FDA Adverse Event Reporting System (FAERS)
FOIA Batch Printing Report for Cases Date - T me: 23-Aug-2023 :27:57 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:

19958733	19982528	20089533	20194982
20235596	20534614	20996582	21159058
21670942	22533952	22593148	22645980

Total Cases: 12

Total number of Inactive cases: *0

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

Case ID: 19958733

Case Information:

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

FDA Rcvd Date: 15-Oct-2021 **Mfr Rcvd Date:** 05-Oct-2021 **Mfr Control #:** US-NOVOPROD-855744 **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	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 suicidal

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Consumer as "severe feelings of depression with suicidal thoughts(Suicidal depression)" with an unspecified onset date, and concerned a Male patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date and ongoing for "drug use for unknown indication". Historical Condition: depression. A patient receiving therapy with Ozempic experienced severe feelings of depression with suicidal thoughts. Action taken to Ozempic was reported as No Change. The outcome for the event "severe feelings of depression with suicidal thoughts(Suicidal depression)" was Unknown. Batch number requested in follow up. Company Comment: Depression suicidal is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. A medical history of depression has been associated with an increased risk for suicidal thoughts, therefore considered a confounder. Limited information as related to age, Ozempic therapy dates, event date, concomitant medications, family/social history, and laboratory/diagnostic evaluations limits further medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

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

Case ID: 19958733

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Depression			No

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: 19982528

Case Information:

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

FDA Rcvd Date: 24-Oct-2021 **Mfr Rcvd Date:** 13-Oct-2021 **Mfr Control #:** US-NOVOPROD-858420 **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		.25 Mg Milligram(S) /	Subcutaneous	0.25 mg	Product used for unknown indication		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic		Yes	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 Physician as "suicidal ideation(Suicidal ideation)" 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". Medical history was not provided. A patient receiving therapy with Ozempic experienced suicidal ideation 2 days after taking Ozempic at 0.25 mg dose. Action taken to Ozempic was reported as Product discontinued due to AE. The outcome for the event "suicidal ideation(Suicidal ideation)" was Recovered. Batch number was unavailable. 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 suspect product therapy dates, medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluations precludes medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

Relevant Medical History:

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

Case ID: 19982528

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: 20089533

Case Information:

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

FDA Rcvd Date: 19-Nov-2021 **Mfr Rcvd Date:** 09-Nov-2021 **Mfr Control #:** AU-NOVOPROD-867691 **Application #:** 209637

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic 0.25/0.50 mg		0.25 Mg Milligram(S) / /WK	Unknown	0.25 mg, qw	Product used for unknown indication		08-Nov-2021

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

Event Information:

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

Suicidal ideation

Depression

Event/Problem Narrative:

This serious Spontaneous case from AUSTRALIA was reported by a Medical Doctor as "suicidal thoughts(Suicidal ideation)" with an unspecified onset date, "depression(Depression)" with an unspecified onset date, and concerned a 52 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from unknown start date to 08-NOV-2021 for "product used for unknown indication", Patient's height, weight and body mass index not reported. Dosage Regimens: Ozempic 0.25/0.50 mg: Not Reported to 08-NOV-2021; Medical history was not provided. On an unknown date, the patient started using Ozempic. Patient reported depression and suicidal thoughts soon after starting on Ozempic The patient has stopped taking Ozempic. Batch Number of Ozempic 0.25/0.50 mg was requested. Action taken to Ozempic 0.25/0.50 mg was reported as Product discontinued. The outcome for the event "suicidal thoughts(Suicidal ideation)" was Not Reported. The outcome for the event "depression(Depression)" was Not Reported. Company comment: ‘Suicidal ideation’ and ‘Depression’ are assessed as unlisted events according to the Novo Nordisk current CCDS information on Ozempic. Depression is a mood disorder that can lead to suicidal thoughts. Information on relevant medical history, family history of depression, social history or environmental circumstances which may have led to suicidal

Case ID: 20089533

ideation, concomitant treatment with psychoactive drugs (e.g. SSRIs or Benzodiazepines) and event outcome are not available 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

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: 20194982

Case Information:

Case Type : Direct **eSub:** N **HP:** **Country:** US **Event Date:** 27-Nov-2021 **Outcomes:** LT **Application Type:** COMP

FDA Rcvd Date: 16-Dec-2021 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2021-94604 **Application #:** 99

Patient Information:

Age: 48 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic 1mg pen	Y	Other / 999	Subcutaneous	OTHER QUANTITY : 1 Injection(s); OTHER FREQUENCY : Once a week;	Diabetes. Lower blood sugars.	03-Sep-2021	26-Nov-2021

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

Event Information:

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

Event/Problem Narrative:

Tell us what happened and how it happened : After increasing Ozempic to 1mg, the second week I was suicidal and had dark depression. I had a plan but did not follow through.;

Relevant Medical History:

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

Case ID: 20194982

List known medical conditions : Diabetes, Depression, Anxiety, ADHD; Please list all allergies : Penicillin, Codeine, Leviquin;

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	High		
Override Auto Calculation Rule	No		
FDA Received Date	16-Dec-2021	CTU Received Date	16-Dec-2021
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	27-Nov-2021
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☑ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

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)

After increasing Ozempic to 1mg, the second week I was suicidal and had dark depression. I had a plan but did not follow through.

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

I have a history of depression and suicidal ideation. I was prescribed Trulicity by my doctor, but insurance denied. I was then given Ozempic.

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	Drug		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Ozempic 1mg pen		
Name of the company that makes (or compounds) the product			
Product Type(check all that apply)	☐ Over-the-Counter ☑ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date			
Lot number			
Dosage Form			
Quantity	Other	If Other	1 Injection(s)
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	03-Sep-2021		
Date the person stopped taking or using the product	26-Nov-2021		
Give best estimate of duration			

	Is therapy still on-going?	

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

Diabetes. Lower blood sugars.

	Returned to Manufacturer On	

Section D - About the Medical Device

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

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

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

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

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

Section E - About the Person Who Had the Problem

	Person's Initials	(b) (6)
	Gender	Female
	Age (specify unit of time for age)	
	Date of Birth	(b) (6)
	Weight	
	Ethnicity (Choose only one)	Not Hispanic/Latino
	Race (Check all that apply)	☐ American Indian or Alaskan Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

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

Diabetes, Depression, Anxiety, ADHD

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

Penicillin, Codeine, Leviquin

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.

Lamotrigine, Cymbalta, Trazadone, Vyvanse,

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

Vitamin D, Vitamin B, Magnesium, Probiotic

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	16-Dec-2021	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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

Case ID: 20235596

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** N **Country:** DE **Event Date:** 07-Nov-2021 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 28-Dec-2021 **Mfr Rcvd Date:** 17-Dec-2021 **Mfr Control #:** DE-NOVOPROD-877054 **Application #:** 209637

Patient Information:

Age: 39 YR **Sex:** Female **Weight:** 100 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		/	Subcutaneous	UNK	Diabetes mellitus	07-Nov-2021	13-Nov-2021

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

Event Information:

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

Suicidal ideation

Event/Problem Narrative:

This serious Spontaneous case received via " BfArM (The Federal Institute for Drugs and Medical Devices), DEU " from GERMANY was reported by a Consumer as "Suicidal thoughts starting 2 hours after injection and lasted for 6.5 days(Suicidal ideation)" beginning on 07-NOV-2021, and concerned a 39 Years old Female patient who was treated with Ozempic (SEMAGLUTIDE) from 07-NOV-2021 to 13-NOV-2021 for "Diabetes", The event Suicidal ideation was not medically confirmed. Patient's height: 170 cm Patient's weight: 100 kg Patient's BMI: 34.60207610. Dosage Regimens: Ozempic: 07-NOV-2021 to 13-NOV-2021; Historical Condition: Diabetes (Type and duration not reported). On 07-NOV-2021, the patient had Suicidal ideation, 2 hours after Ozempic was administered and it lasted for 6.5 days. The Batch Number of Ozempic was Unknown. Action taken to Ozempic was Not reported. On 13-NOV-2021 the outcome for the event "Suicidal thoughts starting 2 hours after injection and lasted for 6.5 days (Suicidal ideation)" was Recovered. References included: Reference Type: E2B Report Duplicate Reference ID#: DE-BFARM-21012007 Reference Notes: BfArM (The Federal Institute for Drugs and Medical Devices), DEU Reference Type: E2B Authority Number Reference ID#: DE-CADRBFARM-2021223653 Reference Notes: BfArM (The Federal Institute for Drugs and Medical Devices), DEU Reference Type: E2B Report Duplicate Reference ID#: DE-CADRBFARM-2021223653 Reference Notes: PEI Webportal Company comment: Suicidal ideation is assessed as unlisted event according to the NovoNordisk current company core data sheet (CCDS) on Ozempic Information regarding medical history of any psychiatric disorders, history of similar episode, family history, history of any emotional stress, concomitant medication details , laboratory investigations reports, history of

Case ID: 20235596

alcohol consumption and any history of any substance abuse are not available for the 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?
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: 20534614

Case Information:

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

FDA Rcvd Date: 02-Mar-2022 **Mfr Rcvd Date:** 22-Feb-2022 **Mfr Control #:** CA-NOVOPROD-894876 **Application #:** 209637

Patient Information:

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

Suspect Products:

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

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

Event Information:

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

Depression suicidal

Event/Problem Narrative:

This serious Spontaneous case from CANADA was reported by a Nurse as "exacerbated her depression symptoms with suicidal thoughts(Depression suicidal)" with an unspecified onset date, and concerned a Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from unknown start date for "product used for unknown indication", Patient's height, weight, body mass index were not reported. Dosage Regimens: Ozempic 0.25/0.50 mg: Current Condition: depression. On an unknown date, patient tried Ozempic 0.25 mg weekly over a year ago and had exacerbated her depression symptoms with suicidal thoughts after first dose. On an unknown date, the patient discontinued the product and was recovered Batch Number of Ozempic 0.25/0.50 mg: not reported Action taken to Ozempic 0.25/0.50 mg was reported as Product discontinued. The outcome for the event "exacerbated her depression symptoms with suicidal thoughts(Depression suicidal)" was Recovered. No further information available Company Comment: "Depression suicidal" is assessed as unlisted event according to the Novo Nordisk current CCDS on Ozempic. Patient’s history of depression could be considered as confounding factor for the event. Information on patient’s age, BMI, family / social history, history of substance abuse, circumstances surrounding the event, and indication of suspect drug are missing for detailed medical evaluation. 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: 20534614

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Depression			

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

Relevant Laboratory Data:

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

Concomitant Products:

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

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: 20996582

Case Information:

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

FDA Rcvd Date: 23-Jun-2022 **Mfr Rcvd Date:** 13-Jun-2022 **Mfr Control #:** CA-NOVOPROD-929972 **Application #:** 209637

Patient Information:

Age: 58 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		/	Unknown	0.25 mg	Product used for unknown indication	Nov-2020	Jan-2021
2	Ozempic		/	Unknown	0.5 mg(dose decreased)			Sep-2021
3	Ozempic		/	Unknown	1 mg		Feb-2021	
4	Ozempic		/	Unknown	0.5 mg		Jan-2021	

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

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Depression suicidal	
Fatigue	
Dizziness	

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

Case ID: 20996582

Event/Problem Narrative:

This serious Spontaneous case from CANADA was reported by a Consumer as "severe depression and suicidal thoughts(Suicidal depression)" with an unspecified onset date, "fatigue(Fatigue)" with an unspecified onset date, "dizziness(Dizziness)" with an unspecified onset date, and concerned a 58 Years old Female patient who was treated with Ozempic (SEMAGLUTIDE) from NOV-2020 to SEP-2021 for "Product used for unknown indication", Patient's height, weight and body mass index not reported Dosage Regimens: Ozempic: ??-NOV-2020 to ??-JAN-2021, ??-JAN-2021 to Not Reported, ??-FEB-2021 to Not Reported, Not Reported to ??-SEP-2021; Medical history was not provided. Historical drug: DPP-4 (non codable) On an unknown date Patient took 2 doses of 1mg Ozempic and complained of debilitating side effects (stating fatigue and dizziness) at which point she was decreased back to 0.5mg and symptoms continued. Patient had detailed the HCP on the severity of her symptoms, including severe depression and suicidal thoughts with no history of psychological illness/depression/suicidal intention. Batch Numbers: Ozempic: ASKU, ASKU, ASKU, ASKU Action taken to Ozempic was reported as Product discontinued. The outcome for the event "severe depression and suicidal thoughts(Suicidal depression)" was Not recovered. The outcome for the event "fatigue(Fatigue)" was Recovered. The outcome for the event "dizziness(Dizziness)" was Recovered. Company Comment: Depression suicidal is assessed as unlisted, Fatigue and Dizziness is assessed as listed according to the Novo Nordisk current CCDS on Ozempic. Information pertaining to event onset (temporal association cannot be established), medical history (any chronic illness), family history, socio-economic status, other relevant laboratory (vitamin B12, folate) and diagnostic evaluation are unavailable for 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

Concomitant Products:

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

Reporter Source:

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

Case ID: 20996582

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: 21670942

Case Information:

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

FDA Rcvd Date: 10-Aug-2023 **Mfr Rcvd Date:** 31-Jul-2023 **Mfr Control #:** US-NOVOPROD-984376 **Application #:** 209637

Patient Information:

Age: 52 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		/	Subcutaneous	UNK (qw)	Diabetes mellitus	01-Jan-2022	08-Aug-2022

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic	33 Day	Yes	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Depression suicidal	
Amnesia	
Depression	
Abnormal behaviour	
Aggression	
Near death experience	
Psychotic behaviour	

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Consumer as "Seriously depressed and suicidal(Depression suicidal)" beginning on 2022, "Memory lapses(loss of memory)" beginning on 03-FEB-2022, "Depression anxiety(Anxiety depression)" beginning on 03-FEB-2022, "Altered mental behaviour(Abnormal behaviour)" beginning on 03-FEB-2022, "Violent(Violent)" beginning on 2022, "Almost died(Near death experience)" with an unspecified onset

date, "Psychotic(Psychotic behavior)" with an unspecified onset date, and concerned a 52 year old male patient who was treated with Ozempic (SEMAGLUTIDE) from 01-JAN-2022 to 08-AUG-2022 for "Diabetes mellitus". Current Condition: Diabetes mellitus(type and duration not reported) A patient, who was receiving therapy with Ozempic, reported the product made him seriously depressed and suicidal with the symptom of feeling not that well. The patient further stated it changed his behavior clarified as became violent. On 03-FEB-2022 date, the patient experienced depression anxiety, memory lapses, and they were seriously depressed. The patient also reported they almost died and were psychotic. Batch Number Ozempic been requested Action taken to Ozempic was reported as Product discontinued. The outcome for the event "Seriously depressed and suicidal(Depression suicidal)" was Not recovered. On 04-SEP-2022 the outcome for the event "Memory lapses(loss of memory)" was Recovered. On 04-SEP-2022 the outcome for the event "Depression anxiety(Anxiety depression)" was Recovered. On 04-SEP-2022 the outcome for the event "Altered mental behaviour(Abnormal behaviour)" was Recovered. The outcome for the event "Violent(Violent)" was Unknown. The outcome for the event "Almost died(Near death experience)" was Not Reported. The outcome for the event "Psychotic(Psychotic behavior)" was Not Reported. Since last submission, the case has been updated with the following information -Added events of almost died and psychotic. -Narrative is updated accordingly. -Company comment updated. Company Comment: Depression suicidal, amnesia, depression, abnormal behavior, aggression, near death experience, and psychotic behavior are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. Limited information as related to medical history aside from diabetes, 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:

unk

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:

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

Case ID: 21670942

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: 22533952

Case Information:

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

FDA Rcvd Date: 08-Jun-2023 **Mfr Rcvd Date:** 30-May-2023 **Mfr Control #:** US-NOVOPROD-1072712 **Application #:** 209637

Patient Information:

Age: 57 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		/	Subcutaneous	UNK	Weight decreased	Aug-2022	01-Jan-2023

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 0.25/0.50 mg		Yes	NA	MP5D705			NOVO NORDISK	

Event Information:

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

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Consumer as "suicidal ideation(Suicidal ideation)" beginning on 01-JAN-2023, "depression worsened(Depression worsened)" beginning on 2022, "prescribed for weight loss(Off label use)" beginning on AUG-2022, and concerned a 57 Years old Female patient who was treated with Ozempic 0.25/0.50 mg (SEMAGLUTIDE) from AUG-2022 to 01-JAN-2023 for "weight loss", Current Condition: Depression Historical Condition: Knee replacement, Suicide attempt Procedure: 23 surgeries. Treatment included - ABILIFY(ARIPIPRAZOLE), PROZAC(FLUOXETINE HYDROCHLORIDE), WELLBUTRIN(BUPROPION HYDROCHLORIDE) The patient who was prescribed the medication for weight loss presented with worsened depression and had suicidal ideation after starting Ozempic therapy. The patient underwent therapy and took abilify, prozac and welbutron as treatment. The patient recovered after discontinuing the medication. Batch Numbers: Ozempic 0.25/0.50 mg: MP5D705 Action taken to Ozempic 0.25/0.50 mg was reported as Product discontinued due to AE. On APR-2023 the outcome for the event "suicidal ideation(Suicidal ideation)" was Recovered. On APR-2023 the outcome for the event "depression worsened(Depression worsened)" was Recovered. On 01-JAN-2023 the outcome for the event "prescribed for

Case ID: 22533952

weight loss(Off label use)" was Recovered. Company Comment: Suicidal ideation is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. A medical history of depression and suicide attempt suggest underlying etiologies. Limited information as related to 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	2011		Yes
Knee arthroplasty			No
Surgery			No
Suicide attempt	2011		No

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: 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: 22645980

Case Information:

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

FDA Rcvd Date: 27-Jun-2023 **Mfr Rcvd Date:** 16-Jun-2023 **Mfr Control #:** US-NOVOPROD-1081647 **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		Unknown	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Depression suicidal	
Abdominal pain upper	
Diarrhoea	

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Consumer as "Patient felt depressed like she might kill herself.(Suicidal depression)" with an unspecified onset date, "stomach pain(Stomach pain)" with an unspecified onset date, "diarrhea(Diarrhea)" with an unspecified onset date, and concerned a Adult Female patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for "Drug use for unknown indication", Medical history was not provided. On unspecified date patient felt depressed like she might kill herself. On unknown date patient experienced stomach pain and diarrhea. Batch Numbers of Ozempic not reported. Action taken to Ozempic was Not reported. The outcome for the event "Patient felt depressed like she might kill herself.(Suicidal depression)" was Not Reported. The outcome for the event "stomach pain(Stomach pain)" was Unknown. The outcome for the event "diarrhea(Diarrhea)" was Unknown. No further information available Company comment: Suicidal depression is assessed as an unlisted event; Stomach pain and diarrhea are assessed as listed 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 (psychological disorders), past history of suicidal attempt, social history, relevant investigation reports, concomitant medication 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 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: