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

Date - T me: 27-Sep-2023 4:25:55 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:

18143068	18340030	20149863	20762799
21159058	22128240	22518701	22593148
22632639	22638742	22638777	22645981

Total Cases: 12

Total number of Inactive cases: *0

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: 18340030

Case Information:

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

FDA Rcvd Date: 10-Dec-2020 **Mfr Rcvd Date:** 14-Oct-2020 **Mfr Control #:** JP-NOVOPROD-754978 **Application #:** 209637

Patient Information:

Age: 54 YR **Sex:** Male **Weight:** 97.4 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic Subcutaneous Injection 0.25mg SD		.25 Mg Milligram(S) / WK	Subcutaneous	0.25 mg, qw	Type 2 diabetes mellitus	27-Aug-2020	15-Sep-2020
2	Tresiba Chu		/	Subcutaneous	UNK	Type 2 diabetes mellitus		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic Subcutaneous Injection 0.25mg SD	19 Day	Not Applicable	NA				NOVO NORDISK	
2	Tresiba Chu		Not Applicable	NA				NOVO NORDISK	

Event Information:

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

Event/Problem Narrative:

This serious Spontaneous case from JAPAN was reported by a Medical Doctor as "Suicide attempt(Suicide attempt)" beginning on (b)(6)*****, "Hypoglycaemia(Hypoglycaemia)" beginning on (b)(6)*****, "Overdose deliberate self-inflicted(Overdose deliberate self-inflicted)" beginning on -(b)(6)**, and concerned a 54 Years old Male patient who was treated with Tresiba Chu (Insulin Degludec) from unknown start date for "Type 2 diabetes mellitus", , Ozempic

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

Case ID: 18340030

Subcutaneous Injection 0.25mg SD(SEMAGLUTIDE) from 27-AUG-2020 to (b)(6)***** for "Type 2 diabetes mellitus". Patient's height: 176 cm Patient's weight: 97.4 kg Patient's BMI: 31.443. Dosage Regimens: Tresiba Chu: Ozempic Subcutaneous Injection 0.25mg SD : 27-AUG-2020 to (b)(6)*****; Current Condition: Type 2 diabetes mellitus (duration not reported), End stage renal failure, Obesity Procedure: Dialysis. On 27-AUG-2020 patient started on Ozempic 0.25 mg. The drug was administered by a nurse after dialysis at a hospital. On 27-AUG-2020 Blood lactate dehydrogenase was 175(units not reported), Blood alkaline phosphatase was 261(units not reported) and 92(units not reported), Estimated glomerular filtration rate was 5.3(units not reported), Blood glucose was 121(units not reported), Red cell distribution width(RDW-SD) was 49.2(units not reported), Red cell distribution width(RDW-CV) was 15.1(units not reported), Platelet distribution width was 8.7(units not reported), Mean platelet volume(MPV) was 9.2(units not reported), Platelet-large cell ratio(P-LCR) was 17.6(units not reported), C-reactive protein(Blood CPR) was 10.5(units not reported), Glycated albumin was 21.3(units not reported), Brain natriuretic peptide(BNP) was 31.0(units not reported), Corrected Ca level was 8.8(units not reported),FIB-4 index 0.54(units not reported) and Mentzer index was 23(units not reported) On (b)(6)***** (three weeks after the initiation of treatment with Ozempic), the patient had overdose deliberate self-inflicted with Tresiba for suicide attempt. The patient developed hypoglycaemia and died. Batch Number of Tresiba Chu and Ozempic Subcutaneous Injection 0.25mg SD has been requested. Action taken to Tresiba Chu was reported as Not Applicable. Action taken to Ozempic Subcutaneous Injection 0.25mg SD was reported as Not Applicable. The outcome for the event "Suicide attempt(Suicide attempt)" was Unknown. On (b)(6)***** the outcome for the event "Hypoglycaemia(Hypoglycaemia)" was Fatal. The outcome for the event "Overdose deliberate self-inflicted(Overdose deliberate self-inflicted)" was Unknown. On 14-OCT-2020, an Amendment was performed. Since last submission, the following information has been amended: suspect product corrected from Semaglutide B 1.34 mg/mL PDS290 to Semaglutide C DV3372. Company comment: Suicide attempt is assessed as unlisted and Hypoglycemia is assessed as listed according to the Novo Nordisk current CCDS information on Ozempic and Tresiba Chu Information on autopsy report, medical history of any psychiatric disorder ,previous attempts of suicide are not available. However death due to overdose of suspect product and hypoglycemia cannot be denied. 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 and Tresiba Chu

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Type 2 diabetes mellitus			
End stage renal disease			
Obesity			
Dialysis			

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
Adjusted calcium					Y
Blood alkaline phosphatase					Y

Case ID: 18340030

Blood alkaline phosphatase	Y
Blood glucose	Y
Blood lactate dehydrogenase	Y
Brain natriuretic peptide	Y
C-reactive protein	Y
Glomerular filtration rate	Y
Glycated albumin	Y
Mean platelet volume	Y
Platelet distribution width	Y
Platelet-large cell ratio	Y
Red cell distribution width	Y
Red cell distribution width	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: 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.

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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: 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

Case ID: 20762799

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: 21159058

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** CA **Event Date:** 11-Jul-2022 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 02-Aug-2022 **Mfr Rcvd Date:** 22-Jul-2022 **Mfr Control #:** CA-NOVOPROD-943524 **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		/		UNK	Type 2 diabetes mellitus	24-May-2022	

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic	48 Day	NA	NA				NOVO NORDISK	

Event Information:

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

Suicide attempt

Depression

Event/Problem Narrative:

This serious Spontaneous case from CANADA was reported by a Endocrinologist as "Suicidal attempt(Attempted suicide)" beginning on 11-JUL-2022, "Started to feel depressed(Depressed state)" with an unspecified onset date, and concerned a Female patient who was treated with Ozempic (SEMAGLUTIDE) from 24-MAY-2022 for "Type 2 diabetes mellitus", Patient's height, weight and body mass index were not reported. Dosage Regimens: Ozempic: 24-MAY-2022 to Not Reported; Current Condition: Type 2 diabetes mellitus (duration not reported), Fibromyalgia. Concomitant products included - METFORMIN, GLICLAZIDE , FLICK AZURE (non-codable) On an unknown date, patient started to feel depressed after taking Ozempic. On (b)(6)*****, the patient did Suicidal attempt, but survived unscathed (took all her meds at once). The patient was seen in ER at Hospital. The patient had been off all antihyperglycemics. Batch Number for Ozempic not reported. Action taken to Ozempic was reported as Product discontinued. The outcome for the event "Suicidal attempt(Attempted suicide)" was Not Reported. The outcome for the event "Started to feel depressed(Depressed state)" was Not Reported. No further information available. Company comment: 'Suicide attempt' and 'Depression' are assessed as unlisted events according to the Novo Nordisk current CCDS on Ozempic. Information regarding concomitant medications (any

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

Case ID: 21159058

illicit drug use) complete medical history (psychological disorder, social disturbances, stress, etc.) and relevant investigation report is 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 of Ozempic.

Relevant Medical History:

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

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Case ID: 22128240

Case Information:

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

FDA Rcvd Date: 03-Apr-2023 **Mfr Rcvd Date:** 23-Mar-2023 **Mfr Control #:** LB-NOVOPROD-1038887 **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 1.0 mg		/		UNK	Product used for unknown indication		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 1.0 mg		Unknown	NA				NOVO NORDISK	

Event Information:

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

Event/Problem Narrative:

This serious Spontaneous case from LEBANON was reported by a Physician as "attempted to commit suicide(Suicide attempt)" with an unspecified onset date, "taking 1 full pen of Ozempic 1mg in one day(Intentional overdose)" with an unspecified onset date, and concerned a Female patient (age not reported) who was treated with Ozempic 1.0 mg (SEMAGLUTIDE) from unknown start date for "Drug use for unknown indication". Patient's height weight and body mass index were not reported Medical history was not provided. Concomitant products included - Xanax(Alprazolam), Stilnox(Zolpidem Tartrate) On an unspecified date, the patient tried to commit suicide by taking 1 full pen of Ozempic 1mg in one day, in addition to Xanax and Stilnox. The patient was hospitalized to the ER. The blood tests were normal. (Test name, values and units were not reported). After that left the hospital. Batch Numbers: Ozempic 1.0 mg: not reported. Action taken to Ozempic 1.0 mg was Not reported. The outcome for the event "attempted to commit suicide(Suicide attempt)" was Not Reported. The outcome for the event "taking 1 full pen of Ozempic 1mg in one day(Intentional overdose)" was Not Reported. No further information available. Since last submission case updated with the following information: New lab data has been added NFI updated Narrative updated accordingly. Company comment: Suicide attempt is assessed as unlisted event and

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

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intentional overdose is assessed as listed event according to NovoNordisk current reference safety information on Ozempic. Information on demographic details of the patient, history of any risk factors like psychiatric disorders, psychological disorders, anxiety, depression, social and family behavior, relevant medical history, relevant clinical and investigation results, action taken with the suspect, event onset dates with outcome, exposure details of the suspect are unavailable for 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?

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 TEST					Y

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Case ID: 22518701

Case Information:

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

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

Patient Information:

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

Suspect Products:

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

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

Event Information:

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

Event/Problem Narrative:

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

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

Case ID: 22518701

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

Relevant Medical History:

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

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text:

MedWatch Voluntary Report

1 2 3 4 5 6

Review & Submit

About Problem

Edit Section

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

CTU #: FDA-CDER-CTU-2023-41147 | Department: CDER | RCT #: RCT-1136245 | CTU Triage Date: 05-Jun-2023 | AER #: 22518701 | Total Pages: 6

Tell us what happened and how it happened:	My brother 13 months ago (April of 2022) was diagnosed with new onset clinical depression. He sought treatment and was doing very well. Around sometime in January or February of 2023 he was prescribed Ozempic for his Type 2 diabetes by his family medicine physician dosed with a build-up to 1 mg per week via injection. Ozempic, SEMAGLUTIDE, or Wegovy SEMAGLUTIDE (stated in section 5.9 of Wegovy's PI) should be avoided in patients with a history of suicidal attempts or active suicidal ideation. Semaglutide, if prescribed, patients should be monitored for the emergence or worsening of depression, suicidal thoughts or behaviors, and /or any unusual changes in mood or behavior. It is well written in literature and a plethora of drug websites that Ozempic can trigger these thoughts, but healthcare providers are not warned and subsequentially patients are not informed. My brother (b) (6) had extreme weight-loss of 60lbs in a matter of months on Ozempic and no monitoring. No screening questions asked - healthcare providers are not being properly detailed on this drug - it is being pushed so heavily for the latest miracle weight- loss drug. There is no black box warning or alert in OZEMPIC prescribing information to alert healthcare providers or patients about suicidal thoughts and it is my belief that many healthcare professionals are not aware of the potential deadly adverse event. Again, Doctors are not being informed properly to screen for this or monitor appropriately. Therefore, this drug is being prescribed to very vulnerable people unaware and triggering suicidal thoughts in some people. On the morning of (b) (6) he got up early, made coffee, while his fiancé was in nearby bedroom, and preceded at some point to go outside to their patio pavilion and kill himself by gun-shot wound to the head. He was on medications he had been on for years. He was not on anything new until Ozempic was prescribed. There were no outward reasons or any warning for this to happen. It seemingly was a spur of the moment decision he made. His life was very good. He was getting married in the fall - he said he was the happiest he had ever been. He had a great job, he was financially secure and had 4 beautiful children, and his second grandchild on the way. He had a very loving and cl

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

About Product

Edit Section

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

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

About Patient

Edit Section

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

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

About Reporter

Edit Section

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

reCAPTCHA *

I'm not a robot

reCAPTCHA

Previous Submit Exit

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

Case ID: 22593148

Case Information:

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

FDA Rcvd Date: 13-Jun-2023 **Mfr Rcvd Date:** 01-Jun-2023 **Mfr Control #:** US-NOVOPROD-1075387 **Application #:** 209637

Patient Information:

Age: 58 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic 2 mg		2 Mg Milligram(S) / / WK	Subcutaneous	2 mg, qw	Type 2 diabetes mellitus	01-Feb-2023	

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 2 mg	102 Day	NA	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Completed suicide	
Suicidal ideation	
Depression	

Event/Problem Narrative:

This serious spontaneous case from the UNITED STATES was reported by a consumer as "took own life(Completed suicide)" beginning on (b)(6)*****, "suicidal thoughts(Suicidal ideation)" beginning in 2023, "anxiety depression(Anxiety depression)" beginning in 2023, and concerned a 58 year old male patient, who was treated with Ozempic 2 mg (semaglutide) from 01-FEB-2023 and ongoing for type 2 diabetes mellitus. Current Condition: type 2 diabetes mellitus. A consumer reported that a patient receiving therapy with Ozempic 2 mg experienced anxiety depression and had suicidal thoughts in 2023. On (b)(6)*****, the patient took his own life (autopsy information not provided). Action taken to Ozempic 2 mg was reported as No Change. On (b)(6)***** the outcome for the event "took own life(Completed suicide)" was Fatal. The outcome for the event "suicidal thoughts(Suicidal ideation)" was Not recovered. The outcome for the event "anxiety depression(Anxiety depression)" was Not Reported. Batch number was requested. Company Comment: Completed suicide is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. Limited information as related to more specific onset dates for the non-serious

Case ID: 22593148

"anxiety depression" and "suicidal ideation", medical history aside from type 2 diabetes, concomitant medications, family/social history, and laboratory/diagnostic evaluations including autopsy report 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?
Type 2 diabetes mellitus			Yes

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

Relevant Laboratory Data:

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

Concomitant Products:

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

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: 22632639

Case Information:

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

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

Patient Information:

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

Suspect Products:

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

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

Event Information:

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

Completed suicide

Event/Problem Narrative:

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

Relevant Medical History:

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

Case ID: 22632639

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

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Case ID: 22638742

Case Information:

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

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

Patient Information:

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

Suspect Products:

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

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

Event Information:

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

Depression

Completed suicide

Event/Problem Narrative:

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

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

Case ID: 22638742

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Case ID: 22638777

Case Information:

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

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

Patient Information:

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

Suspect Products:

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

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

Event Information:

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

Event/Problem Narrative:

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

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

Case ID: 22638777

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

Relevant Medical History:

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

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

Relevant Laboratory Data:

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

Concomitant Products:

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

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

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

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

Case ID: 22638777

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

Reporter Source:

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

Literature Text:

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

Case ID: 22645981

Case Information:

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

FDA Rcvd Date: 07-Aug-2023 **Mfr Rcvd Date:** 26-Jul-2023 **Mfr Control #:** US-NOVOPROD-1082919 **Application #:** 209637

Patient Information:

Age: 73 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) /	Subcutaneous	0.25 mg	Product used for unknown indication	28-Mar-2023	11-Apr-2023
2	CYMBALTA		/		60 mg	Mental disorder		
3	XANAX		/		0.5 mg	Mental disorder		
4	XANAX		1 Mg Milligram(S) / BID		1 mg, bid			

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 0.25/0.50 mg		No	NA	MZF4F86			NOVO NORDISK	
2	CYMBALTA		Unknown	NA					
3	XANAX		Unknown	NA					
4	XANAX		Unknown	NA	VNO122013A				

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Depression	
Suicidal ideation	
Drug interaction	

Nightmare

Headache

Gastrointestinal disorder

Constipation

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Consumer as "felt more depressed(Depression aggravated)" beginning on MAR-2023, "wanted to kill self(Suicidal ideation)" beginning on MAR-2023, "reactions with Cymbalta and Xanax(Drug interaction)" beginning on MAR-2023, "bad dreams(Bad dreams)" beginning on MAR-2023, "headaches(Headache)" beginning on MAR-2023, "severe gastrointestinal issues(Gastrointestinal disorder)" beginning on MAR-2023, "constipation(Constipation)" beginning on MAR-2023, and concerned a 73 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from 28-MAR-2023 to 11-APR-2023 for "Drug use for unknown indication", , a non-Novo Nordisk suspect product CYMBALTA (DULOXETINE HYDROCHLORIDE) from unknown start date for "mental health issues", , a non-Novo Nordisk suspect product XANAX (ALPRAZOLAM) from unknown start date for "mental health issues", Dosage Regimens: Ozempic 0.25/0.50 mg: 28-MAR-2023 to 11-APR-2023; Current Condition: depression, mental. A patient, who was receiving therapy with Ozempic, had a medical history of mental health issues and depression but had felt more depressed, had headaches and bad dreams in MAR-2023. The patient wanted to kill herself while on the Ozempic. The patient felt the events were possibly coming from a reaction with Ozempic, Cymbalta, and Xanax. In MAR-2023, the patient also experienced severe gastrointestinal issues including constipation. The patient was on Ozempic for two weeks and switched to Rybelsus. Batch Numbers: Ozempic 0.25/0.50 mg: MZF4F86 Action taken to Ozempic 0.25/0.50 mg was reported as Product discontinued due to AE. Action taken to CYMBALTA was Not reported. Action taken to XANAX was Not reported. The outcome for the event "felt more depressed(Depression aggravated)" was Unknown. The outcome for the event "wanted to kill self(Suicidal ideation)" was Unknown. The outcome for the event "reactions with Cymbalta and Xanax(Drug interaction)" was Not yet recovered. The outcome for the event "bad dreams(Bad dreams)" was Unknown. The outcome for the event "headaches(Headache)" was Not yet recovered. The outcome for the event "severe gastrointestinal issues(Gastrointestinal disorder)" was Not yet recovered. The outcome for the event "constipation(Constipation)" was Not yet recovered. Since the last submission, the following details were updated -Batch number and dose details for the suspect Xanax was added -Dose for the suspect cymbalta was added -Narrative was updated Company Comment: Depression (aggravated) and suicidal ideation are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. A medical history of depression and mental health issues suggest alternative etiologies. Limited information as related to indication for Ozempic use, 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.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Depression			Yes
Mental disorder			Yes

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

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

Case ID: 22645981

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: