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

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Run by: KIA.BAZEMORE@FDA.HHS.GOV

Disclaimer:

Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distributor, 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:

22318079	22714710	22729365	22729370
22770378	22770379	22833280	22886242
22919550	22954833	22969158	22982269

Total Cases: 12

Total number of Inactive cases: *0

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

Case ID: 22318079

Case Information:

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

FDA Rcvd Date: 19-Jul-2023 **Mfr Rcvd Date:** 13-Jul-2023 **Mfr Control #:** US-NOVOPROD-1060259 **Application #:** 209637

Patient Information:

Age: 35 YR **Sex:** Female **Weight:** 97.959 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Semaglutide		0.5 Mg Milligram(S) /	Subcutaneous	0.5 mg	Feb-2023	Apr-2023	Weight control

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Semaglutide		Yes	NA	04042023			NOVO NORDISK	

Device Products:

#	Product Name	Combination Product	Common Device Name	Brand Name	Product Code	Malfunction?

Event Information:

Preferred Term (MedDRA Version: v.26.1)	ReC
Abortion spontaneous	
Counterfeit product administered	
Maternal exposure during pregnancy	

Event/Problem Narrative:

This serious spontaneous case from the UNITED STATES was reported by a consumer and confirmed by a physician as "miscarriage(Miscarriage)" beginning on 30-APR-2023, "maternal exposure during pregnancy(Maternal exposure during pregnancy)" beginning in MAR-2023, "took compounded semaglutide(Counterfeit product administered)" beginning in FEB-2023, and concerned a 35 year old female patient who was treated with semaglutide from FEB-2023 to APR-2023 for weight loss. Patient's height: 167.6 cm Patient's weight: 98 kg Patient's BMI: 34.857 The patient had no relevant medical history per physician. Historical Drug:

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FOIA Case Report Information

Case ID: 22318079

Ozempic (semaglutide). Treatment included Cytotec (misoprostol). A physician reported that a patient started therapy with compounded semaglutide in FEB-2023. In (b)(6)*** the patient went to the emergency department for evaluation of symptoms nausea, fatigue, and heart rate increased. The patient was found to be pregnant. The patient's first day of last menstrual period was 26-MAR-2023. The patient's due date was 21-DEC-2023. The patient was unsure how many fetuses she carried, as no ultrasound was performed. The patient was not admitted. On (b)(6)*****, the patient experienced a miscarriage at (b)(6) weeks of pregnancy with symptoms of vaginal bleeding, abdominal cramping, and back pain. As treatment, Cytotec was given. No testing was performed and patient was not admitted to the hospital. Action taken to semaglutide was reported as Product discontinued due to AE. On (b)(6)***** the outcome for the event "miscarriage(Miscarriage)" was Recovered. On (b)(6)***** the outcome for the event "maternal exposure during pregnancy(Maternal exposure during pregnancy)" was Recovered. In (b)(6)** the outcome for the event "took compounded semaglutide(Counterfeit product administered)" was Recovered. Batch number was requested. The patient felt that the miscarriage was possibly related to therapy with compounded semaglutide. Since last submission, the following has been updated: - Analysis results: Name: compounded semaglutide Batch: 04042023 The reported batch number was not valid. The product was not returned for examination. No conclusion can be made without a sample or a valid batch number. Without a sample or photo it was not possible to conclude if the product was a genuine Novo Nordisk product. Company Comment: Abortion spontaneous is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Semaglutide. Counterfeit product administered noted by reporter as possible reason for abortion spontaneous. Limited information on concomitant medications, 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.

Case Summary and Reporter's Comments Text:

Relevant Medical History:

The patient's first day of last menstrual period was 26-Mar-2023 with due date of 21-Dec-2023. Patient is unsure of how many fetus and no ultrasound was performed.

Disease/Surgical Procedure	Start Date	End Date	Continuing?

Medical History Product(s)	Start Date	End Date	Indications	Events
OZEMPIC	Jan-2023	Feb-2023	Product used for unknown indication	No adverse event

Relevant Laboratory Data:

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

Concomitant Products:

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

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FOIA Case Report Information

Case ID: 22318079

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: 22714710

Case Information:

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

FDA Rcvd Date: 18-Jul-2023 **Mfr Rcvd Date:** 07-Jul-2023 **Mfr Control #:** US-NOVOPROD-1089679 **Application #:** 209637

Patient Information:

Age: 64 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Semaglutide		/	Subcutaneous	UNK	Oct-2022	Mar-2023	Weight decreased

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

Device Products:

#	Product Name	Combination Product	Common Device Name	Brand Name	Product Code	Malfunction?

Event Information:

Preferred Term (MedDRA Version: v.26.1)	ReC
Endometrial cancer metastatic	
Counterfeit product administered	
Product use in unapproved indication	

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Consumer as "stage 3 endometrial cancer which spread in stomach lining(Endometrial cancer metastatic)" with an unspecified onset date, "used suspected counterfeit compounded semaglutide being advertised as Ozempic(Counterfeit drug administered)" beginning on OCT-2022, "used compounded semaglutide falsely marketed as Ozempic for weight loss(Drug use for unapproved indication)" beginning on OCT-2022, and concerned a 64 Year old Female patient who was treated with Semaglutide (SEMAGLUTIDE) from

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

Case ID: 22714710

OCT-2022 to MAR-2023 for "weight loss". Medical history was not provided. A consumer reported that a patient began using counterfeit semaglutide falsely marketed by a medical spa as Ozempic that was supplied by a compounding pharmacy for weight loss in OCT-2022. The patient obtained the suspected counterfeit compounded semaglutide in vials being advertised as Ozempic. As a result, the patient experienced very severe adverse medical conditions/health problems clarified as stage 3 endometrial cancer and discontinued the product in MAR-2023. The stage 3 endometrial cancer spread to the stomach lining in MAY-2023. The patient was receiving unspecified treatment. Action taken to Semaglutide was reported as Product discontinued due to AE. The outcome for the event "stage 3 endometrial cancer which spread in stomach lining(Endometrial cancer metastatic)" was Not Reported. In MAR-2023 the outcome for the event "used suspected counterfeit compounded semaglutide being advertised as Ozempic(Counterfeit drug administered)" was Recovered. In MAR-2023 the outcome for the event "used compounded semaglutide falsely marketed as Ozempic for weight loss(Drug use for unapproved indication)" was Recovered. Batch Number for Semaglutide has been requested. Company Comment: Endometrial cancer metastatic is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Semaglutide. Limited information as related to event onset date, medical history, concomitant medications, family/social history, and laboratory/ diagnostic evaluations limits medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

Case Summary and Reporter's Comments Text:

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	Start Date	End Date	Indication(s)	Interval 1st Dose to Event

Reporter Source:

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

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

Case ID: 22714710

Literature Text:

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

Case ID: 22729365

Case Information:

Case Type : Non-Expedited **eSub:** Y **HP:** Y **Country:** US **Event Date:** **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 20-Jul-2023 **Mfr Rcvd Date:** 18-May-2023 **Mfr Control #:** US-NOVOPROD-1067291 **Application #:** 209637

Patient Information:

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

Suspect Products:

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

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

Device Products:

#	Product Name	Combination Product	Common Device Name	Brand Name	Product Code	Malfunction?

Event Information:

Preferred Term (MedDRA Version: v.26.1) **ReC**

Pancreatitis

Suspected counterfeit product

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Physician via a company representative as "Pancreatitis(Pancreatitis)" with an unspecified onset date, "shots of compounded Sema given by Med spa(Suspected counterfeit product)" with an unspecified onset date, and concerned an adult female patient who was treated with Semaglutide (SEMAGLUTIDE) from unknown start date for "drug use for unknown indication". Medical history was not provided. A physician reported via a company representative that a patient who received shots of compounded semaglutide from a Med spa became sick and was

Case ID: 22729365

diagnosed with pancreatitis. Action taken to Semaglutide was Not reported. The outcome for the event "Pancreatitis(Pancreatitis)" was Not Reported. The outcome for the event "shots of compounded Sema given by Med spa(Suspected counterfeit product)" was Not Reported. Batch number not available.

Case Summary and Reporter's Comments Text:

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	Start Date	End Date	Indication(s)	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: 22729370

Case Information:

Case Type : Non-Expedited **eSub:** Y **HP:** Y **Country:** US **Event Date:** Oct-2022 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 20-Jul-2023 **Mfr Rcvd Date:** 10-Feb-2023 **Mfr Control #:** US-NOVOPROD-1024045 **Application #:** 209637

Patient Information:

Age: 32 YR **Sex:** Female **Weight:** 86.168 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Semaglutide		0.4 Ml Millilitre(S) / / WK	Subcutaneous	0.4 mL, qw	07-Oct-2022	31-Oct-2022	

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Semaglutide	24 Day	Yes	NA				NOVO NORDISK	

Device Products:

#	Product Name	Combination Product	Common Device Name	Brand Name	Product Code	Malfunction?

Event Information:

Preferred Term (MedDRA Version: v.26.1)	ReC
Nausea	
Vomiting	
Weight decreased	
Counterfeit product administered	

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Physician as "severe nausea(Nausea)" beginning on(b)(6)******* "severe vomiting(Vomiting)" beginning on (b)(6)*****, "lost weight(Lost weight)" beginning on OCT-2022, "was taking compounded semaglutide 2.5mg/mL(Counterfeit

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product administered)" beginning on 07-OCT-2022, and concerned a 32 Years old Female patient who was treated with Semaglutide (SEMAGLUTIDE) from 07-OCT-2022 to 31-OCT-2022. Patient's weight: 86.2 kg Medical history was not provided. On 07-OCT-2022, a patient started taking compounded semaglutide 2.5mg/mL. The patent lost weight. On (b)(6)*****, the patient presented to the emergency room with severe nausea and vomiting. The patient was rehydrated and recovered. Semaglutide was discontinued. Action taken to Semaglutide was reported as Product discontinued due to AE. The outcome for the event "severe nausea(Nausea)" was Recovered. The outcome for the event "severe vomiting(Vomiting)" was Recovered. On OCT-2022 the outcome for the event "lost weight(Lost weight)" was Recovered. On (b)(6)***** the outcome for the event "was taking compounded semaglutide 2.5mg/mL(Counterfeit product administered)" was Recovered. Batch number requested in follow-up.

Case Summary and Reporter's Comments Text:

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	Start Date	End Date	Indication(s)	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: 22770378

Case Information:

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

FDA Rcvd Date: 01-Aug-2023 **Mfr Rcvd Date:** 21-Jul-2023 **Mfr Control #:** US-NOVOPROD-1096583 **Application #:** 209637

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Semaglutide		/	Subcutaneous	UNK			Obesity

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

Device Products:

#	Product Name	Combination Product	Common Device Name	Brand Name	Product Code	Malfunction?

Event Information:

Preferred Term (MedDRA Version: v.26.1) **ReC**

Disseminated intravascular coagulation

Suspected counterfeit product

Diarrhoea

Abdominal pain

Event/Problem Narrative:

This serious spontaneous case from the UNITED STATES was reported by a physician via a company representative as "disseminated intravascular coagulation(Disseminated intravascular coagulation)" with an unspecified onset date, "took one dose of compounded semaglutide(Suspected counterfeit

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product)" with an unspecified onset date, "diarrhea(Diarrhea)" with an unspecified onset date, "abdominal pain(Abdominal pain)" with an unspecified onset date, and concerned an adult female patient, who was treated with semaglutide from an unknown start date for obesity. Current Condition: obesity. A physician reported that a patient took one dose of compounded semaglutide subcutaneously and experienced diarrhea and abdominal pain within hours. The next day, the patient suddenly died (date unknown) due to disseminated intravascular coagulation. Since the patient was obese yet otherwise healthy, an autopsy (Autopsy) was performed but results were not provided. Action taken to semaglutide was Not reported. The outcome for the event "disseminated intravascular coagulation(Disseminated intravascular coagulation)" was Fatal. The outcome for the event "took one dose of compounded semaglutide(Suspected counterfeit product)" was Fatal. The outcome for the event "diarrhea(Diarrhea)" was Not recovered. The outcome for the event "abdominal pain(Abdominal pain)" was Not recovered. The physician felt that the events were possibly related to therapy with the compounded semaglutide due to the proximity of product use and the events. Batch number was requested. Company Comment: Disseminated intravascular coagulation and suspected counterfeit with fatal outcome are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Semaglutide. Limited information as related to suspect product therapy dates, 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.

Case Summary and Reporter's Comments Text:

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Obesity			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
AUTOPSY					Y

Concomitant Products:

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

Reporter Source:

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

Case ID: 22770378

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: 22770379

Case Information:

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

FDA Rcvd Date: 01-Aug-2023 **Mfr Rcvd Date:** 24-Jul-2023 **Mfr Control #:** US-NOVOPROD-1096728 **Application #:** 209637

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Semaglutide		/	Subcutaneous	UNK			Obesity

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

Device Products:

#	Product Name	Combination Product	Common Device Name	Brand Name	Product Code	Malfunction?

Event Information:

Preferred Term (MedDRA Version: v.26.1)	ReC
Disseminated intravascular coagulation	
Suspected counterfeit product	
Diarrhoea	
Abdominal pain	

Event/Problem Narrative:

This serious spontaneous case from the UNITED STATES was reported by a nurse via a company representative as "disseminated intravascular coagulation(Disseminated intravascular coagulation)" with an unspecified onset date, "took one dose of compounded semaglutide(Suspected counterfeit

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product)" with an unspecified onset date, "diarrhea(Diarrhea)" with an unspecified onset date, "abdominal pain(Abdominal pain)" with an unspecified onset date, and concerned a female patient who was treated with semaglutide from an unknown start date for obesity. Current Condition: obesity. A nurse practitioner reported that a patient took one dose of compounded semaglutide subcutaneously and experienced diarrhea and abdominal pain within hours. The next day, the patient suddenly died (date unknown) due to disseminated intravascular coagulation. Since the patient was obese yet otherwise healthy, an autopsy (Autopsy) was performed but results were not provided. Action taken to semaglutide was Not reported. The outcome for the event "disseminated intravascular coagulation(Disseminated intravascular coagulation)" was Fatal. The outcome for the event "took one dose of compounded semaglutide(Suspected counterfeit product)" was Fatal. The outcome for the event "diarrhea(Diarrhea)" was Not Reported. The outcome for the event "abdominal pain(Abdominal pain)" was Not Reported. The nurse practitioner felt that the events were possibly related to therapy with the compounded semaglutide due to the proximity of product use and the events. Batch number was requested. Company Comment: Disseminated intravascular coagulation and suspected counterfeit product with fatal outcome are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Semaglutide. Limited information as related to suspect product therapy dates, 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.

Case Summary and Reporter's Comments Text:

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Obesity			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
AUTOPSY					Y

Concomitant Products:

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

Reporter Source:

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

Case ID: 22770379

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: 22833280

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** N **Country:** US **Event Date:** 31-Jul-2023 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 18-Aug-2023 **Mfr Rcvd Date:** 07-Aug-2023 **Mfr Control #:** US-NOVOPROD-1101287 **Application #:** 209637

Patient Information:

Age: 57 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Semaglutide		/	Subcutaneous	UNK	02-Oct-2022		Product used for unknown indication

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Semaglutide	302 Day	NA	NA				NOVO NORDISK	

Device Products:

#	Product Name	Combination Product	Common Device Name	Brand Name	Product Code	Malfunction?

Event Information:

Preferred Term (MedDRA Version: v.26.1)	ReC
Road traffic accident	
Wrist fracture	
Counterfeit product administered	

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Consumer as "car accident(Automobile accident)" beginning on 31-JUL-2023, "broke both wrists(Broken wrist)" beginning on 31-JUL-2023, "compounded semaglutide used in a syringe(Counterfeit drug administered)" with an unspecified

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onset date, and concerned a 57 year old female patient who was treated with Semaglutide (SEMAGLUTIDE) from 02-OCT-2022 and ongoing for "drug use for unknown indication". Dosage Regimens: Semaglutide: 02-OCT-2022 to Not Reported (Dosage Regimen Ongoing); Medical history was not provided. A patient receiving therapy with compounded Semaglutide, reported that they were in a car accident and broke both of their wrists. The patient stated the car accident and broken wrists were not related to the compounded Semaglutide. Action taken to Semaglutide was reported as No Change. The outcome for the event "car accident(Automobile accident)" was Unknown. The outcome for the event "broke both wrists(Broken wrist)" was Unknown. The outcome for the event "compounded semaglutide used in a syringe(Counterfeit drug administered)" was Unknown. Batch number requested in follow up. Company Comment: Road traffic accident and wrist fracture are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Semaglutide. Of note, the wrist fracture was reported as a consequence of the road traffic accident. Limited information as related to how the road traffic accident occurred, medical history, concomitant medications, social history, and laboratory/diagnostic evaluation results limits further medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

Case Summary and Reporter's Comments Text:

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	Start Date	End Date	Indication(s)	Interval 1st Dose to Event

Reporter Source:

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

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FOIA Case Report Information

Case ID: 22833280

Literature Text:

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

Case ID: 22886242

Case Information:

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

FDA Rcvd Date: 31-Aug-2023 **Mfr Rcvd Date:** 21-Aug-2023 **Mfr Control #:** GB-NOVOPROD-1106743 **Application #:** 209637

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
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		NA	NA				NOVO NORDISK	

Device Products:

#	Product Name	Combination Product	Common Device Name	Brand Name	Product Code	Malfunction?

Event Information:

Preferred Term (MedDRA Version: v.26.1)	ReC
Adverse event	
Suspected counterfeit product	

Event/Problem Narrative:

Case Summary and Reporter's Comments Text:

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

Case ID: 22886242

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	Start Date	End Date	Indication(s)	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: 22919550

Case Information:

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

FDA Rcvd Date: 08-Sep-2023 **Mfr Rcvd Date:** 29-Aug-2023 **Mfr Control #:** US-NOVOPROD-1109846 **Application #:** 209637

Patient Information:

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

Suspect Products:

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

Device Products:

#	Product Name	Combination Product	Common Device Name	Brand Name	Product Code	Malfunction?

Event Information:

Preferred Term (MedDRA Version: v.26.1)	ReC
Liver disorder	
Ill-defined disorder	
Mass	

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

Case ID: 22919550

Suspected counterfeit product

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Nurse as "liver issues(Liver disorder)" with an unspecified onset date, "problems(ill-defined disorder)" with an unspecified onset date, "some type of mass(Mass)" with an unspecified onset date, "possibly getting compounded semaglutide(Suspected counterfeit product)" with an unspecified onset date, and concerned an adult male patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for "Drug use for unknown indication", Semaglutide (SEMAGLUTIDE) from unknown start date for "drug use for unknown indication". Medical history was not provided. A nurse reported via company representative that they were unsure if a patient was getting Ozempic or Compounded Semaglutide online. The patient went to the hospital with liver issues, previous problems, and then ended up having some type of mass. Action taken to Ozempic was reported as No Change. Action taken to Semaglutide was reported as No Change. The outcome for the event "liver issues(Liver disorder)" was Not Reported. The outcome for the event "problems(ill-defined disorder)" was Not Reported. The outcome for the event "some type of mass(Mass)" was Not Reported. The outcome for the event "possibly getting compounded semaglutide(Suspected counterfeit product)" was Not Reported. Batch number requested in follow up. Company Comment: Liver disorder, ill-defined disorder, and mass are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic and Semaglutide. Limited information as related to Ozempic and Semaglutide therapy dates, event onset dates, weight, BMI, more details on the reported evented (any medical diagnosis), medical history, concomitant medications, and social history limits further medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the products.

Case Summary and Reporter's Comments Text:

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	Start Date	End Date	Indication(s)	Interval 1st Dose to Event

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

Case ID: 22919550

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: 22954833

Case Information:

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

FDA Rcvd Date: 18-Sep-2023 **Mfr Rcvd Date:** 08-Sep-2023 **Mfr Control #:** US-NOVOPROD-1114825 **Application #:**

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Semaglutide		0.25 Mg Milligram(S) / /WK	Subcutaneous	0.25 mg, qw	Aug-2023	07-Sep-2023	Product used for unknown indication

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

Device Products:

#	Product Name	Combination Product	Common Device Name	Brand Name	Product Code	Malfunction?

Event Information:

Preferred Term (MedDRA Version: v.26.1)	ReC
Platelet count decreased	
Skin discolouration	
Fatigue	
Injection site bruising	
Counterfeit product administered	

Event/Problem Narrative:

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

Case ID: 22954833

This serious Spontaneous case from the UNITED STATES was reported by a Physician as "platelets were extremely low(Low platelets)" beginning on 2023, "developed spots all over body(skin discoloration)" beginning on 2023, "fatigue(Fatigue)" beginning on 2023, "experienced bruising at site(Injection site bruising)" beginning on 2023, "started using compound semaglutide(counterfeit product administered)" beginning on AUG-2023, and concerned an adult female patient who was treated with Semaglutide (SEMAGLUTIDE) from AUG-2023 to (b)(6)***** for "drug use for unknown indication". Medical history was not provided. A physician reported via company representative that a patient started compounded semaglutide. After the patient's first shot of the compounded semaglutide, the patient experienced bruising at the site. After the patient's second shot a week later, the patient developed spots all over their body and fatigue. The patient's platelets were extremely low. On (b)(6)*****, the patient was hospitalized. The patient's provider confirmed that the compounded semaglutide was not Ozempic. Action taken to Semaglutide was reported as Product discontinued. On 2023 the outcome for the event "platelets were extremely low(Low platelets)" was Recovered. On 2023 the outcome for the event "developed spots all over body(skin discoloration)" was Recovered. On 2023 the outcome for the event "fatigue(Fatigue)" was Recovered. On 2023 the outcome for the event "experienced bruising at site(Injection site bruising)" was Recovered. On (b)(6)***** the outcome for the event "started using compound semaglutide(counterfeit product administered)" was Recovered. Batch number requested in follow up. Company Comment: Platelet count decreased and skin discoloration are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Semaglutide. Fatigue is assessed as listed according to the Semaglutide CCDS. Limited information as related to more details on the event onset dates, medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluations limits medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

Case Summary and Reporter's Comments Text:

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	Start Date	End Date	Indication(s)	Interval 1st Dose to Event

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

Case ID: 22954833

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: 22969158

Case Information:

Case Type :30-Day **eSub:** Y **HP:** N **Country:** GB **Event Date:** **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 05-Oct-2023 **Mfr Rcvd Date:** 25-Sep-2023 **Mfr Control #:** GB-NOVOPROD-1115459 **Application #:** 209637

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Ozempic 1.0 mg		/		UNK			Weight control

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 1.0 mg		Unknown	NA	MP5D775			NOVO NORDISK	

Device Products:

#	Product Name	Combination Product	Common Device Name	Brand Name	Product Code	Malfunction?

Event Information:

Preferred Term (MedDRA Version: v.26.1)	ReC
Loss of consciousness	
Device issue	
Blood glucose decreased	
Counterfeit product administered	
Product use in unapproved indication	

Event/Problem Narrative:

This serious Spontaneous case from the UNITED KINGDOM was reported by a Consumer as "almost fainted and then collapsed(Transient loss of consciousness)" with an unspecified onset date, "when patient turn it to select a dose the dial comes out at the end.(Device component detached)" with an unspecified onset

date, "blood sugars came down too quick, body shaking(Blood glucose decreased)" with an unspecified onset date, "Suspected counterfeit(Counterfeit product administered)" with an unspecified onset date, "Ozempic used for weightloss(Product use in unapproved indication)" with an unspecified onset date, and concerned a Female patient who was born in 1960 and treated with Ozempic 1.0 mg (SEMAGLUTIDE) from unknown start date for "weight loss", Patient's height, weight and body mass index was not reported. Medical history was not provided. On an unknown date, patient almost fainted and collapsed when took ozempic as if the blood sugars came down too quick (values not reported) with the body shaking. The patient is using ozempic for weight loss and the patient doesn't think it is real and suspected counterfiet. On an unknown date, the patient stated it was “like a syringe with no plastic” and when it was turned to select a dose the dial comes out at the end. Current location of device : Manufacturer Period of use : Unknown. Batch Numbers: Ozempic 1.0 mg: MP5D775 Action taken to Ozempic 1.0 mg was Not reported. The outcome for the event "almost fainted and then collapsed(Transient loss of consciousness)" was Unknown. The outcome for the event "when patient turn it to select a dose the dial comes out at the end.(Device component detached)" was Not Reported. The outcome for the event "blood sugars came down too quick, body shaking(Blood glucose decreased)" was Unknown. The outcome for the event "Suspected counterfeit(Counterfeit product administered)" was Unknown. The outcome for the event "Ozempic used for weightloss(Product use in unapproved indication)" was Unknown. Investigational result Name: Ozempic 1 mg 3.0 ml, Batch Number: MP5D775 The number of complaints on the batch was evaluated and, when applicable, relevant actions were taken. The returned product pictures were examined visually. Based on the performed investigation, it was concluded that the returned product is NOT a genuine Novo Nordisk product. We highly advise not to use the product. Use of a suspected product can have severe health consequences. Since last submission the case has been updated with the following: Investigation result added IMDRF Codes added Based on investigation result - suspected counterfeit updated to Counterfeit product administered Narrative updated accordingly Final Manufacturer's comment: 04-OCT-2023 Upon investigation of the returned suspected device (Ozempic), it was concluded that the returned product is NOT a genuine Novo Nordisk product. Use of a suspected counterfeit product can have severe health consequences.This could have contributed to the patient experiencing reported events. Company comment: Transient loss of consciousness and blood glucose decreased are assessed as unlisted events according to the Novo Nordisk current CCDS in Ozempic. There is positive temporal association as event transient loss of consciousness happened after the patient taken product. However, relevant information on final diagnosis, investigation of suspected counterfeit product, action taken with Ozempic and outcome of the events are unavailable for complete causality assessment. This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

Case Summary and Reporter’s Comments Text:

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:

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

Case ID: 22969158

#	Product Name:	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)	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: 22982269

Case Information:

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

FDA Rcvd Date: 26-Sep-2023 **Mfr Rcvd Date:** 15-Sep-2023 **Mfr Control #:** GB-NOVOPROD-1117696 **Application #:** 209637

Patient Information:

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

Suspect Products:

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

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

Device Products:

#	Product Name	Combination Product	Common Device Name	Brand Name	Product Code	Malfunction?

Event Information:

Preferred Term (MedDRA Version: v.26.1) **ReC**

Circulatory collapse

Suspected counterfeit product

Product use in unapproved indication

Event/Problem Narrative:

This serious Spontaneous case from the UNITED KINGDOM was reported by a Consumer as "collapsed after taking Ozempic(Circulatory collapse)" with an unspecified onset date, "concerned that the Ozempic bought from the pharmacy was counterfeit, does not look like Ozempic as it was a different shape and colour(Suspected counterfeit product)" with an unspecified onset date, "Ozempic used for Weight loss(Product use in unapproved indication)" with an unspecified onset date, and concerned a Female patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for "Weight loss". Patient's height, weight

Case ID: 22982269

and body mass index were not reported. Medical history was not provided. On an unknown date, the patient was concerned that the Ozempic she bought from the pharmacy was counterfeit, did not look like Ozempic as it was a different shape and colour. The patient started taking ozempic for weight loss. The patient collapsed after taking it. Batch Numbers: Ozempic: Not available. Action taken to Ozempic was Not reported. The outcome for the event "collapsed after taking Ozempic(Circulatory collapse)" was Not Reported. The outcome for the event "concerned that the Ozempic bought from the pharmacy was counterfeit, does not look like Ozempic as it was a different shape and colour(Suspected counterfeit product)" was Not Reported. The outcome for the event "Ozempic used for Weight loss(Product use in unapproved indication)" was Not Reported. No further information available. Company comment: Circulatory collapse is assessed as unlisted event, suspected counterfeit product is assessed as listed event according to the Novo Nordisk current CCDS in Ozempic. There is positive temporal association with circulatory collapse. However, patient suspects the product as counterfeit product (shape and colour are different), we need more information on the investigation of suspected product confirm if it is counterfeit or not. If the suspected product is found to be counterfeit, then we can not assure the safety of the product. This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

Case Summary and Reporter's Comments Text:

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	Start Date	End Date	Indication(s)	Interval 1st Dose to Event

Reporter Source:

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

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

Case ID: 22982269

Literature Text: