FDA Adverse Event Reporting System (FAERS)
FOIA Batch Printing Report for Cases

Date - T me: 0-Aug-2023 5:02:53 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:

19073132	19932827	20149863	20723013
20762799	21043767	21251594	21264047
21501458	21597702	21619626	22107527

Total Cases: 12

Total number of Inactive cases: *0

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

Case ID: 19073132

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** BR **Event Date:** Jan-2021 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 30-Mar-2021 **Mfr Rcvd Date:** 19-Mar-2021 **Mfr Control #:** BR-NOVOPROD-798434 **Application #:** 209637

Patient Information:

Age: **Sex:** Female **Weight:** 95 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		/	Unknown	0.25 mg	Weight control	Jan-2021	Jan-2021

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 0.25/0.50 mg		Yes	Unknown	JP53334			NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Off label use	

Event/Problem Narrative:

This serious Spontaneous case from BRAZIL was reported by a Consumer as "suicidal ideation(Suicidal ideation)" beginning on JAN-2021, "off label use for weight loss(Off label use)" beginning on JAN-2021, and concerned a Adult Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from JAN-2021 to JAN-2021 for "Weight loss", Patient's height: 171 cm Patient's weight: 95 kg Patient's BMI: 32.488629. Historical Condition: Gestational diabetes. On an unspecified date in JAN-2021, Patient used Ozempic for weight loss. It was reported when patient was about to take second dose , she had nightmare and suicidal thought of playing from the 10th floor . Informed that she had to hold on in bed not to throw herself and the sensation to commit suicide continued even after she woke up. The patient informed that she has no psychological problems or health problems, declared that she realized that it could be a reaction to the use of the medication, as she was not using any other product besides Ozempic. The patient said that she never had a psychotic thought and that it was very strange. It was reported that the pen had already expired. The Batch Numbers of Ozempic 0.25/0.50 mg: JP53334 Action taken to Ozempic 0.25/0.50 mg was reported as Product discontinued due to AE. On JAN-2021 the outcome for the event "suicidal ideation(Suicidal ideation)" was Recovered. On JAN-2021 the outcome for the event "off label use for weight loss(Off label use)" was Recovered. Company comment: Suicidal ideation is assessed as unlisted according to the Novo Nordisk current CCDS information on Ozempic Information on relevant medical and family history, concomitant medication is not available. As only limited information is

available, it is difficult to perform a thorough medical evaluation. 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?
Gestational diabetes			

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: 19932827

Case Information:

Case Type : Direct **eSub:** N **HP:** **Country:** IL **Event Date:** 12-Sep-2021 **Outcomes:** LT , DS , RI , OT **Application Type:**

FDA Rcvd Date: 07-Oct-2021 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2021-74585 **Application #:**

Patient Information:

Age: 39 YR **Sex:** Male **Weight:** 99 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		/ QW	Subcutaneous	OTHER FREQUENCY:Once a week;	weight reduction	07-Jul-2021	21-Sep-2021

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic		No	Not Applicable	LP56280	31-Oct-2023		NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Fatigue	NA
Somnolence	NA
Impaired driving ability	NA
Depression	NA
Suicidal ideation	NA
Affective disorder	NA
Condition aggravated	NA
Off label use	NA

Event/Problem Narrative:

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

Case ID: 19932827

I began Ozempic as off label for weight loss in about July 2021. After increasing the dosage from 0.1 mg up to 0.4 mg/week I started suffering an extreme fatigue. One time I was so sleepy while driving I almost fell asleep and made am accident, which had never happened to me before. This was the "easy" part. About two months after starting the drug I began suffering from depressive symptoms. I've been diagnosed with an affective disorder under regular same regimen of drugs and stable for more than 16 years. Since diagnosis this was the first time I've ever suffered extremely bad symptoms up to serious suicidal thoughts. I would like to point out that there were no external circumstances that could explain this unexpected aggravation. I finally came to the conclusion I did have some minor cyclic mood changes after injection the drug at the beginning, which were connected to the drug apparently and eventually reached a threshold that resulted in a significant suffering. I'm a dermatologist and I thought this would be an extremely important to report as people should be aware of the dangers. I'm so sorry I used this medication after been well balanced for years! The fatigue and sleepiness were extreme and almost resulted in a car accident but the influence on my mood is currently devastating and people with mood problems should be warned (regardless of suicidal ideation in the past) in my opinion.

Relevant Medical History:

List Known Medical Conditions:Affective disorder Dyslipidemia GERD Please list all allergies:None List any other important information about the person:

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	CIPRALEX	/						
2	REBOXETINE	/						
3	CLONAZEPAM	/						
4	FAMOTIDINE	/						
5	LANSOPRAZOLE	/						
6	FINASTERIDE	/						
7	SIMVASTATIN	/						

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

Case ID: 19932827

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	07-Oct-2021	CTU Received Date	07-Oct-2021
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(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	12-Sep-2021
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)

I began Ozempic as off label for weight loss in about July 2021. After increasing the dosage from 0.1 mg up to 0.4 mg/week I started suffering an extreme fatigue. One time I was so sleepy while driving I almost fell asleep and made am accident, which had never happened to me before. This was the "easy" part. About two months after starting the drug I began suffering from depressive symptoms. I've been diagnosed with an affective disorder under regular same regimen of drugs and stable for more than 16 years. Since diagnosis this was the first time I've ever suffered extremely bad symptoms up to serious suicidal thoughts. I would like to point out that there were no external circumstances that could explain this unexpected aggravation. I finally came to the conclusion I did have some minor cyclic mood changes after injection the drug at the beginning, which were connected to the drug apparently and eventually reached a threshold that resulted in a significant suffering. I'm a dermatologist and I thought this would be an extremely important to report as people should be aware of the dangers. I'm so sorry I used this medication after been well balanced for years! The fatigue and sleepiness were extreme and almost resulted in a car accident but the influence on my mood is currently devastating and people with mood problems should be warned (regardless of suicidal ideation in the past) in my opinion.

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	Drug		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Ozempic		
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	1 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?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date	31-Oct-2023		
Lot number	LP56280		
Dosage Form			
Quantity		If Other	

Frequency	Other	If Other	Once a week	
How was it taken or used	Subcutaneous	If Other		
Date the person first started taking or using the product	07-Jul-2021			
Date the person stopped taking or using the product	21-Sep-2021			
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

weight reduction

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)
Gender	Male
Age (specify unit of time for age)	39 Year(s)
Date of Birth	
Weight	99 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaskan 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)

Affective disorder Dyslipidemia GERD

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

None

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.

Cipralex Reboxetine Clonazepam Famotidine Lansoprazole Finasteride Simvastatin

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	(b) (6)
Number/Street	
City	(b) (6)
State/Province	
Country	ISRAEL
ZIP or Postal code	
Telephone number	
Email address	(b) (6)

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	07-Oct-2021	
	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: 20149863

Case Information:

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

FDA Rcvd Date: 06-Dec-2021 **Mfr Rcvd Date:** 24-Nov-2021 **Mfr Control #:** FR-NOVOPROD-871294 **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		/	Unknown	UNK	Product used for unknown indication		

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

Event Information:

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

Suicide attempt

Intentional overdose

Event/Problem Narrative:

This serious Spontaneous case from FRANCE was reported by a Physician as "attempted suicide(Attempted suicide)" with an unspecified onset date, "overdosing with Ozempic(Drug overdose deliberate self-inflicted)" with an unspecified onset date, and concerned a Female patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for "product used for unknown indication", Patient height, weight and body mass index was not reported. Medical history was not provided. On an unknown date patient attempted suicide by overdosing with Ozempic due to which she was hospitalised. Batch Numbers: Ozempic: Requested. Action taken to Ozempic was reported as Unknown. The outcome for the event "attempted suicide(Attempted suicide)" was Unknown. Company comment: Suicidal attempt is assessed as unlisted event according to the NovoNordisk current company core data sheet (CCDS) on Ozempic The information regarding complete medical history (psychiatric disorders), previous history of suicide attempt, concomitant medications, relevant investigation reports are unavailable which limits the medical assessment of the case This single case report is not considered to change the current knowledge of the safety profile Ozempic The outcome for the event "overdosing with Ozempic(Drug overdose deliberate self-inflicted)" was Not Reported.

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

Case ID: 20149863

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: 20723013

Case Information:

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

FDA Rcvd Date: 19-Apr-2022 **Mfr Rcvd Date:** 08-Apr-2022 **Mfr Control #:** US-NOVOPROD-909727 **Application #:** 209637

Patient Information:

Age: 38 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		0.5 Mg Milligram(S) /	Subcutaneous	0.5 mg	Product used for unknown indication	Nov-2021	

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

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Hallucination	
Suicidal ideation	
Night sweats	

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a physician via a company representative as "Hallucinations(Hallucinations)" with an unspecified onset date, "Suicidal(Suicidal ideation)" with an unspecified onset date, and"night sweats(Night sweats)" with an unspecified onset date, and concerned a 38 year-old male patient, who was treated with Ozempic (semaglutide) from NOV-2021 for an or unknown indication. Medical history was not provided. A physician reported that a patient, receiving therapy with Ozempic ,experienced hallucinations, was suicidal and had night sweats. Action taken to Ozempic was Not reported. The outcome for the event "Hallucinations(Hallucinations)" was Not recovered. The outcome for the event "Suicidal(Suicidal ideation)" was Not recovered. The outcome for the event "night sweats(Night sweats)" was Not recovered. Batch number was requested upon follow-up. Company Comment: Hallucination and suicidal ideation are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. Limited information as

Case ID: 20723013

related to event onset date, medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluations limits 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?

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: 20762799

Case Information:

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

FDA Rcvd Date: 28-Apr-2022 **Mfr Rcvd Date:** 18-Apr-2022 **Mfr Control #:** AU-NOVOPROD-911528 **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		/	Unknown	UNK	Product used for unknown indication		

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

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicide attempt	
Depression	
Product availability issue	

Event/Problem Narrative:

This serious Spontaneous case from AUSTRALIA was reported by a Consumer as "she tried to commit suicide(Suicide attempt)" with an unspecified onset date, "So depressed(Depression)" with an unspecified onset date, "Now we can't get it, she can't keep up with her prescription(product availability issue)" with an unspecified onset date, and concerned a Female patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for "Product used for unknown indication", Patient's Height, Weight and Body Mass Index was not reported Current Condition: overweight. It was reported that Ozempic gave us a good start on new lives. Patient has been overweight most of her life; finally found something that works and was helping and nowcan't get it. On an unknown date patient was so depressed she can't keep up with her prescription that she tried to commit suicide. Patient was given antidepressants(unspecified) as treatment drug for Depression Batch Number was requested Action taken to Ozempic was Not reported. The outcome for the event "she tried to commit suicide(Suicide attempt)" was Not Reported. The outcome for the event "So depressed(Depression)" was Not Reported. The outcome for the event "Now we can't get it, she can't keep up

with her prescription(product availability issue)" was Not Reported. Company Comment: “Suicide attempt” and “Depression” are assessed as unlisted according to the Novo Nordisk current CCDS information on Ozempic. Information on medical history including any psychiatric illness, social and family behaviour, previous episodes of suicide attempt would have helped in thorough medical assessment. Patient being overweight is assessed as risk factor for depression and suicide attempt. 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?
Overweight			

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: 21043767

Case Information:

Case Type : Direct **eSub:** N **HP:** **Country:** US **Event Date:** 24-Jun-2022 **Outcomes:** LT **Application Type:**

FDA Rcvd Date: 01-Jul-2022 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2022-52286 **Application #:**

Patient Information:

Age: 28 YR **Sex:** Female **Weight:** 112.5 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		/			Weight loss	24-Jun-2022	28-Jun-2022

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

Event Information:

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

Suicidal ideation NA

Event/Problem Narrative:

Tell us what happened and how it happened : I increased my dose of Ozempic to 1 mg and started experiencing serious suicidal thoughts.;

Relevant Medical History:

List known medical conditions : Prediabetes, hypothyroidism, bipolar 1 disorder, generalized anxiety disorder; Please list all allergies : None;

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

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

Case ID: 21043767

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	Lamictal	/						
2	Levothyroxine	/						
3	Vraylar	/						

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	01-Jul-2022	CTU Received Date	01-Jul-2022
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	24-Jun-2022
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 increased my dose of Ozempic to 1 mg and started experiencing serious suicidal thoughts.

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)	Ozempic		
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?	Yes		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

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	24-Jun-2022		
Date the person stopped taking or using the product	28-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

Weight loss

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)	28 Year(s)
Date of Birth	
Weight	112.5 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)
Prediabetes, hypothyroidism, bipolar 1 disorder, generalized anxiety disorder

Please list all allergies (such as to drugs, foods, pollen or others)
None

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.
Lamictal 200 mg once a day Levothyroxine 25 mcg once a day Vraylar 3 mg once a day

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		
Email address		
Fax		
Reporter Organization		

	Department		
	Reporter Speciality		
	Today's date	01-Jul-2022	
	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: 21251594

Case Information:

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

FDA Rcvd Date: 25-Aug-2022 **Mfr Rcvd Date:** 17-Aug-2022 **Mfr Control #:** US-NOVOPROD-950873 **Application #:** 213051

Patient Information:

Age: 50 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Rybelsus 7 mg		/	Oral	UNK	Product used for unknown indication		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Rybelsus 7 mg		Yes	NA				NOVO NORDISK	

Event Information:

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

Suicidal ideation

Depression

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Physician as "suicidal thoughts(Suicidal ideation)" with an unspecified onset date, "depression(Depression)" with an unspecified onset date, and concerned a 50 Years old Female patient who was treated with Rybelsus 7 mg (SEMAGLUTIDE) from unknown start date for "drug use for unknown indication". Medical history was not provided. A patient receiving therapy with Rybelsus experienced suicidal thoughts and depression. Action taken to Rybelsus 7 mg was reported as Product discontinued. The outcome for the event "suicidal thoughts(Suicidal ideation)" was Recovered. The outcome for the event "depression(Depression)" was Recovered. Batch number was requested in follow up. Company Comment: Suicidal ideation is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Rybelsus. Limited information as related to Rybelsus therapy dates, event onset dates, medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluations limits medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

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

Case ID: 21251594

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: 21264047

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** N **Country:** GB **Event Date:** 14-Aug-2022 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 15-Dec-2022 **Mfr Rcvd Date:** 05-Dec-2022 **Mfr Control #:** GB-NOVOPROD-949727 **Application #:** 213051

Patient Information:

Age: 36 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Rybelsus 3 mg		3 Mg Milligram(S) / QD		3 mg, qd (morning)	Product used for unknown indication		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Rybelsus 3 mg		Unknown	NA				NOVO NORDISK	

Event Information:

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

Suicidal ideation

Depression

Event/Problem Narrative:

This serious Spontaneous case received via Regulatory Authority from the UNITED KINGDOM was reported by a Consumer as "Suicide(Suicidal ideation)" beginning on 14-AUG-2022, "Depression(Depression aggravated)" beginning on 14-AUG-2022, and concerned a 36 Years old Female patient who was treated with Rybelsus 3 mg (SEMAGLUTIDE) from unknown start date for "Product used for unknown indication", The events suicide and depression were not medically confirmed. Patient's weight, height and body mass index was not reported. Current Condition: depression. Concomitant products included - MIRTAZAPINE, VENLAFAXINE On 14-AUG-2022, patient had aggravation of depression and suicidal ideation. Patient had been taking them for a month and a half. After this time depression was slowly getting worse I thought it was due to getting the coil but nope. Sunday patient could not get out of bed. Wanted to kill herself and her son. Sister had to come and help. Patient was on mirtazapine and velafaxine so that should not have happened. Spoken to the doctor and he told me to stop them. Batch Numbers: Rybelsus 3 mg: was not reported Action taken to Rybelsus 3 mg was reported as Unknown. The outcome for the event "Suicide(Suicidal ideation)" was Unknown. The outcome for the event "Depression(Depression aggravated)" was Unknown. No further information available. Since last submission

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

Case ID: 21264047

the case has been updated with the following : -“Patient pregnant” updated as “No” - Medical history updated -Action taken to suspect updated as “Unknown” - Patient has prior history of event updated as "yes" for event depression -Event coding for suicide and depression updated to suicidal ideation and depression aggravated -Narrative has been updated accordingly. References included: Reference Type: E2B Authority Number Reference ID#: GB-MHRA-ADR 27214203 Reference Notes: MHRA (The Medicines and Healthcare products Regulatory Agency) Reference Type: E2B Report Duplicate Reference ID#: GB-MHRA-MED-202208152114152840-JGWPZ Reference Notes: ELECTRONICYCPROD Company comment: 'Suicidal ideation' and 'Depression' are assessed as unlisted events according to Novo Nordisk current CCDS information on Rybelsus. Depression is a mood disorder that can present with suicidal thoughts; hence, patient's medical history of depression is a confounding factor for suicidal ideation. However, information on product indication, relevant history on mental health, family history of depression, social history or environmental circumstances which may have led to suicidal ideation, concomitant treatment with psychoactive drugs (e.g. SSRIs or Benzodiazepines), event outcome and action taken to Rybelsus are not available for thorough medical assessment. This single case report is not considered to change the current knowledge of the safety profile of Rybelsus.

Relevant Medical History:

Patient is not pregnant,Patient is not currently breastfeeding

Disease/Surgical Procedure	Start Date	End Date	Continuing?
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

Concomitant Products:

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

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

Case ID: 21264047

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: 21501458

Case Information:

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

FDA Rcvd Date: 25-Oct-2022 **Mfr Rcvd Date:** 13-Oct-2022 **Mfr Control #:** AU-NOVOPROD-970983 **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 0.25/0.50 mg		/		qw (dose and dose units not reported)	Weight control		

#	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	

Event Information:

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

Suicidal ideation

Product use in unapproved indication

Event/Problem Narrative:

This serious Spontaneous case from AUSTRALIA was reported by a Medical Doctor as "she was really suicidal(Suicidal ideation)" with an unspecified onset date, "Ozempic for weight loss(Product use in unapproved indication)" with an unspecified onset date, and concerned a Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from unknown start date for "weight loss". Patient's height, weight were not reported. Body mass index (BMI): 31.5 Current Condition: Pre diabetic (duration not reported). Treatment included - LEXAPRO(ESCITALOPRAM OXALATE) From and unknown date patient started using ozempic and on 3rd day after taking one dose she felt suicidal which lasted till day 5. The patient also reported that she had never felt like that. Batch Numbers: Ozempic 0.25/0.50 mg: has been requested Action taken to Ozempic 0.25/0.50 mg was reported as Product discontinued. The outcome for the event "she was really suicidal(Suicidal ideation)" was Recovered. The outcome for the event "Ozempic for weight loss(Product use in unapproved indication)" was Not Reported. Company comment: 'Suicidal ideation' is assessed as an unlisted event according to Novo Nordisk current CCDS information on Ozempic. Information on patient's age, relevant medical and family history of depression, social history or environmental circumstances which may have led to suicidal ideation and alternative

aetiology for the reported event are not available for thorough medical assessment. Concomitant medication (Escitalopram- antidepressant drug) is used to treat depression and anxiety serves as plausible explanation for underlying disease condition which could be the reason for 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?
Glucose tolerance impaired			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
BODY MASS INDEX					Y

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: 21597702

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** N **Country:** US **Event Date:** 10-Oct-2022 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 09-Dec-2022 **Mfr Rcvd Date:** 29-Nov-2022 **Mfr Control #:** US-ELI_LILLY_AND_COMPANY-US202211002493 **Application #:** 215866

Patient Information:

Age: 29 YR **Sex:** Female **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) /	Unknown	2.5 mg, unknown	10065542	10-Oct-2022	
2	Mounjaro 2.5mg		/			10022489		
3	Mounjaro 2.5mg		/			10052424		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Mounjaro 2.5mg	21 Day	Yes	NA				ELI LILLY AND CO	
2	Mounjaro 2.5mg	21 Day	Yes	NA				ELI LILLY AND CO	
3	Mounjaro 2.5mg	21 Day	Yes	NA				ELI LILLY AND CO	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Palpitations	
Anxiety	
Depression	
Insomnia	

Case ID: 21597702

Feeding disorder

Product dose omission issue

Off label use

Event/Problem Narrative:

This spontaneous case, reported by a consumer who contacted the company to report adverse events, concerned a 29-year-old female patient of unknown origin. Medical history included anxiety and having anxiety attacks, the last one when she was 20 and historical drug of metformin for type two diabetes and insulin resistance which caused gastrointestinal disorders. Concomitant medications included metformin for type two diabetes and insulin resistance. The patient received tirzepatide (Mounjaro 2.5 mg) injections, via pre-filled pen, 2.5 mg with unknown frequency, for the treatment of prediabetes, insulin resistance and high glycosylated hemoglobin, beginning on 10-Oct-2022. Route of administration was not reported. She took her first shot of tirzepatide on the stomach and after four days, on 14-Oct-2022 she woke up with a mild anxiety attack from which she recovered on an unspecified date. She took her second dose with no side effects. On 24-Oct-2022, she took her third shot in her stomach and on (b)(6)***** she had heart palpations and suicidal thoughts which were scary and made her think of self-harm, due to this she had to go to the emergency room. The event of suicidal thoughts was considered serious by the company for medical significance. She was not hospitalized because of the events and as of(b)(6)****** was recovering from them. She was supposed to take her fourth tirzepatide dose while traveling, but the pen was frozen and because of this she missed her dose, so she took metformin instead. As of (b)(6)*****, she was severe anxious and in depression now. She had insomnia and could not eat. She was not like this before starting the injection. It had been one month since her last injection, and she had not gotten any better. Information regarding corrective treatments was not reported. Outcome of the suicidal ideation and palpitations was recovering and outcome of the event of anxiety was not recovered, and outcome of remaining events was not reported. Tirzepatide treatment status was discontinued. The reporting consumer related the anxiety attack, suicidal thoughts and heart palpitations to tirzepatide and did not provide an assessment for the remaining events with tirzepatide therapy. Update 05-Dec-2022: Additional information was received from initial reporter on (b)(6)*****. Added three non-serious events of depression, insomnia and feeding disorder. Updated action taken for the suspect tirzepatide therapy from unknown to drug discontinued and verbatim and outcome for the event of anxiety. Update narrative with new information.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Anxiety			

Medical History Product(s)	Start Date	End Date	Indications	Events
METFORMIN			10067585	10017944

Relevant Laboratory Data:

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

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

Case ID: 21597702

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	METFORMIN	/		UNK	10022489			
2	METFORMIN	/			10067585			

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: 21619626

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** US **Event Date:** 2022 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 21-Nov-2022 **Mfr Rcvd Date:** 10-Nov-2022 **Mfr Control #:** US-NOVOPROD-981197 **Application #:** 209637

Patient Information:

Age: 33 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic 0.25/0.50 mg		0.25 Mg Milligram(S) / /WK	Subcutaneous	0.25 mg, qw	Product used for unknown indication	Oct-2022	Nov-2022

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

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 nurse via a company representative as "suicidal ideation(Suicidal ideation)" beginning in 2022, and concerned a 33 year old female patient, who was treated with Ozempic 0.25/0.50 mg (semaglutide) from OCT-2022 to NOV-2022 for an unknown indication. Current Condition: mild depression. A nurse practitioner reported that a patient, who was receiving therapy with Ozempic 0.25 mg, experienced suicidal ideation in 2022. The suicidal ideation was described by patient to nurse practitioner as "all of a sudden wanted to drive off a cliff." As treatment, the patient was staying with friends and being closely watched. Action taken to Ozempic 0.25/0.50 mg was reported as Product discontinued due to AE. The outcome for the event "suicidal ideation(Suicidal ideation)" was Not Reported. The nurse practitioner felt that the event was related to Ozempic therapy, as she could not think of any other precipitating factor other than the recently started Ozempic. Batch number was requested. Company Comment: Suicidal ideation is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. A medical history of depression which may be associated with suicidal thoughts considered a confounder. Limited information on concomitant medications, family/social history, and laboratory/diagnostic evaluations limits further medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

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

Case ID: 21619626

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Depression			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:

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: 22107527

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** US **Event Date:** 26-Dec-2022 **Outcomes:** HO **Application Type:**

FDA Rcvd Date: 18-May-2023 **Mfr Rcvd Date:** 08-May-2023 **Mfr Control #:** US-NOVOPROD-1036583 **Application #:** 213051

Patient Information:

Age: 61 YR **Sex:** Male **Weight:** 90.884 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Rybelsus 7 mg		/ QD	Oral	Dose decreased	Obesity	09-Jan-2023	
2	Rybelsus 7 mg		7 Mg Milligram(S) / QD	Oral	7 mg, qd	Diabetes mellitus	13-Dec-2022	08-Jan-2023
3	ANTIVERT [MECLOZINE HYDROCHLORIDE]		/	Oral	UNK	Product used for unknown indication		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Rybelsus 7 mg	14 Day	Yes	NA				NOVO NORDISK	
2	Rybelsus 7 mg	14 Day	Yes	NA				NOVO NORDISK	
3	ANTIVERT [MECLOZINE HYDROCHLORIDE]		Unknown	NA					

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Suicide attempt	

Event/Problem Narrative:

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

Case ID: 22107527

This serious Spontaneous case from the UNITED STATES was reported by a company representative and confirmed by a medical doctor as "suicidal ideations(Suicidal ideation)" beginning on 26-DEC-2022, "unsuccessful attempt to kill self with tequila and pills(Unsuccessful suicide)" beginning on 26-DEC-2022, and concerned a 61 Year old Male patient who was treated with Rybelsus 7 mg (SEMAGLUTIDE) from 13-DEC-2022 and ongoing for "diabetes", "obesity" and a non-Novo Nordisk suspect product ANTIVERT [MECLOZINE HYDROCHLORIDE] (MECLOZINE HYDROCHLORIDE) from unknown start date for an unknown indication. Patient's height: 175.3 cm Patient's weight: 90.9 kg Patient's BMI: 29.57492150. Current Condition: diabetes, obesity, hypertension, metabolic syndrome, borderline personality, alcohol use, cough, dyspnea Historical Condition: arthritis, palpitations, abdominal pain, eczema eyelid, cough, dyspnea, anxiety, insomnia, groin rash Historical Drug: ranitidine, tramadol. Concomitant products included - NAPROSYN E(NAPROXEN), METFORMIN, PHENTERMINE, AMLODIPINE, TESTOSTERONE CYPIONATE(TESTOSTERONE CIPIONATE), TADALAFIL, DHEA, FINASTERIDE, TAMSULOSIN, LOSARTAN HCTZ(HYDROCHLOROTHIAZIDE, LOSARTAN POTASSIUM), MAG GLYCINATE(MAGNESIUM GLYCINATE), ATORVASTATIN, ELIDEL(PIMECROLIMUS), SILDENAFIL, OMEGA 3 FISH OILS(FISH OIL), ZINC ACETATE, D3 5000(COLECALCIFEROL), ALLEGRA D [FEXOFENADINE HYDROCHLORIDE;PHENYLEPHRINE HYDROCHLORIDE](FEXOFENADINE HYDROCHLORIDE, PHENYLEPHRINE HYDROCHLORIDE), ADVAIR(FLUTICASONE PROPIONATE, SALMETEROL XINAFOATE), ALBUTEROL HFA(SALBUTAMOL), VALIUM(DIAZEPAM), VOLTAREN [DICLOFENAC] (DICLOFENAC), KETOCONAZOLE, FLUTICASONE FLUTICASONE PROPIONATE, COQ 10(UBIDECARENONE), MULTIVITAMIN AND MINERAL(ASCORBIC ACID, CALCIUM PANTOTHENATE, CALCIUM PHOSPHATE DIBASIC, COLECALCIFEROL, COPPER SULFATE, CYANOCOBALAMIN, DL-ALPHA TOCOPHERYL ACETATE, FERROUS FUMARATE, MAGNESIUM OXIDE, MANGANESE SULFATE, NICOTINAMIDE, POTASSIUM IODIDE, POTASSIUM SULFATE, PYRIDOXINE HYDROCHLORIDE, RETINOL ACETATE, RIBOFLAVIN, THIAMINE MONONITRATE, ZINC OXIDE), B12/Folate A physician reported that a patient receiving therapy with Rybelsus 7 mg experienced suicidal ideations and had an unsuccessful attempt to kill self by having overdosed with tequila and an unknown number of Antivert pills on(b)(6)******. The patient was involuntarily hospitalized. The patient described the suicidal ideations as feeling like going out of their mind. Laboratory data showed: cholesterol normal, thyroid normal, complete blood cell count normal, lipids normal, comprehensive metabolic panel (chem 12) normal, protein urine 100 (units, reference range not provided), urine analysis trace leukocytes, and urine toxicology screen negative. As treatment, the Rybelsus dose was decreased and patient underwent alcohol moderation counseling. On (b)(6)*****, the patient was discharged. Action taken to Rybelsus 7 mg was reported as Dose Decreased. Action taken to ANTIVERT [MECLOZINE HYDROCHLORIDE] was Not reported. On 01-JAN-2023 the outcome for the event "suicidal ideations(Suicidal ideation)" was Recovered. On (b)(6)*******the outcome for the event "unsuccessful attempt to kill self with tequila and pills(Unsuccessful suicide)" was Recovered. The physician felt that both event were related to therapy with Rybelsus and felt that no alternative etiology was likely. However, the patient had a break up with his boyfriend before(b)(6)********** ********** Batch number was unavailable. Since last submission, the following has been updated: -Added lab -Added medical history -Added co-suspect product: Antivert -Added concomitant products -Added indication to concomitant product: phentermine -Updated event start date for both events -Updated hospitalization start date for both events -Updated event verbatim from "unsuccessful attempt to kill self with pills" to "unsuccessful attempt to kill self with tequila and pills" - Narrative updated with the new information from the physician. Company Comment: Suicidal ideation and suicide attempt are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Rybelsus. A medical history of borderline personality and alcohol use requiring alcohol moderation counseling considered possible confounders. Limited information as related to family history and laboratory/diagnostic evaluations limits further 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?
Diabetes mellitus			Yes
Obesity			Yes
Hypertension			Yes

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

Case ID: 22107527

Metabolic syndrome	Yes
Borderline personality disorder	Yes
Alcohol use	Yes
Arthritis	No
Palpitations	No
Abdominal pain	No
Eczema eyelids	No
Cough	No
Dyspnoea	No
Anxiety	No
Insomnia	No
Genital rash	No
Cough	Yes
Dyspnoea	Yes

Medical History Product(s)	Start Date	End Date	Indications	Events
RANITIDINE			Product used for unknown indication	Arthritis
TRAMADOL			Product used for unknown indication	Palpitations

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
BLOOD CHOLESTEROL					Y
BLOOD GLUCOSE	175	mg/dL			N
BLOOD THYROID STIMULATING HORMONE					Y
FULL BLOOD COUNT					Y
LIPIDS					Y
METABOLIC FUNCTION TEST					Y

Case ID: 22107527

PROTEIN URINE	Y
TOXICOLOGIC TEST	Y
URINE ANALYSIS	Y
WEIGHT	Y

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	METFORMIN	1000 Mg Milligram(S) / BID	Oral	1000 mg, bid	Diabetes mellitus			
2	PHENTERMINE	15 Mg Milligram(S) / QD	Oral	15-30 mg, qd in AM, prn	Weight decreased			
3	AMLODIPINE	5 Mg Milligram(S) / QD	Oral	5 mg, qd at HS	Product used for unknown indication			
4	TESTOSTERONE CYPIONATE	/	Intramuscular	200 mg/mL, every 2 weeks	Product used for unknown indication			
5	TADALAFIL	5 Mg Milligram(S) / QD	Oral	5 mg, qd	Product used for unknown indication			
6	DHEA	25 Mg Milligram(S) / QD	Oral	25 mg, qd	Product used for unknown indication			
7	FINASTERIDE	5 Mg Milligram(S) / QD	Oral	5 mg, qd	Product used for unknown indication			
8	TAMSULOSIN	0.8 Mg Milligram(S) / QD	Oral	0.8 mg, qd	Product used for unknown indication			
9	LOSARTAN HCTZ	/	Oral	100 mg/25 mg, qd	Product used for unknown indication			
10	MAG GLYCINATE	200 Mg Milligram(S) /	Oral	200 mg	Product used for unknown indication			

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11	ATORVASTATIN	10 Mg Milligram(S) / QD	Oral	10 mg, qd at HS	Product used for unknown indication		
12	ELIDEL	1 % Percent / BID	Topical	1 %, bid, prn	Eczema eyelids		
13	SILDENAFIL	/	Oral	50-100 mg , qd, prn	Product used for unknown indication		
14	OMEGA 3 FISH OILS	2000 Mg Milligram(S) / BID	Oral	2000 mg, bid	Product used for unknown indication		
15	ZINC ACETATE	25 Mg Milligram(S) / QD	Oral	25 mg, qd	Product used for unknown indication		
16	D3 5000	/	Oral	2 capsules per day	Product used for unknown indication		
17	ALLEGRA D [FEXOFENADINE HYDROCHLORIDE;PHENYLEPHRINE HYDROCHLORIDE]	/	Oral	1 tablet, twice a day, prn	Product used for unknown indication		
18	NAPROSYN E	500 Mg Milligram(S) / BID	Oral	500 mg, bid with food, prn	Product used for unknown indication		
19	VALIUM	/	Oral	UNK	Product used for unknown indication	25-Apr-2019	1342 Day
20	ADVAIR	/	Respiratory (inhalation)	1 puff bid prn	Product used for unknown indication		
21	ALBUTEROL HFA	/	Respiratory (inhalation)	2 puff q4-6 hour prn	Cough		
22	ALBUTEROL HFA	/			Dyspnoea		
23	VOLTAREN [DICLOFENAC]	/	Topical	1 application on skin TID prn	Product used for unknown indication		
24	KETOCONAZOLE	/		1 application on skin bid prn	Rash		
25	FLUTICASONE [FLUTICASONE PROPIONATE]	/	Respiratory (inhalation)	2 squirt in nostrils at bedtime prn	Product used for unknown indication		

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26	COQ 10	100	Mg Milligram(S) / QD		100 mg, qd	Product used for unknown indication
27	MULTIVITAMIN AND MINERAL /			Oral	1 tablet qd	Product used for unknown indication

Reporter Source:

Study report?: No

Sender organization: NOVO NORDISK

503B Compounding Outsourcing Facility?:

Literature Text: