal behavior and considered a confounder. Limited information on medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluations precludes medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Type 2 diabetes mellitus			Yes
Chronic kidney disease			Yes
Hypertension			Yes

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22533945

Study report?: No

Sender organization: NOVO NORDISK

503B Compounding Outsourcing Facility?:

Literature Text:

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22632639

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** US **Event Date:** **Outcomes:** DE **Application Type:**

FDA Rcvd Date: 23-Jun-2023 **Mfr Rcvd Date:** 13-Jun-2023 **Mfr Control #:** US-NOVOPROD-1079624 **Application #:** 209637

Patient Information:

Age: **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		/	Subcutaneous	UNK	Product used for unknown indication		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic		Not Applicable	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0) **ReC**

Completed suicide

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Physician as "Committed suicide(Completed suicide)" with an unspecified onset date, and concerned a Female patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for "drug use for unknown indication", Current Condition: Bipolar disease. On an unspecified date, the patient committed suicide while taking the medication. Batch Numbers for Ozempic has been requested Action taken to Ozempic was reported as Not Applicable. The outcome for the event "Committed suicide(Completed suicide)" was Fatal. Company Comment: “Completed suicide” is assessed as unlisted according to the Novo Nordisk current CCDS information on Ozempic. Information on medical history including social and family behavior, any depression, details of severity of bipolar disorder and treatment adherence, circumstances that lead to the suicide attempt, any previous episodes of suicide attempt would have helped in thorough medical assessment. Patients medical history of bipolar disorder is assessed as risk factor for the reported event. This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

Relevant Medical History:

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22632639

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Bipolar disorder			

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study report?: No **Sender organization:** NOVO NORDISK **503B Compounding Outsourcing Facility?:**

Literature Text:

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22638742

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** IL **Event Date:** **Outcomes:** DE **Application Type:**

FDA Rcvd Date: 26-Jun-2023 **Mfr Rcvd Date:** 12-Jun-2023 **Mfr Control #:** IL-NOVOPROD-1078441 **Application #:** 209637

Patient Information:

Age: **Sex:** Male **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		/		UNK	Product used for unknown indication		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic		NA	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0) **ReC**

Depression

Completed suicide

Event/Problem Narrative:

This serious Spontaneous case from ISRAEL was reported by a General physician as "depression who suicide(Depression)" with an unspecified onset date, "suicide(Suicide)" with an unspecified onset date, and concerned a Male patient (age not reported) who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for "product use for unknown indication", Dosage Regimens: Ozempic: Medical history was not provided. On an unknown date, patient was in depression and committed suicide. Batch Numbers: Ozempic: not reported Action taken to Ozempic was reported as No Change. The outcome for the event "depression who suicide(Depression)" was Fatal. The outcome for the event "suicide(Suicide)" was Fatal. No further information available. Company comment: Depression and suicide are assessed as unlisted events according to Novo Nordisk current CCDS on Ozempic The information regarding event and therapy dates, indication for use of the suspect product, complete medical history, previous history of suicide attempt, relevant investigation reports, concomitant medications, are unavailable which limits the medical assessment of the case. Depression is considered as significant risk factor for committing suicide. This single case report is not considered to change the current knowledge of the safety profile of Ozempic

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22638742

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study report?: No **Sender organization:** NOVO NORDISK **503B Compounding Outsourcing Facility?:**

Literature Text:

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22638777

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** CA **Event Date:** **Outcomes:** HO **Application Type:**

FDA Rcvd Date: 26-Jun-2023 **Mfr Rcvd Date:** 14-Jun-2023 **Mfr Control #:** CA-NOVOPROD-1080133 **Application #:** 209637

Patient Information:

Age: 63 YR **Sex:** Female **Weight:** 93 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic 0.25/0.50 mg		0.5 Mg Milligram(S) / / WK	Subcutaneous	0.5 mg, qw	Type 2 diabetes mellitus		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 0.25/0.50 mg		Unknown	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Gastrointestinal pain	
Decreased appetite	

Event/Problem Narrative:

This serious Spontaneous Regulatory Authority case received from the Health Canada, CA, CANADA was reported by a Pharmacist as "Suicidal ideation(Suicidal ideation)" with an unspecified onset date, "Gastrointestinal pain(Gastrointestinal pain)" with an unspecified onset date, "Decreased appetite(Decreased appetite)" with an unspecified onset date, and concerned a 63 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from unknown start date for "Type 2 Diabetes mellitus", Patient's height: 154 cm Patient's weight: 93 kg Patient's BMI: 39.21403270. Dosage Regimens: Ozempic 0.25/0.50 mg: Current Condition: Type 2 diabetes mellitus. Concomitant products included - ASA, CALCIUM, COLACE(DOCUSATE SODIUM), COVERSYL PERINDOPRIL ARGININE, DEXILANT(DEXLANSOPRAZOLE), DIAMICRON(GLICLAZIDE), LIPITOR(ATORVASTATIN CALCIUM), LYRICA(PREGABALIN), METFORMIN, MIRAPEX(PRAMIPEXOLE DIHYDROCHLORIDE MONOHYDRATE), MONOCOR(BISOPROLOL FUMARATE), MYRBETRIQ(MIRABEGRON), NASONEX(MOMETASONE FUROATE), NOROMBY(ENOXAPARIN SODIUM), PEGALAX(MACROGOL 3350),

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22638777

SYNTHROID(LEVOTHYROXINE SODIUM), TRELEGY ELLIPTA(FLUTICASONE FUROATE, UMECLIDINIUM BROMIDE, VILANTEROL TRIFENATATE), TYLENOL(PARACETAMOL), VITAMIN B12 [VITAMIN B12 NOS], VITAMIN D [VITAMIN D NOS], DEEP RELIEF ULTRA (NON-CODABLE) On an unknown date, patient experienced decreased appetite, gastrointestinal pain, suicidal ideation and was hospitalized (Other details of hospitalization were not reported). Batch Numbers of Ozempic 0.25/0.50 mg was not available. Action taken to Ozempic 0.25/0.50 mg was Not reported. The outcome for the event "Suicidal ideation(Suicidal ideation)" was Recovered. The outcome for the event "Gastrointestinal pain(Gastrointestinal pain)" was Recovered. The outcome for the event "Decreased appetite(Decreased appetite)" was Recovered. No further information available References included: Reference Type: E2B Authority Number Reference ID#: CA- HEALTHCANVIG- 001036287 Reference Notes: Health Canada, CA Company Comment: “Suicidal ideation” is assessed as unlisted; “Gastrointestinal pain” and “Decreased appetite” as listed according to the Novo Nordisk current CCDS information on Ozempic. Information on event onset date and suspected product exposure details, relevant medical history including any previous episodes of suicidal thoughts , social circumstance, anxiety, depression or other psychiatric illness in the past are missing. Limited information precludes thorough medical assessment of the event suicidal ideation This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Type 2 diabetes mellitus			Yes

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	ASA	/		UNK	Product used for unknown indication			
2	CALCIUM	/		UNK	Product used for unknown indication			
3	COLACE	/		UNK	Product used for unknown indication			

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22638777

4	COVERSYL [PERINDOPRIL ARGININE]	/	UNK	Product used for unknown indication
5	DEXILANT	/	UNK	Product used for unknown indication
6	DIAMICRON	/	UNK	Product used for unknown indication
7	LIPITOR	/	UNK	Product used for unknown indication
8	LYRICA	/	UNK	Product used for unknown indication
9	METFORMIN	/	UNK	Product used for unknown indication
10	MIRAPEX	/	UNK	Product used for unknown indication
11	MONOCOR	/	UNK	Product used for unknown indication
12	MYRBETRIQ	/	UNK	Product used for unknown indication
13	NASONEX	/	UNK	Product used for unknown indication
14	NOROMBY	/	UNK	Product used for unknown indication
15	PEGALAX	/	UNK	Product used for unknown indication
16	SYNTHROID	/	UNK	Product used for unknown indication
17	TRELEGY ELLIPTA	/	UNK	Product used for unknown indication

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22638777

18	TYLENOL	/	UNK	Product used for unknown indication
19	VITAMIN B12 [VITAMIN B12 NOS]	/	UNK	Product used for unknown indication
20	VITAMIN D [VITAMIN D NOS]	/	UNK	Product used for unknown indication

Reporter Source:

Study report?: No **Sender organization:** NOVO NORDISK **503B Compounding Outsourcing Facility?:**

Literature Text:

FDA - Adverse Event Reporting System (FAERS)
FOIA Case Report Information

Case ID: 22651073

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** N **Country:** US **Event Date:** **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 28-Jun-2023 **Mfr Rcvd Date:** 23-Jun-2023 **Mfr Control #:** US-ELI_LILLY_AND_COMPANY-US202306016940 **Application #:** 215866

Patient Information:

Age: **Sex:** **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Mounjaro		/	Unknown	UNK UNK, unknown	10012594		
2	Mounjaro		/	Unknown	UNK UNK, unknown			

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Mounjaro		Unknown	NA				ELI LILLY AND CO	
2	Mounjaro		Unknown	NA				ELI LILLY AND CO	

Event Information:

Preferred Term (MedDRA Version: v.26.0) **ReC**

Suicidal ideation

Event/Problem Narrative:

This spontaneous case, reported by a consumer via digital media who contacted the company to report an adverse event, concerned a patient of an unknown age, gender and ethnicity. Medical history and concomitant medications were not reported. The patient received tirzepatide (Mounjaro), via a prefilled pen, at an unknown dose, at an unknown frequency, via an unknown route of administration, for the treatment of diabetes, beginning on an unknown date. On an unknown date, when tirzepatide dose was increased after two months, patient started getting suicidal. The event of suicidal ideation was considered serious by company due to its medical significant reason. Information regarding corrective treatment, outcome of event and status of tirzepatide therapy was not provided. Follow-up not

possible since the case is entered upon information received via digital media. No reporter and treating physician contact details were provided. The initial reporting consumer related the event with tirzepatide therapy.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

Medical History Product(s)	Start Date	End Date	Indications	Events

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event

Reporter Source:

Study report?: No **Sender organization:** ELI LILLY AND CO **503B Compounding Outsourcing Facility?:**

Literature Text: