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

Date - T me: 3-Sep-2023 09:4 : 2 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:

7654626	15351842	15665625	17471038
18143068	22198091	22291720	22295577
22295640	22329030	22329031	22353054

Total Cases: 12

Total number of Inactive cases: *0

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

Case ID: 7654626

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** JP **Event Date:** 13-Oct-2010 **Outcomes:** DE **Application Type:**

FDA Rcvd Date: 19-Nov-2010 **Mfr Rcvd Date:** 16-Nov-2010 **Mfr Control #:** JP-NOVOPROD-317420 **Application #:** 22341

Patient Information:

Age: 44 YR **Sex:** Female **Weight:** 52 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	VICTOZA HIKACHU INJECTION		3 Mg Milligram(S) /	Subcutaneous	03 mg, qd	TYPE 2 DIABETES MELLITUS	08-Sep-2010	
2	VICTOZA HIKACHU INJECTION		1 Mg Milligram(S) /	Subcutaneous	0.9 mg, qd		22-Sep-2010	

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	VICTOZA HIKACHU INJECTION	35 Day	Unknown	NA	NA			NOVO NORDISK	
2	VICTOZA HIKACHU INJECTION	35 Day	Unknown	NA				NOVO NORDISK	

Event Information:

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

Completed suicide

Event/Problem Narrative:

Spontaneous report received from JAPAN and reported by a Medical Doctor as "Suicide". It concerns a 44-year-old female patient treated with Victoza Hikachu injection (liraglutide) from 09-SEP-2010 and ongoing for "Type 2 diabetes mellitus". Medical history included depression and unsuccessful suicide attempt. The event occurred on (b)(6)*****. The patient, who used Victoza, committed suicide. The patient had been using antidepressant due to depression and she had

Case ID: 7654626

experienced unsuccessful suicide. This time, the method of suicide was not reported but the method was not an overdose of Victoza. On 03-JUN-2010 the patient started treatment for diabetes at other clinic. This treatment consisted of diet for diabetes 1600 kcal/day, Lantus 6 units/day and FASTIC 45 mg/day. HbA1c was 7.6% On 23-AUG-2010 the patient visited reporter"s clinic. The reporter recommended the patient to continue current treatment for diabetes. The patient was very concerned about the insulin therapy and hypoglycaemia. On 03-SEP-2010 a Glucagon loading test was performed to measure the secretory capacity of insulin. The result of the test was CPR delta 0-5 0.9. On 08-SEP-2010 she started to use Victoza 0.3mg with MELBIN 500mg. On 21-SEP-2010 the patient, visited to the clinic for regular check. Blood Glucose level was PPG(1.25hr) 195mg/dL. On 22-SEP-2010, the dosage of Victoza was increased to 0.9 mg. On(b)(6)****** when she visited the clinic for regular check, internal bleeding at facial surface was noted. She explained that it was caused by rear-ended of truck. The reporter instructed to her to visit and consult a psychiatrist as soon as possible. She took her own life at the same evening. It is unknown if the suicides was caused by exacerbated depression and if an exacerbated depression could be related to Victoza. The overall outcome is reported as "Fatal". The reporting doctor has evaluated the causality with Victoza as "not related". No further information expected. Since last submission the case has been updated with the following information: - Cause of suicide unknown - Relation between depression and suspected product unknown - No further information expected - Narrative updated accordingly Comment: company comment: The patient had a medical history of depression and unsuccessful suicide attempt which provides a likely etiology for the event. According the reporter the event was not related to Victoza and it was not caused by an overdose of Victoza.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Suicide attempt			Unknown
Type 2 diabetes mellitus			Unknown
Depression			Unknown

Medical History Product(s)	Start Date	End Date	Indications	Events
LANTUS /01483501/	03-Jun-2010	08-Sep-2010		
FASTIC	03-Jun-2010	08-Sep-2010		

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Blood glucose	195	milligram per decilitre			Y
HbA1C	7.6	% percent			N

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: 7654626

1	ANTIDEPRESSANTS	/			DEPRESSION		
2	MELBIN /00082702/	1000 Mg Milligram(S) /	Oral	1000 mg, qd	TYPE 2 DIABETES MELLITUS	08-Sep-2010	
3	AMOXAN	5 Mg Milligram(S) /	Oral	5 mg, qd			
4	SOLANAX	1 Mg Milligram(S) /		0.8 mg, qd			
5	MYSLEE	5 Mg Milligram(S) /		5 mg, qd			
6	LENDEM	0 Mg Milligram(S) /	Oral	0.25 mg, qd			
7	KAMIKIHITOU	5 G Gram(S) /	Oral	5 g, qd			

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: 15351842

Case Information:

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

FDA Rcvd Date: 05-Sep-2018 **Mfr Rcvd Date:** 27-Aug-2018 **Mfr Control #:** US-NOVOPROD-619034 **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		/	Subcutaneous	UNK	Drug use for unknown indication		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic		Yes	NA	UNKNOWN			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 medical doctor via a company representative as "severe depression with suicidal thoughts" with an unspecified onset date, and concerned a male patient who was treated with Ozempic (SEMAGLUTIDE) from an unknown start date due to an unknown indication. Medical history was not provided. A physician who was also the patient, reported experiencing severe depression with suicidal thoughts after taking the first dose of Ozempic. Action taken to Ozempic was reported as Product discontinued due to AE. The outcome for the event "severe depression with suicidal thoughts" was Recovered. Batch number has been requested upon follow-up. Company Comment: "Severe depression with suicidal thoughts" is assessed as unlisted according to the Novo Nordisk CCDS on Ozempic. There is positive temporal relationship and positive dechallenge. However, relevant information regarding the patient's health status prior to suspect drug therapy, indication for use, assessment of current medical conditions specifically psychiatric evaluation, negative change in life circumstances, previous depression, suicide threats or attempts, family history of mental disorder, drug or alcohol abuse, and concomitant

medications would be necessary for complete medical assessment of the case. 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?

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: 15665625

Case Information:

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

FDA Rcvd Date: 28-Nov-2018 **Mfr Rcvd Date:** 19-Nov-2018 **Mfr Control #:** US-NOVOPROD-634937 **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		.25 Mg Milligram(S) /	Subcutaneous	0.25 mg, UNK	Drug use for unknown indication		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic		NA	NA	UNKNOWN			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 General physician and office staff member, via a company representative, as "suicidal ideation" with an unspecified onset date, and concerned a male patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date due to an unknown indication. Medical history included mentally ill. A patient, who was receiving therapy with Ozempic, was reported to have suicidal ideation. Action taken to Ozempic was reported as Product discontinued. The outcome for the event "suicidal ideation" was Not Reported. Batch number will be requested in follow-up. Company Comment: "Suicidal ideation" is assessed as unlisted according to the Novo Nordisk CCDS for Ozempic. The patient's medical history of mentally ill may offer an alternative explanation towards the onset of the event, "suicidal ideation". Additional information regarding the patient's health status prior to suspect drug therapy, indication for use, medical history (e.g., depression, suicide threats or attempts, unusual changes in mood or behavior, drug or alcohol abuse), assessment of current medical conditions specifically psychiatric evaluation, negative change in life circumstances, family history of mental disorder, and concomitant medications would prove helpful for complete assessment of the case. 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: 15665625

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Mental disorder			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: 17471038

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** US **Event Date:** 2020 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 27-Feb-2020 **Mfr Rcvd Date:** 19-Feb-2020 **Mfr Control #:** US-NOVOPROD-714488 **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 0.25/0.50 mg		/	Subcutaneous	UNK	Product used for unknown indication	Jan-2020	2020
2	Ozempic 0.25/0.50 mg		.5 Mg Milligram(S) /	Subcutaneous	0.5 mg		2020	

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

Event Information:

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

Suicidal ideation

Vomiting

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Nurse via company representative as "suicidal thoughts(suicidal ideation)" beginning in 2020, "vomiting profusely(vomiting)" beginning in 2020, and concerned a Male patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from JAN-2020 for "drug use for unknown indication". Dosage Regimens: Ozempic 0.25/0.50 mg: ??-JAN-2020 to ??-???-2020, ??-???-2020 to Not Reported; Medical history was not provided. In 2020, after the first dose of 0.5 mg Ozempic (and 5th Ozempic dose total), the patient experienced profuse vomiting and suicidal thoughts. Action taken to Ozempic 0.25/0.50 mg was Not reported. The outcome for the event "suicidal thoughts(suicidal ideation)" was Not Reported. The outcome for the event "vomiting profusely(vomiting)" was Not Reported. Batch number was requested. Company Comment: The event, "suicidal thoughts(suicidal

Case ID: 17471038

ideation)" is assessed as unlisted according to the NN current reference safety information on Ozempic 0.25/0.50 mg. As only limited information has been obtained so far, it is difficult to perform a thorough medical evaluation of the case. The following important information is lacking: patient's health status prior to suspect drug therapy, indication for use, medical history (e.g., diabetes, depression, suicide threats or attempts, unusual changes in mood or behavior, drug or alcohol abuse), assessment of current medical conditions specifically psychiatric evaluation, negative change in life circumstances, family history of mental disorder, and concomitant medications. This single case report is not considered to change the current knowledge of the safety profile of Ozempic 0.25/0.50 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

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: 18143068

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** BE **Event Date:** 04-Aug-2020 **Outcomes:** HO **Application Type:**

FDA Rcvd Date: 21-Aug-2020 **Mfr Rcvd Date:** 14-Aug-2020 **Mfr Control #:** BE-NOVOPROD-745831 **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 0.5 mg		6 Mg Milligram(S) / QD	Unknown	6 mg, qd (3 or 4 pen of 0,5mg)		04-Aug-2020	
2	Ozempic 0.5 mg		/	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 0.5 mg		Unknown	Unknown				NOVO NORDISK	
2	Ozempic 0.5 mg		Unknown	Unknown				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicide attempt	
Intentional overdose	
Vomiting	
Nausea	

Event/Problem Narrative:

This serious Spontaneous case from BELGIUM was reported by a Diabetes Nurse Specialist as "suicide attempt by taking 6 mg Ozempic at once(Suicide attempt)" beginning on (b)(6)*****, "Patient has injected 6 mg Ozempic at once(Intentional overdose)" beginning on(b)(6)******, "vomit(Vomiting)" beginning on (b)(6)*****,

Case ID: 18143068

"nauseous(Nauseous)" beginning on(b)(6)******, and concerned a Male patient who was treated with Ozempic 0.5 mg (SEMAGLUTIDE) from unknown start date for "Product used for unknown indication", Medical history was not provided. Treatment included - LITICAN ALIZAPRIDE HYDROCHLORIDE, GLUCOSE The patient's height, weight and body mass index were not reported. Dosage Regimens: Ozempic 0.5 mg: Not Reported to Not Reported, (b)(6)***** to Not Reported; On (b)(6)***** ,Patient made a suicide attempt by Injecting overdose of 6 mg Ozempic at once and is on intensive care (3 or 4 pen of 0,5 mg), and was hospitalised on the same day. The patient had vomited and was nauseous at the emergency. However afterwards, the patient did not present any special gastrointestinal problems. It was reported that patient was given Litican i.v./ under glucose infusion, the glycaemia remained stable. Patient appears to be unfair in his story to the doctors, also with regard to the injected dose. One day it's 6mg and the next patient claims to have only injected 4mg. On an unknown date, patient's glycaemia of the patient is normal, between 100-130 mg/dl. It was reported that the patient would not have had a psychiatric history. The patient was not on psychotropic drugs. The overdose took place in the context of a relational problem, in which the patient said that the patient acted impulsively. Batch Numbers: Ozempic 0.5 mg: ASKU, ASKU Action taken to Ozempic 0.5 mg was Not reported. The outcome for the event "suicide attempt by taking 6 mg Ozempic at once(Suicide attempt)" was Recovered. The outcome for the event "Patient has injected 6 mg Ozempic at once(Intentional overdose)" was Recovered. The outcome for the event "vomit(Vomiting)" was Recovered. The outcome for the event "nauseous(Nauseous)" was Recovered. Since last submission, the fllowing have been updated: -New event, nauseous added -Treatment medications added -Narrative updated accordingly Company comment: 'Suicide attempt' was assessed as unlisted event and 'Nausea', 'Vomiting', were assessed as listed events according to the Novo Nordisk current CCDS on Ozempic. Information on suspect product start date, prior suicidal ideations/attempts, action taken to the drug and relevant investigations were not available for thorough medical evaluation. However overdose of Ozempic could have caused 'nausea' and 'Vomiting'. This single case report is not considered to change the current knowledge of safety profile of Ozempic.

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
Blood glucose	100-130	milligram per decilitre			N

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: 18143068

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: 22198091

Case Information:

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

FDA Rcvd Date: 11-Apr-2023 **Mfr Rcvd Date:** 03-Apr-2023 **Mfr Control #:** US-ELI_LILLY_AND_COMPANY-US202304001659 **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	10057097		

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

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Perineal infection	
Constipation	

Event/Problem Narrative:

This spontaneous case, reported by a consumer who contacted the company to report adverse events via internet, concerned a patient of an unknown age, gender and origin. Medical history and concomitant medications were not provided. The patient received tirzepatide (Mounjaro), via pre-filled pen. Details regarding dose, frequency, route of administration, indication for use and therapy start date were not provided. On an unknown date, while on tirzepatide therapy, the patient experienced suicidal thoughts, infections on the skin of perineum and constipation. The event of suicidal ideation was considered as serious by the company due to medically significant reason. The information regarding the corrective treatment, outcome of the events and tirzepatide therapy status were not reported.

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

Case ID: 22198091

Follow-up was not possible as collection of personal and health care professional contact information was not permitted due to privacy guidelines within the Digital Intelligence Lab. The reporting consumer did not provide an opinion of relatedness of the events 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:

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

Case ID: 22291720

Case Information:

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

FDA Rcvd Date: 05-May-2023 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2023-33638 **Application #:**

Patient Information:

Age: 40 YR **Sex:** Female **Weight:** 63.9 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Semaglutide		/ 999	Subcutaneous	OTHER FREQUENCY :Once a week;	Weight loss	10-Apr-2023	17-Apr-2023

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Semaglutide		Yes	Yes					

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Anxiety	Yes
Panic attack	Yes
Palpitations	Yes
Chest pain	Yes
Paraesthesia	Yes
Hypoaesthesia	Yes
Middle insomnia	Yes
Crying	Yes
Fear	Yes
Restlessness	Yes

Case ID: 22291720

Feeling abnormal	Yes
Suicidal ideation	Yes

Event/Problem Narrative:

Tell us what happened and how it happened : I took Semaglutide (.25mg) by injection on April 10th. I started to feel increased anxiety 2 days later. By the 3rd day I started having full blown panic attacks that would not stop. My heart was racing and my chest was on fire. My hands and arms would tingle and go numb. I would get a few minutes of relief and then the panic and massive amounts of anxiety would start right back up again. I had to take medication to sleep and even then I would wake up to panic attacks throughout the night. I cried frequently because of how scared I was. I couldn't hardly sit still. I felt completely out of my mind and like I was a prisoner in my own body. I could not be left alone because I started having suicidal thoughts and didn't want to live anymore. The panic subsided some by days 5 and 6, but was still present. I took a 2nd injection on April 17th. It peaked again on day 3 with massive amounts of panic and anxiety. The 2nd week was worse than the first. Today it has been 17 days since I took the last shot. The anxiety is still subsiding, it has gotten better as time passes.;

Relevant Medical History:

Please list all allergies : Percocet;

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	Pristique	/						
2	Mirtazapine	/						
3	Buspirone	/						
4	Lorazepam	/						
5	Estradiol	/						

Case ID: 22291720

6	Claritin	/
7	Vitamin D	/
8	Omega 3	/

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	05-May-2023	CTU Received Date	05-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-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)

I took Semaglutide (.25mg) by injection on April 10th. I started to feel increased anxiety 2 days later. By the 3rd day I started having full blown panic attacks that would not stop. My heart was racing and my chest was on fire. My hands and arms would tingle and go numb. I would get a few minutes of relief and then the panic and massive amounts of anxiety would start right back up again. I had to take medication to sleep and even then I would wake up to panic attacks throughout the night. I cried frequently because of how scared I was. I couldn't hardly sit still. I felt completely out of my mind and like I was a prisoner in my own body. I could not be left alone because I started having suicidal thoughts and didn't want to live anymore. The panic subsided some by days 5 and 6, but was still present. I took a 2nd injection on April 17th. It peaked again on day 3 with massive amounts of panic and anxiety. The 2nd week was worse than the first. Today it has been 17 days since I took the last shot. The anxiety is still subsiding, it has gotten better as time passes.

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?	No
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)	Semaglutide		
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?	Yes		

Drug Therapy 1 of 1

Expiration date			
Lot number			
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	10-Apr-2023		

	Date the person stopped taking or using the product	17-Apr-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

	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)	40 Year(s)
	Date of Birth	
	Weight	63.9 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)

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

Percocet

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.

Pristique, Mirtazapine, Buspirone, Lorazepam, Estradiol

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

Claritin, Vitamin D, Omega 3

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	05-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: 22295577

Case Information:

Case Type : Direct **eSub:** N **HP:** **Country:** CA **Event Date:** 01-Jan-2020 **Outcomes:** LT **Application Type:**

FDA Rcvd Date: 07-May-2023 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2023-34040 **Application #:**

Patient Information:

Age: 37 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		/			Diabetes		

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

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Personality change	Yes
Suicidal ideation	Yes
Anxiety	Yes
Depression	Yes
Crying	Yes
Intentional self-injury	Yes
Emotional distress	Yes
Pain	Yes
Chest discomfort	Yes
Morbid thoughts	Yes

Event/Problem Narrative:

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

Case ID: 22295577

Tell us what happened and how it happened : I used a generic date as I experienced this during the year I took ozempic. Not listed side effects- anxiety, anxiety attacks, suicidal ideation? Suicidal thoughts and serious personality changes. I already suffer anxiety and depression but ozempic increased them 10 fold. Between months 8-12 on ozempic when I had increased my dosage, I wanted to die. I layer in bed every day crying, lost in dark thoughts. I even planned my suicide. What kept me.alive was having 4 children. My husband lost his wife the day I started ozempic. I slowly started changing and anxiety prevented us from doing family activities, driving in a vehicle. Every day normal things became dangerous. I did not clue in. It was not on the package of side effects. Then I increased and things got worse. I could go on but ozempic almost cost me my life. The month I increased to 1mg dosage was when I clued in that it was the ozempic. Within 24 hours I was uselessly crying in bed and physically hurting myself. While hiding my pain due to embarrassment. I threw it away and within a month I was almost back to normal. I think back now on that year ozempic stole from me and I get pressure in my chest at the thought of how close I was to death;

Relevant Medical History:

List known medical conditions : Diabetes, depression, anxiety, pcos, NAFLD,; Please list all allergies : Tylenol, codeine, sulpha antibiotics, erythromycin, tetracycline;

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	Insulin	/						
2	metforming	/						
3	Paxil	/						
4	lansoprosol	/						
5	Magnesium	/						
6	vitamin D	/						
7	vitamin B 12	/						

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

Case ID: 22295577

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-May-2023	CTU Received Date	07-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	01-Jan-2020
	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 used a generic date as I experienced this during the year I took ozempic. Not listed side effects- anxiety, anxiety attacks, suicidal ideation? Suicidal thoughts and serious personality changes. I already suffer anxiety and depression but ozempic increased them 10 fold. Between months 8-12 on ozempic when I had increased my dosage, I wanted to die. I layer in bed every day crying, lost in dark thoughts. I even planned my suicide. What kept me.alive was having 4 children. My husband lost his wife the day I started ozempic. I slowly started changing and anxiety prevented us from doing family activities, driving in a vehicle. Every day normal things became dangerous. I did not clue in. It was not on the package of side effects. Then I increased and things got worse. I could go on but ozempic almost cost me my life. The month I increased to 1mg dosage was when I clued in that it was the ozempic. Within 24 hours I was uselessly crying in bed and physically hurting myself. While hiding my pain due to embarrassment. I threw it away and within a month I was almost back to normal. I think back now on that year ozempic stole from me and I get pressure in my chest at the thought of how close I was to death

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?	No
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?	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				

Date the person stopped taking or using the product	
Date the person reduced dose of the product	
Give best estimate of duration	1 Year
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

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	Female
Gender	Cisgender woman/girl
Please Specify Other Gender	
Age (specify unit of time for age)	37 Year(s)
Date of Birth	
Weight	
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, depression, anxiety, pcos, NAFLD,

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

Tylenol, codeine, sulpha antibiotics, erythromycin, tetracycline

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.

Insulin, metforming, Paxil, lansoprosol

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

Magnesium, vitamin D, vitamin B 12

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	07-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	

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

Case ID: 22295640

Case Information:

Case Type : Direct **eSub:** N **HP:** N **Country:** US **Event Date:** 07-May-2023 **Outcomes:** LT , OT **Application Type:**

FDA Rcvd Date: 07-May-2023 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2023-34050 **Application #:**

Patient Information:

Age: 64 YR **Sex:** Male **Weight:** 104.85 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		.05 Mg Milligram(S) / QW	Intramuscular	Frequency : Weekly;	Type 2 Diabetes		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic		No	NA	(10) MS7H17B-1	31-Jul-2027	Ozempic	NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Anxiety	
Nightmare	
Depression	
Nausea	
Infrequent bowel movements	

Event/Problem Narrative:

Tell us what happened and how it happened : Describe Event, Problem, or Product Use Error: URGENT! My name is (b)(6)*****. I am a retired police detective and was recently prescribed Ozempic by my family physician for uncontrolled type II diabetes. I have fallen into a very dark place, and I am on the verge of suicide as a result of this medication. I have lost interest in everything, and I struggle to get out of bed to even take a shower. I am no longer myself, and I am experiencing

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

Case ID: 22295640

terrible anxiety, depression and nightmares. I feel nauseated constantly and have unusual bowel movements. Please call or text me if you receive this urgent message. My telephone number is US (b)(6)******, and email(b)(6)****************** If you need to confirm my identity my full name is (b)(6)******************* ************************* *************. I currently live in(b)(6)**********. Please contact me at your earliest convenience this medication is going to cause someone to take their own life if someone hasn't already done so! Warm regards (b)(6)******************* ************************* ******

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:** 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 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	07-May-2023	CTU Received Date	07-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)

A. PATIENT INFORMATION

Patient Identifier (In Confidence)	(b) (6)
Age	64 Year(s)
Date of Birth	
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Weight	104.85 kg
Ethnicity (Check single best answer)	Not Hispanic/Latino
Race (Check all that apply)	☐ Asian ☐ American Indian or Alaska Native ☐ Black or African American ☑ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

Type of Report (check all that apply)	☑ Adverse Event ☐ Product Use/Medication Error ☑ Product Problem (e.g., defects/malfunctions) ☐ Problem with Different Manufacturer of Same Medicine
Serious	Yes
Outcome Attributed to Adverse Event (Check all that apply)	☐ Death ☑ Life Threatening ☐ Hospitalization (initial or prolonged) ☑ Other Serious or Important Medical Events ☐ Disability or Permanent Damage

	☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
Date of Death	
Date of Event	07-May-2023
Date of this Report	07-May-2023

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: URGENT! My name is (b) (6) . I am a retired police detective and was recently prescribed Ozempic by my family physician for uncontrolled type II diabetes. I have fallen into a very dark place, and I am on the verge of suicide as a result of this medication. I have lost interest in everything, and I struggle to get out of bed to even take a shower. I am no longer myself, and I am experiencing terrible anxiety, depression and nightmares. I feel nauseated constantly and have unusual bowel movements. Please call or text me if you receive this urgent message. My telephone number is US (b) (6) , and email (b) (6) If you need to confirm my identity my full name is (b) (6) . I currently live in (b) (6) . Please contact me at your earliest convenience this medication is going to cause someone to take their own life if someone hasn't already done so! Warm regards (b) (6) ??(b) (6) Show quoted text

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

Other Relevant History, Including Preexisting Medical Conditions

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	Yes
Returned to Manufacturer on	
Do you have a picture of the product? (check yes if you are including a picture)	Yes

D. PRODUCT(S) 1 of 1

Suspect	Yes
Primary?	Yes
Type	Drug/Biologic
This report involves:	Other

Name,Strength,Manufacturer/Compounder (from product label)

Product Name	Ozempic		
Strength	0.5 mg milligram(s)	If Other	

Manufacturer/Compounder	Novo Nordisc
NDC# or Unique ID	Ozempic
Product Type(check all that apply)	☐ OTC ☐ Compounded ☑ Generic ☐ Biosimilar
Event Abated After Use Stopped or Dose Reduced?	No
Event Reappeared after Reintroduction ?	

Drug Therapy 1 of 1

Dose or Amount	.05 mg milligram(s)	If Other	
Frequency	Other	If Other	Weekly
Route	Intramuscular	If Other	
Dosage Form			
Start			
Stop			
Dose Reduced			
Therapy Duration	1 Month	If Other	
Is therapy still on-going?	Yes		
Lot Number	(10) MS7H17B-1		
Expiration Date	31-Jul-2027		

Diagnosis for Use (indication) 1 of 1

Type 2 Diabetes

E. SUSPECT MEDICAL DEVICE

Brand Name	
Common Device Name	
Procode	
Manufacturer Name	
City	
State	
Model #	
Lot #	
Catalog #	
Expiration Date	
Serial #	
Unique Identifier (UDI)#	
Operator of Device	☐ Health Professional ☐ Patient/Consumer ☐ Other
Other	

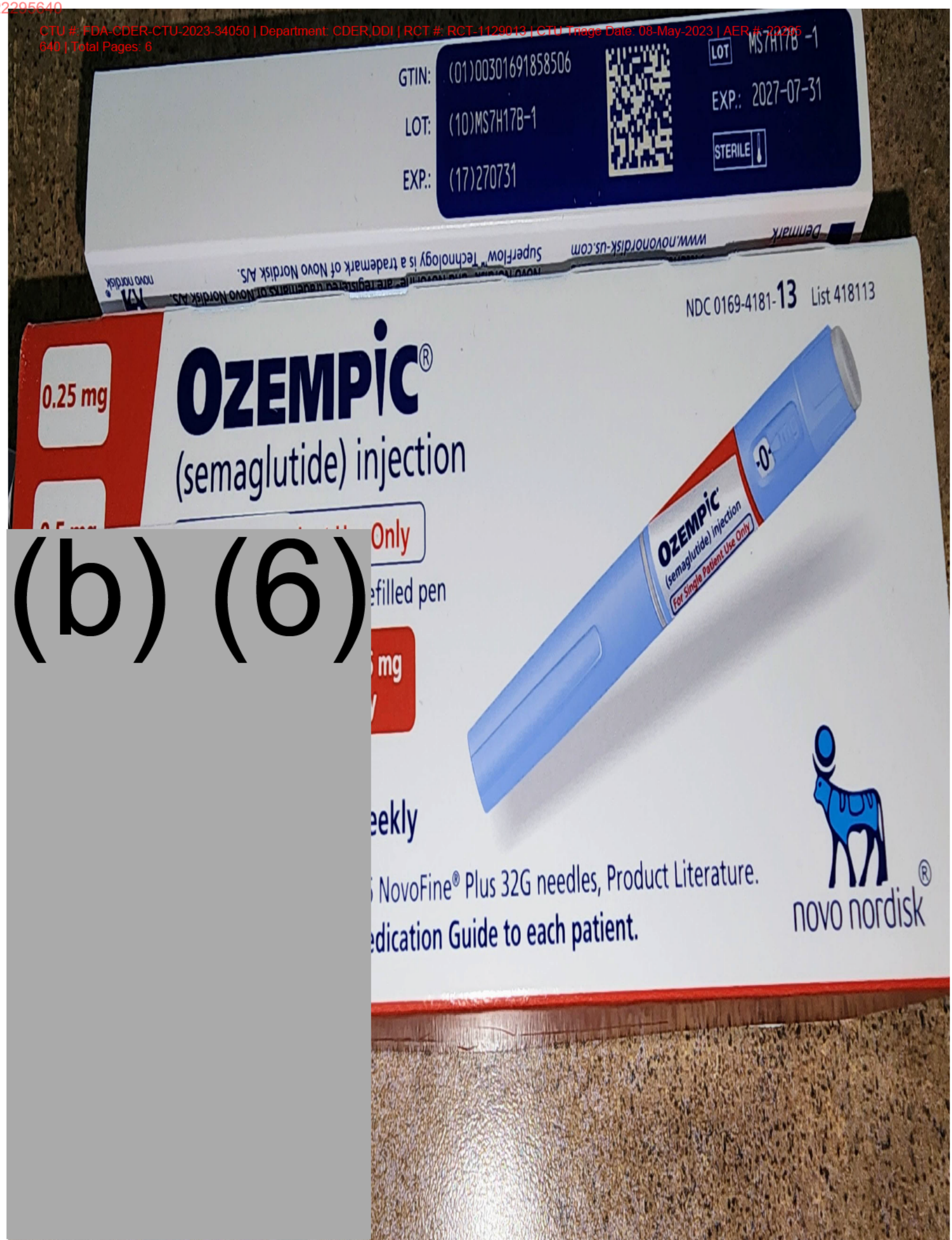
If Implanted, Give Date	
If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	
Was this device serviced by a third party?	

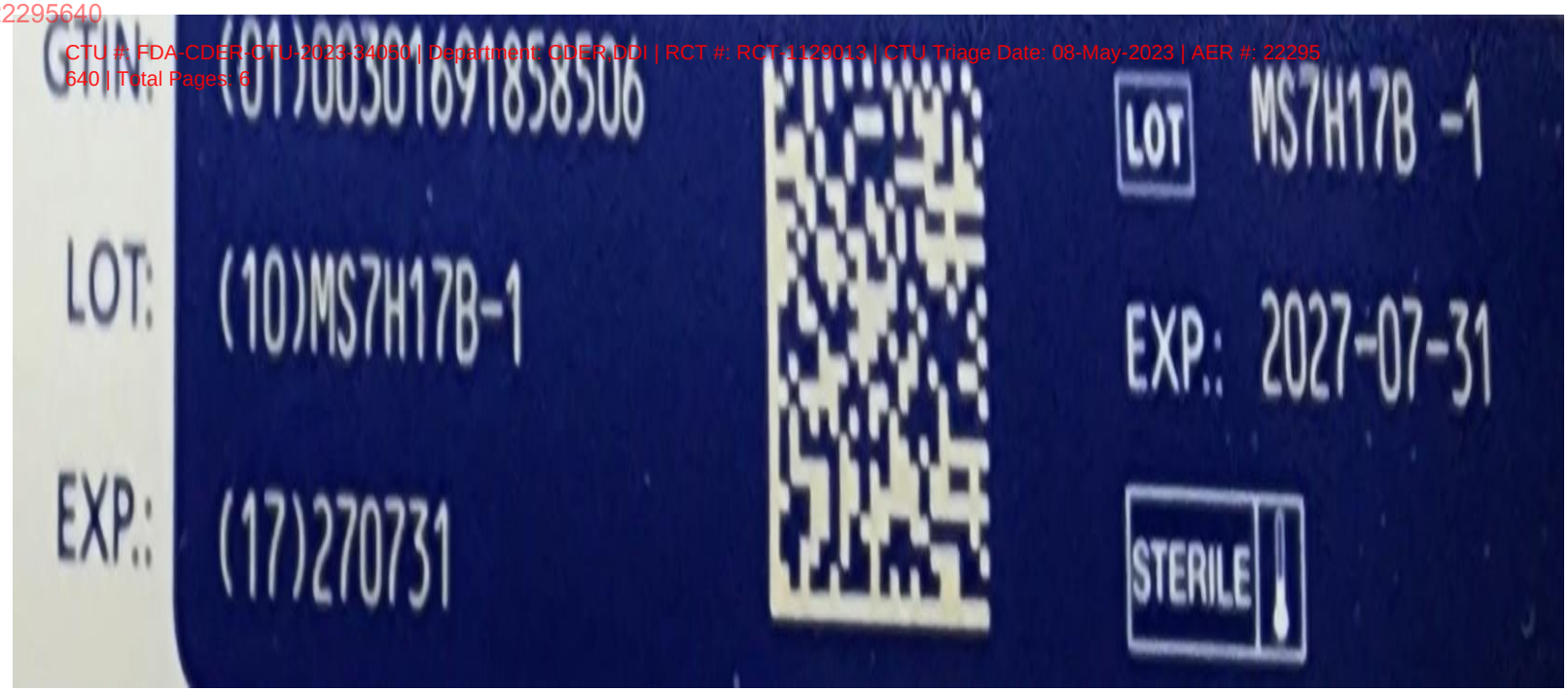
F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER

Primary?	Yes
Reporter is Patient?	
Title	
Last Name	(b) (6)
Middle Name	
First Name	
Address	
City	
State/Province/Region	
Country	f Other
ZIP/Postal Code	
Phone	
Email	
Fax	
Reporter Organization	
Department	
Reporter Speciality	
Health Professional?	No
Occupation	Consumer/other non health professional — If Other
Also Reported to	☑ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer
If you do NOT want your identity disclosed to the manufacturer	No




GTIN:
(01)00301691858506
LOT:
(10)MS7H17B-1
EXP.:
(17)270731
LOT
MS7H17B -1
EXP.: 2027-07-31
STERILE

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

Case ID: 22329030

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** N **Country:** US **Event Date:** 11-Apr-2023 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 17-May-2023 **Mfr Rcvd Date:** 07-May-2023 **Mfr Control #:** US-NOVOPROD-1063697 **Application #:** 209637

Patient Information:

Age: 64 YR **Sex:** Male **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		0.5 Mg Milligram(S) / / WK	Subcutaneous	0.5 mg	Type 2 diabetes mellitus	04-Apr-2023	

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 0.25/0.50 mg	7 Day	NA	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Anxiety	
Depression	
Nightmare	
Bowel movement irregularity	
Nausea	

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Consumer as "verge of suicide(Suicidal ideation)" beginning on 11-APR-2023, "anxiety(Anxiety)" beginning on 11-APR-2023, "depression(Depression)" beginning on 11-APR-2023, "nightmares(Nightmares)" beginning on 11-APR-2023, "unusual bowel movements(Bowel movement irregularity)" beginning on 11-APR-2023, "nauseated constantly(Nausea)" beginning on 11-APR-2023, and

Case ID: 22329030

concerned a 64 Years old Male patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from 04-APR-2023 and ongoing for "uncontrolled type 2 diabetes mellitus". Current Condition: uncontrolled type 2 diabetes mellitus. Concomitant products included - NovoFine Plus 4mm (32G)(Needle) Beginning on 11-APR-2023, a patient who was receiving therapy with Ozempic, reported having fallen into a very dark place clarified as being on the verge of suicide as a result of the product. The patient lost interest in everything and struggled to get out of bed or even take a shower. The patient felt no longer themselves clarified as experiencing terrible anxiety, depression, and nightmares. The patient felt nauseated constantly and had unusual bowel movements. Action taken to Ozempic 0.25/0.50 mg was reported as No Change. The outcome for the event "verge of suicide(Suicidal ideation)" was Not recovered. The outcome for the event "anxiety(Anxiety)" was Not recovered. The outcome for the event "depression(Depression)" was Not recovered. The outcome for the event "nightmares(Nightmares)" was Not recovered. The outcome for the event "unusual bowel movements(Bowel movement irregularity)" was Not recovered. The outcome for the event "nauseated constantly(Nausea)" was Not 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 Ozempic. Limited information as related to medical history aside from uncontrolled type 2 diabetes mellitus, 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?
Diabetes mellitus inadequate control			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?:**

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

Case ID: 22329030

Literature Text:

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

Case ID: 22329031

Case Information:

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

FDA Rcvd Date: 17-May-2023 **Mfr Rcvd Date:** 08-May-2023 **Mfr Control #:** GB-NOVOPROD-1062947 **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	Semaglutide		/		UNK	Product used for unknown indication		

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

Event Information:

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

Anxiety

Suicidal ideation

Event/Problem Narrative:

This serious Spontaneous Regulatory Authority case received via The Medicines and Healthcare products Regulatory Agency(MHRA) from the UNITED KINGDOM was reported by a Other Health Care Professional as "Anxious mood(Anxious mood)" with an unspecified onset date, "Suicidal ideation(Suicidal ideation)" with an unspecified onset date, "and concerned a Female patient who was treated with Semaglutide (SEMAGLUTIDE) from unknown start date for "drug use for unknown indication", Patient's height, weight and body mass index were not reported. Historical Condition: Anxiety, panic attack. On an unknown date, patient experienced Anxious mood, Suicidal ideation and panic attacks. It was reported that the symptoms reduced but not resolved by lowering dose. Patient didn't think this reaction occurred as a result of a mistake made in the prescription, dosing, dispensing or administration of the medication Batch Numbers: Semaglutide: Unknown Action taken to Semaglutide was reported as Unknown. The outcome for the event "Anxious mood(Anxious mood)" was Not recovered. The outcome for the event "Suicidal ideation(Suicidal ideation)" was Not recovered. No further information available. References included: Reference Type: E2B Company Number Reference ID#: GB-MHRA-MED-20230507113859925O-LMGFT Reference Notes: Reference Type: E2B Report Duplicate Reference ID#: GB-MHRA-ADR

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

Case ID: 22329031

27890405 Reference Notes: MHRA Reference Type: E2B Report Duplicate Reference ID#: GB-MHRA-MED-202305071138599250-LMGFT Reference Notes: ELECTRONICYCPROD Company Comment: 'Suicidal ideation', 'Anxiety' are assessed as unlisted events according to current NovoNordisk CCDS information on Semaglutide Information on event and suspected product start date, relevant medical history like previous episodes of suicidal thoughts, substance abuse, social circumstance, definitive diagnosis are missing. However historical conditions of anxiety and panic attacks are confounders. This single case report is not considered to change the current knowledge of the safety profile of Semaglutide

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Anxiety			
Panic attack			

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: 22353054

Case Information:

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

FDA Rcvd Date: 23-May-2023 **Mfr Rcvd Date:** 12-May-2023 **Mfr Control #:** CA-NOVOPROD-1065208 **Application #:** 209637

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		/		UNK	Diabetes mellitus		

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

Event Information:

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

Suicidal ideation

Anxiety

Mental disorder

Event/Problem Narrative:

This serious Spontaneous case from CANADA was reported by a Consumer as "Suicidal(Suicidal ideation)" with an unspecified onset date, "Anxiety(Anxiety)" with an unspecified onset date, "Mental health issues(Mental disorder)" with an unspecified onset date, and concerned a patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for "Diabetes mellitus". Patient's Height, Weight and Body Mass Index (BMI) was not reported. Current Condition: Diabetes mellitus(Type and Duration was not reported) On an unknown date, the patient experienced anxiety, mental health issues and was suicidal. Batch Numbers: Ozempic was not reported. Action taken to Ozempic was Not reported. The outcome for the event "Suicidal(Suicidal ideation)" was Not Reported. The outcome for the event "Anxiety(Anxiety)" was Not Reported. The outcome for the event "Mental health issues(Mental disorder)" was Not Reported. No further information available. Company Comment: "Suicidal ideation", "Anxiety" and "Mental disorder" are assessed as unlisted according to the Novo Nordisk current CCDS information on Ozempic. Information on events onset date and suspected product exposure details, relevant medical history including any previous

episodes of suicidal thoughts , social circumstance, psychiatric disorders , details of mental health issues and definitive diagnosis are missing. Limited information precludes thorough medical assessment. 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?
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

Reporter Source:

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

Literature Text: