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

Date - T me: 20-Ju -2023 09: 6:56 EDT

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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:

12419571	15746941	16867156	17971467
19014613	20334416	20502066	21360692
21854592	21974341	21979556	22040650

Total Cases: 12

Total number of Inactive cases: *0

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

Case ID: 12419571

Case Information:

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

FDA Rcvd Date: 31-May-2016 **Mfr Rcvd Date:** 18-May-2016 **Mfr Control #:** CA-NOVOPROD-493067 **Application #:** 206321

Patient Information:

Age: 19 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Saxenda		.6 Mg Milligram(S) / QD	Unknown	0.6 mg, qd	Product used for unknown indication		
2	Saxenda		1.2 Mg Milligram(S) / QD	Unknown	1.2 mg, qd			
3	Saxenda		.6 Mg Milligram(S) / QD	Unknown	0.6 mg, qd			

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

Event Information:

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

Suicidal ideation

Nausea

Event/Problem Narrative:

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

Case ID: 12419571

This serious spontaneous case from Canada was reported by a Endocrinologist as "suicidal ideation" with an unspecified onset date, "nausea" with an unspecified onset date, and concerned a 19-year-old female patient who was treated with Saxenda (liraglutide) from unknown start date for unknown indication. Patient's height, weight and BMI(body mass index):not reported. Medical history included depression, anxiety, obese. No previous history of suicidal thoughts It was reported that the patient presented to the emergency department with suicidal ideation and was admitted to hospital. As of last night, the patient remains in hospital. The patient started Saxenda 2 weeks prior to this event with a dose of 0.6 mg qd and tried to go upto 1.2 mg qd with increased nausea returned to 0.6 mg dose. Action taken to Saxenda was Not reported. The outcome for the event "Suicidal ideation" was Not Reported. The outcome for the event "Nausea" was Not Reported. Company Comment: Suicidal Ideation is an unlisted event according to the NN current reference safety information on Saxenda. Depression and anxiety are risk factors for suicidal ideation. Studies also suggest that the suicidal ideation increases with increased BMI (body mass index) in females; thus, obesity is a possible risk factor even though the body mass index is not provided. Family history, suspect drug therapy details, action taken to suspect drug, clinical course in hospital and details of concomitant medication is not provided. This single case report is not considered to change the current knowledge of the safety profile of suspected product.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Depression			Yes
Anxiety			Yes
Obesity			

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: 12419571

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: 15746941

Case Information:

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

FDA Rcvd Date: 20-Dec-2018 **Mfr Rcvd Date:** 31-Oct-2018 **Mfr Control #:** ES-NOVOPROD-631437 **Application #:** 206321

Patient Information:

Age: 35 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Saxenda		.6 Mg Milligram(S) / QD	Unknown	0.6 mg, qd	Obesity	29-Oct-2018	

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

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicide attempt	
Faeces discoloured	
Diarrhoea	

Event/Problem Narrative:

This serious Spontaneous case from SPAIN was reported by a General physician as "commit a suicide" with an unspecified onset date, "Green stools" with an unspecified onset date, "Diarrhoea" with an unspecified onset date, and concerned a 35 Years old Male patient who was treated with Saxenda (liraglutide) from 29-OCT-2018 due to "Obesity", Patients height, weight were not reported Patient's BMI: 35. Medical history included obesity, psychiatric illness. Concomitant products included - abilify(aripiprazole), olanzapine(olanzapine), lorazepam(lorazepam), cardyl(atorvastatin calcium), enalapril(enalapril) On an unknown date, the patient experienced diarrhoea, green stools and went to emergency services On an unknown date, the patient tried to commit a suicide by taking tablets (unknown) and admitted to intensive care Batch number was not available. It was reported that Saxenda was discontinued on an unknown date. Action taken to Saxenda for primary event 'commit a suicide' was reported as Not reported. Action taken to Saxenda for 'Green stools, Diarrhoea' were reported as Product discontinued The outcome for the event "commit a suicide" was Not Reported. The outcome for the event "Green stools" was Not Reported. The outcome for the event "Diarrhoea"

was Not Reported. No further information available This case was reclassified from non-serious to serious on 12-DEC-2018 upon follow up due to the addition of the event "commit a suicide" with a seriousness criterion of "hospitalization". Company comment: Suicide attempt and green stool is assessed as unlisted, diarrhoea is assessed as listed according to the Novo Nordisk current CCDS information on Saxenda. The following important information is lacking: details of the psychiatric illness the patient is suffering from, previous suicide attempts, substance abuse, family history of mental illness or suicide, circumstances that led to the suicide attempt. The history of psychiatric illness is a significant risk factor for the suicide attempt. This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

Relevant Medical History:

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

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

Relevant Laboratory Data:

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	ABILIFY	/	Unknown	5 mg				
2	OLANZAPINE	/	Unknown	5 mg				
3	LORAZEPAM	/	Unknown	1 mg				
4	CARDYL	/	Unknown	10 mg				
5	ENALAPRIL	/		UNK				

Reporter Source:

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

Case ID: 15746941

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: 16867156

Case Information:

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

FDA Rcvd Date: 23-Nov-2020 **Mfr Rcvd Date:** 12-Nov-2020 **Mfr Control #:** GB-NOVOPROD-672421 **Application #:** 206321

Patient Information:

Age: 46 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Saxenda		/	Unknown	231	Weight control		

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

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Suicide attempt	
Loss of consciousness	
Depression	
Drug ineffective	
Mental impairment	
Drug diversion	
Product use in unapproved indication	
Weight loss poor	

Event/Problem Narrative:

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

Case ID: 16867156

This serious Spontaneous Regulatory Authority case received via MHRA (Medicines and Healthcare Products Regulatory Agency), GBR from UNITED KINGDOM was reported by a Nurse as "using Saxenda is making her feel suicidal(Suicidal intention)" with an unspecified onset date, "tried to kill herself-Attempted suicide(Attempted suicide)" with an unspecified onset date, "slumped(Unconsciousness)" with an unspecified onset date, "Had become depressed within weeks(Depression)" with an unspecified onset date, "Drug ineffective(Drug ineffective)" with an unspecified onset date, "deterioration in her mental health(Mental deterioration)" with an unspecified onset date, "Taking controversial weight loss injection jabs (Saxenda)(Drug diversion)" with an unspecified onset date, "Having healthy Body Mass Index took saxenda(Drug use for unapproved indication)" with an unspecified onset date, "weight was the same(Weight loss poor)" with an unspecified onset date and concerned a 46 Years old Female patient who was treated with Saxenda (liraglutide) from unknown start date for "Weight loss", The patient weight, height and body mass index were not reported Medical history was not provided. On an unknown date patient started using a controversial weight loss injection Jabs (Saxenda), despite having healthy body mass index. On an unknown date the patient tried to kill herself using a controversial weight loss injection. After three weeks of treatment with saxenda the patient weight was same, it was reported that the drug was ineffective and began to feel depressed the patient was also crying all the time and did not know why. The patient was rushed to hospital after overdosing on a cocktail of pills (not specified). On an unknown date, the police found the patient slumped in the car and immediately got the patient to the hospital and discontinued the product. The hospital had said that the patient using Saxenda was making the patient feel suicidal. It was reported that the patient was referred on (b)(6)******due to a deterioration in her mental health and will remain with the team until her condition improves, the patient had not attended any of the appointments that had been scheduled for her to attend. On an unknown date, Body mass index of the patient was reported as 27 Batch number of Saxenda was not available. Action taken to Saxenda was reported as Product discontinued. The outcome for the event "using Saxenda is making her feel suicidal(Suicidal intention)" was Unknown. The outcome for the event "tried to kill herself-Attempted suicide(Attempted suicide)" was Unknown. The outcome for the event "slumped(Unconsciousness)" was Unknown. The outcome for the event "Had become depressed within weeks(Depression)" was Unknown. The outcome for the event "Drug ineffective(Drug ineffective)" was Not Reported. The outcome for the event "deterioration in her mental health(Mental deterioration)" was Not Reported. The outcome for the event "Taking controversial weight loss injection jabs (Saxenda)(Drug diversion)" was Not Reported. The outcome for the event "Having healthy Body Mass Index took saxenda(Drug use for unapproved indication)" was Not Reported. The outcome for the event "weight was the same(Weight loss poor)" was Unknown. References included: Reference Type: E2B Company Number Reference ID#: GB-NOVOPROD-672421 Reference Notes: No further information was available Since last submission the case was updated - Non-HCP added as reporter -Lab data updated - Dose description and action taken to suspect drug updated - Outcome of the unconsciousness updated -Narrative updated accordingly Company Comment: 'Suicidal ideation', 'suicide attempt', 'Loss of consciousness', 'depression', 'drug diversion', 'mental impairement' was assessed as unlisted and 'drug ineffective', 'weight loss poor' was assessed as listed event according to Novo Nordisk current CCDS on Saxenda. Information on relevant medical history including risk factors (psychiatric illness, substance abuse, previous history of suicide attempts, familial history of depression), details of the cocktail of drugs are all required for thorough medical assessment. Suicidal ideation and suicide attempt can be due to depression, loss of consciousness can be secondary to overdose with cocktail of pills. This single case report is not considered to change the current knowledge of the safety profile of Saxenda

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Case ID: 16867156

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
Body mass index					Y

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Case ID: 17971467

Case Information:

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

FDA Rcvd Date: 08-Feb-2021 **Mfr Rcvd Date:** 19-Jun-2020 **Mfr Control #:** SE-NOVOPROD-736179 **Application #:** 206321

Patient Information:

Age: 44 YR **Sex:** Male **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Saxenda		/	Subcutaneous	UNK	Obesity	Jan-2019	Jan-2020

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

Event Information:

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

Major depression

Suicidal ideation

Event/Problem Narrative:

This serious Spontaneous Regulatory Authority case from SWEDEN was reported via Medical Products Agency/Läkemedelsverket, SWE (MPA) by a Physician as "Major depression(Major depression)" beginning on 15-MAY-2020, "Suicidal ideation(Suicidal ideation)" beginning on 15-MAY-2020, and concerned a 44 Years old Male patient who was treated with Saxenda (liraglutide) from JAN-2019 to JAN-2020 for "Obesity", The events Major depression and Suicidal ideation were medically confirmed. Patient's height, weight and BMI were not reported. Dosage Regimens: Saxenda: ??-JAN-2019 to ??-JAN-2020; Current Condition: Obesity, Hypertension. On 15-MAY-2020, the patient began to experience major depression and have suicidal ideation. Batch Numbers: Saxenda: UNK Action taken to Saxenda was reported as Product discontinued. The outcome for the event "Major depression(Major depression)" was Recovered. The outcome for the event "Suicidal ideation(Suicidal ideation)" was Recovered. No further information available. References included: Reference Type: E2B Report Duplicate Reference ID#: SE-MPA-2020-003527 Reference Notes: MPA Reference Type: E2B Authority Number Reference ID#: SE-MPA-2020-003527 Reference Notes: On 08-FEB-2021, it was discovered during preparation of an aggregate report that the events are listed according to the local label. Therefore, the initial submission of this report to the FDA was not required. As the events have been updated from unlisted to listed, the case will be re-submitted to let the FDA know of the change in status. COMPANY COMMENT - Major depression and suicidal ideation are assessed as unlisted according to the Novo Nordisk current CCDS information on Saxenda.

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

Case ID: 17971467

The information on relevant medical history (on traumatic or stressful events, substance abuse) are not available. However, chronic medical conditions like obesity and hypertension are risk factors for developing depression. Hence the medical history of the patient is confounding factor in the case. This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Obesity			Yes
Hypertension			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: 19014613

Case Information:

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

FDA Rcvd Date: 03-Feb-2022 **Mfr Rcvd Date:** 14-Jan-2021 **Mfr Control #:** CA-NOVOPROD-781457 **Application #:** 206321

Patient Information:

Age: 43 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Saxenda		/	Unknown	3 mg	Weight control	Jul-2020	Dec-2020
2	Saxenda		/	Unknown	0.6 mg		05-Jan-2021	10-Jan-2021

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

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Night sweats	
Hypersomnia	
Nausea	
Vomiting	
Fatigue	

Event/Problem Narrative:

This serious Spontaneous case from CANADA was reported by a Consumer as "suicidal thoughts(Suicidal tendency)" beginning on NOV-2020, "night sweats(Night sweats)" beginning on NOV-2020, "sleeping a lot(Sleep excessive)" beginning on NOV-2020, "nausea(Nausea)" with an unspecified onset date,

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

Case ID: 19014613

"vomiting(Vomiting)" with an unspecified onset date, "intense fatigue(Fatigue extreme)" beginning on NOV-2020, and concerned a 43 Years old Female patient who was treated with Saxenda (liraglutide) from JUL-2020 to 10-JAN-2021 for "weight loss". Patient's height, weight and BMI not reported. Dosage Regimens: Saxenda: ??-JUL-2020 to ??-DEC-2020, 05-JAN-2021 to 10-JAN-2021; Medical history was not provided. On an unknown date, patient had nausea and vomiting. On NOV-2020, patient had night sweats so much that clothes and bed sheets were wet, really low moral (mood) and suicidal thoughts. Patient slept a lot, had intense fatigue. On 2nd week of DEC-2020, patient discontinued Saxenda and after 1 week being off, her moral (mood) returned. But on 05-JAN-2021, patient re-started Saxenda again and felt psychological distress returned. Patient moral (mood)was also back. Batch Numbers: Saxenda: ASKU, ASKU Action taken to Saxenda was reported as Product discontinued. The outcome for the event "suicidal thoughts(Suicidal tendency)" was Recovering/resolving. The outcome for the event "night sweats(Night sweats)" was Recovering/resolving. The outcome for the event "sleeping a lot(Sleep excessive)" was Not recovered. The outcome for the event "nausea(Nausea)" was Not Reported. The outcome for the event "vomiting(Vomiting)" was Not Reported. The outcome for the event "intense fatigue(Fatigue extreme)" was Not recovered. On 03-FEB-2022 an amendment was performed. Since last submission, it was discovered during preparation of an aggregate report that this case did not require expedited reporting to the FDA as the event is labelled per the USPI. The case is being re-submitted to notify FDA of the change in status Company comment: 'Suicidal ideation', 'Night sweats', Hypersomnia' were assessed as unlisted events and 'Nausea', Vomiting' and 'Fatigue' were assessed as listed events according to Novo Nordisk reference safety information (CCDS) on Saxenda. Information on patient's BMI, medical history of any chronic illness, psychiatric disorder, history of any stressful life event, feeling hopeless or socially isolated, history of substance abuse problem, family history of mental disorders or substance, concomitant medications, socioeconomic status were not available for 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 Saxenda.

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: 19014613

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: 20334416

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** N **Country:** ZA **Event Date:** 10-Dec-2021 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 25-Jan-2022 **Mfr Rcvd Date:** 14-Jan-2022 **Mfr Control #:** ZA-NOVOPROD-882166 **Application #:** 206321

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Saxenda		/	Unknown	3 mg			29-Dec-2021
2	Saxenda		/	Unknown	UNK (low dose)	Weight control	Nov-2021	

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Saxenda		No	NA				NOVO NORDISK	
2	Saxenda		No	NA				NOVO NORDISK	

Event Information:

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

Suicidal ideation

Depression suicidal

Event/Problem Narrative:

This serious spontaneous case from South Africa was reported by a consumer as "She is not herself mentally (suicidal thoughts)(Suicidal tendency)" beginning on 10-DEC-2021, "Depression and suicidal thoughts(Depression suicidal)" beginning on 10-DEC-2021, and concerned a female patient (age not reported) who was treated with Saxenda (liraglutide) from NOV-2021 to 29-DEC-2021 for "weight loss". Patient's height weight and body mass index (BMI) not reported Dosage Regimens: Saxenda: ??-NOV-2021 to Not Reported, Not Reported to 29-DEC-2021; Medical history was not provided. On 10-DEC-2021, patient was not herself mentally. Patient suffered from depression and suicidal thoughts. Action taken to Saxenda was reported as Product discontinued. The outcome for the event "She is not herself mentally (suicidal thoughts)(Suicidal tendency)" was Not yet recovered. The outcome for the event "Depression and suicidal thoughts(Depression suicidal)" was Not yet recovered. Since last submission following information has been added: -Product stop date updated -action taken updated -event onset date updated -event outcome updated -narrative updated Company comment: 'Suicidal ideation' and 'Depression suicidal' are assessed as unlisted according to the

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

Case ID: 20334416

Novo Nordisk current CCDS information on Saxenda. Information on medical history including comorbidties, psychiatric illness like anxiety or depression, social and family circumstances, substance abuse, previous episodes of suicide attempt would have helped in thorough medical assessment. This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

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: 20502066

Case Information:

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

FDA Rcvd Date: 22-Feb-2022 **Mfr Rcvd Date:** 01-Jan-2021 **Mfr Control #:** US-NOVOPROD-779681 **Application #:** 206321

Patient Information:

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

Suspect Products:

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

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

Event Information:

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

Event/Problem Narrative:

This serious spontaneous case from the UNITED STATES was reported by a consumer as "strong thoughts of suicide(Suicidal ideation)" with an unspecified onset date, "depression(Depression)" with an unspecified onset date, and concerned an adult female patient, who was treated with Saxenda (liraglutide) from an unknown start date for an unknown indication. Medical history was not provided. A patient, who was receiving therapy with Saxenda, developed strong thoughts of suicide and depression, described as felt terrified and lost. Action taken to Saxenda was Not reported. The outcome for the event "strong thoughts of suicide(Suicidal ideation)" was Not recovered. The outcome for the event "depression(Depression)" was Not recovered. Patient declined to provide any further information including product batch number. Company Comment: Suicidal ideation is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Saxenda. Limited information as related to indication for Saxenda use, weight, BMI, age, medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluations limits medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

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

Case ID: 20502066

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: 21360692

Case Information:

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

FDA Rcvd Date: 24-Oct-2022 **Mfr Rcvd Date:** 12-Oct-2022 **Mfr Control #:** US-ELI_LILLY_AND_COMPANY-US202209005617 **Application #:** 215866

Patient Information:

Age: **Sex:** Male **Weight:** 258 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Mounjaro 2.5mg		2.5 Mg Milligram(S) /	Subcutaneous	2.5 mg, unknown	10045242	18-Aug-2022	06-Sep-2022

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

Event Information:

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

Event/Problem Narrative:

This spontaneous case, reported by a physician via a sales representative, concerns a 65-years-old Caucasian male patient. The patients medical history included Type 2 diabetes mellitus. Historical medications included Ozempic for Type 2 diabetes mellitus. The patient was switched from Ozempic to tirzepatide. Concomitant medications included insulin aspart, insulin aspart protamine, motine, hydrochlorothiazide, valsartan, insulin glargine, gabapentine, nystatin, pravastatin, econazole nitrate, dapagliflozin propanediol monohydrate, pioglitazone, metformin, tadalafil, paracetamol and amlodipine, all for an unknown indication. The patient received tirzepatide (Mounjaro), 2.5 mg, for type II diabetes, unknown frequency, subcutaneously, beginning on 18Aug2022. On an unknown date, reported as the second week of treatment, the patient started to have anxiety, depression, and suicidal thoughts. The event of suicidal thoughts was

Case ID: 21360692

considered serious by the company due to medically significant reasons. On 25Aug2022, the patient administrated last dose of tirzepatide therapy (as reported). On 06Sep2022, the patient s physician immediately discontinued the treatment upon being informed of the events. No treatment was administered. As of follow up information on 12Oct2022, the patient was recovered from the events. The physician stated that there was no motive or trigger for suicidal thoughts, there was no history of depression in past. The tirzepatide therapy was not restarted. No further information was provided. The reporting physician related all the events to tirzepatide and did not relate all the events to the device. No other relatedness opinion was provided. Update 20Oct2022: Additional information received from the physician on 12Oct2022. Added drug start date and last date of drug administration details. Added patient s demographics (initials, date of birth, height, and weight). Added medical history and concomitant medication. Added tirzepatide therapy route of administration. Updated outcome of all the events from unknown to recovered. Narrative and corresponding fields were updated accordingly.

Relevant Medical History:

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

Medical History Product(s)	Start Date	End Date	Indications	Events
OZEMPIC			10067585	10067482

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	NOVOLOG MIX	/	Unknown	UNK, unknown	10070592			
2	VALSARTAN HYDROCHLOROTHIAZIDE KRKA	/	Unknown	UNK, unknown	10070592			
3	LANTUS	/	Unknown	UNK, unknown	10070592			
4	GABAPENTINE	/	Unknown	UNK, unknown	10070592			
5	NYSTATIN	/	Unknown	UNK, unknown	10070592			
6	PRAVASTATIN	/	Unknown	UNK, unknown	10070592			

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

Case ID: 21360692

7	ECONAZOLE [ECONAZOLE NITRATE]	/	Unknown	UNK, unknown	10070592
8	FARXIGA	/	Unknown	UNK, unknown	10070592
9	PIOGLITAZONE	/	Unknown	UNK, unknown	10070592
10	METFORMIN	/	Unknown	UNK, unknown	10070592
11	TADALAFIL	/	Unknown	UNK, unknown	10070592
12	TYLENOL	/	Unknown	UNK, unknown	10070592
13	AMLODIPINE	/	Unknown	UNK, unknown	10070592

Reporter Source:

Study report?: No **Sender organization:** ELI LILLY AND CO **503B Compounding Outsourcing Facility?:**

Literature Text:

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

Case ID: 21854592

Case Information:

Case Type : Direct **eSub:** N **HP:** **Country:** US **Event Date:** 08-Jan-2023 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 11-Jan-2023 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2023-3141 **Application #:**

Patient Information:

Age: 34 YR **Sex:** Male **Weight:** 117.9 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Wegovy 1mg/0.5mL four pen injectors (1mg per injector)		1 Dosage Form / 999	Subcutaneous	OTHER QUANTITY : 1 Injection(s); OTHER FREQUENCY : 1/wk;	Obesity (weight management)	08-Jan-2023	
2	mounjaro		/					

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Wegovy 1mg/0.5mL four pen injectors (1mg per injector)		Yes	Not Applicable				NOVO NORDISK	
2	mounjaro		NA	NA					

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Depressed mood	NA
Suicidal ideation	NA
Nausea	NA
Motion sickness	NA
Vomiting	NA

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

Case ID: 21854592

Decreased appetite	NA

Event/Problem Narrative:

Took 1mg Wegovy subQ injector pen on Jan 8th, side effects were strong sadness feelings, suicidal ideation (for about 48 hours) and nausea / motion sickness for 72 hours that required treatment via anti-nausea meds to be able to walk around at all. Vomited once on the 9th, for essentially everything in my stomach at the time (which wasn't much). Was essentially unable to eat from late 8th to mid 11th due to nausea / lack of appetite I had taken mounjaro 2.5mg weekly previously for 4 weeks total without much side effects (mild nausea for a few hours after injection) That's why my Dr wrote the script for 1mg wegovy, since I wasn't 'naive' to that type of weight management med at the time It took about a month to get wegovy supplied, so by then I had run out of mounjaro and had about a month between doses I changed to 0.5mg wegovy so that may help with side effects

Relevant Medical History:

List known medical conditions : Obesity, Major Depressive Disorder;

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	Lexapro	/						
2	Lamictol	/						
3	Promethazine	/						
4	women's multivitamin	/						
5	fish oil	/						

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

Case ID: 21854592

Reporter Source:

Study report?: No

Sender organization: FDA-CTU

503B Compounding Outsourcing Facility?:

Literature Text:

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	11-Jan-2023	CTU Received Date	11-Jan-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	08-Jan-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Took 1mg wegovy subQ injector pen on Jan 8th, side effects were strong sadness feelings, suicidal ideation (for about 48 hours) and nausea / motion sickness for 72 hours that required treatment via anti-nausea meds to be able to walk around at all. Vomited once on the 9th, for essentially everything in my stomach at the time (which wasn't much). Was essentially unable to eat from late 8th to mid 11th due to nausea / lack of appetite I had taken mounjaro 2.5mg weekly previously for 4 weeks total without much side effects (mild nausea for a few hours after injection) That's why my Dr wrote the script for 1mg wegovy, since I wasn't 'naive' to that type of weight management med at the time It took about a month to get wegovy supplied, so by then I had run out of mounjaro and had about a month between doses I changed to 0.5mg wegovy so that may help with side effects

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	

Low Test Range		High Test Range		
More Information Available?				

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	
Do you have a picture of the product? (check yes if you are including a picture)	No

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Other		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Wegovy 1mg/0.5mL four pen injectors (1mg per injector)		
Name of the company that makes (or compounds) the product	Novo Nordisk		
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength	1mg / 0.5mL mg milligram(s)	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	1/wk	
How was it taken or used	Subcutaneous	If Other		

	Date the person first started taking or using the product	08-Jan-2023
	Date the person stopped taking or using the product	
	Date the person reduced dose of the product	11-Jan-2023
	Give best estimate of duration	
	Is therapy still on-going?	Yes

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

	Obesity (weight management)

	Returned to Manufacturer On	

Section D - About the Medical Device

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

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

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

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

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

Section E - About the Person Who Had the Problem

	Person's Initials	(b) (6)
	Sex	Male
	Gender	Other Gender category
	Please Specify Other Gender	demi-masc
	Age (specify unit of time for age)	34 Year(s)
	Date of Birth	
	Weight	117.9 kg
	Ethnicity (Choose only one)	Not Hispanic/Latino

Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

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

Obesity, Major Depressive Disorder

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

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.

Lexapro (20mg 1/d) Lamictol (150mg 2/d) Promethazine 12.5mg (as needed)

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

women's multivitamin, fish oil

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	(b) (6)	
	Email address		
	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	11-Jan-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	

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

Case ID: 21974341

Case Information:

Case Type : Direct **eSub:** N **HP:** Y **Country:** US **Event Date:** 02-Feb-2023 **Outcomes:** LT **Application Type:**

FDA Rcvd Date: 08-Feb-2023 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2023-10933 **Application #:**

Patient Information:

Age: 55 YR **Sex:** Male **Weight:** 168.75 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Mounjaro (tirzepatide)		5 Mg Milligram(S) / 999	Subcutaneous	OTHER FREQUENCY :weekly;	Type 2 diabetes mellitus	23-Jan-2023	

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Mounjaro (tirzepatide)		Not Applicable	Not Applicable			0002-1495-80	ELI LILLY AND CO	

Event Information:

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

Event/Problem Narrative:

Tell us what happened and how it happened : Describe Event, Problem, or Product Use Error: Two weeks after increasing his Mounjaro (tirzepatide) dose to 5 mg, the patient became depressed with suicidal ideation. After two days it lessened but had not gone away completely. He had previously been on Ozempic (semaglutide) without issue. Since starting the Mounjaro (tirzepatide) his appetite had decreased significantly, though his weight hadn't changed.;

Relevant Medical History:

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

Case ID: 21974341

List known medical conditions : NKDA, History of hypertension, hyperlipidemia, Type 2 diabetes mellitus with neuropathy, allergic rhinitis, morbid obesity, metabolic syndrome, GERD, depression, erectile dysfunction, spinal stenosis;

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
HGA1C					
CREATININE					

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	Duloxetine	/						
2	insulin glargine	/						
3	famotidine	/						
4	pregabalin	/						
5	Humalog	/						
6	hydrochlorathiazide	/						
7	amlodipine	/						
8	metformin	/						
9	lisinopril	/						
10	atorvastatin	/						
11	sildenafil	/						
12	ibuprofen	/						

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

Case ID: 21974341

Reporter Source:

Study report?: No

Sender organization: FDA-CTU

503B Compounding Outsourcing Facility?:

Literature Text:

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	08-Feb-2023	CTU Received Date	08-Feb-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

A. PATIENT INFORMATION

Patient Identifier (In Confidence)	(b) (6)
Age	
Date of Birth	(b) (6)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Weight	168.75 kg
Ethnicity (Check single best answer)	Not Hispanic/Latino
Race (Check all that apply)	☐ Asian ☐ American Indian or Alaska Native ☐ Black or African American ☑ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

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

	☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
Date of Death	
Date of Event	02-Feb-2023
Date of this Report	08-Feb-2023

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Two weeks after increasing his Mounjaro (tirzepatide) dose to 5 mg, the patient became depressed with suicidal ideation. After two days it lessened but had not gone away completely. He had previously been on Ozempic (semaglutide) without issue. Since starting the Mounjaro (tirzepatide) his appetite had decreased significantly, though his weight hadn't changed.

Relevant Test/Laboratory Data 1 of 2

Test Name	HGA1C	Test Date	03-Feb-2023
Test Result	6.5	Test Unit	PERCENT
Low Test Range		High Test Range	< 5.7
More Information Available?			

Relevant Test/Laboratory Data 2 of 2

Test Name	CREATININE	Test Date	03-Feb-2023
Test Result	0.86	Test Unit	MICROGRAMS PER DEC ILITRE
Low Test Range	0.7	High Test Range	1.5
More Information Available?			

Additional Comments

Other Relevant History, Including Preexisting Medical Conditions

NKDA, History of hypertension, hyperlipidemia, Type 2 diabetes mellitus with neuropathy, allergic rhinitis, morbid obesity, metabolic syndrome, GERD, depression, erectile dysfunction, spinal stenosis

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	No
Returned to Manufacturer on	
Do you have a picture of the product? (check yes if you are including a picture)	No

D. PRODUCT(S) 1 of 13

Suspect	Yes
Primary?	Yes

Type	Drug/Biologic			
This report involves:	Other			

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

Product Name	Mounjaro (tirzepatide)		
Strength	5 mg milligram(s)	If Other	
Manufacturer/Compounder	Lilly		
NDC# or Unique ID	0002-1495-80		
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
Event Abated After Use Stopped or Dose Reduced?	Doesn't Apply		
Event Reappeared after Reintroduction ?	Doesn't Apply		

Drug Therapy 1 of 1

Dose or Amount	5 mg milligram(s)	If Other	
Frequency	Other	If Other	weekly
Route	Subcutaneous	If Other	
Dosage Form			
Start	23-Jan-2023		
Stop			
Dose Reduced	07-Feb-2023		
Therapy Duration		If Other	
Is therapy still on-going?	Yes		
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

Type 2 diabetes mellitus

D. PRODUCT(S) 2 of 13

Concomitant	Yes		
Primary?			
Type	Drug/Biologic		
This report involves:			

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

Product Name	Duloxetine		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded		

	☐ Generic ☐ Biosimilar
Event Abated After Use Stopped or Dose Reduced?	
Event Reappeared after Reintroduction ?	

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start	24-Sep-2019		
Stop			
Dose Reduced			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 3 of 13

Concomitant	Yes
Primary?	
Type	Drug/Biologic
This report involves:	

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

Product Name	insulin glargine		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
Event Abated After Use Stopped or Dose Reduced?			
Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	

	Dosage Form			
	Start			
	Stop			
	Dose Reduced			
	Therapy Duration		If Other	
	Is therapy still on-going?			
	Lot Number			
	Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 4 of 13

	Concomitant	Yes
	Primary?	
	Type	Drug/Biologic
	This report involves:	

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

	Product Name	famotidine		
	Strength		If Other	
	Manufacturer/Compounder			
	NDC# or Unique ID			
	Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
	Event Abated After Use Stopped or Dose Reduced?			
	Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

	Dose or Amount		If Other	
	Frequency		If Other	
	Route		If Other	
	Dosage Form			
	Start			
	Stop			
	Dose Reduced			
	Therapy Duration		If Other	
	Is therapy still on-going?			
	Lot Number			
	Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 5 of 13

Concomitant	Yes
Primary?	
Type	Drug/Biologic
This report involves:	

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

Product Name	pregabalin		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
Event Abated After Use Stopped or Dose Reduced?			
Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start	29-Mar-2017		
Stop			
Dose Reduced			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 6 of 13

Concomitant	Yes
Primary?	
Type	Drug/Biologic
This report involves:	

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

Product Name	Humalog			
Strength		If Other		
Manufacturer/Compounder				
NDC# or Unique ID				
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar			
Event Abated After Use Stopped or Dose Reduced?				
Event Reappeared after Reintroduction ?				

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Dose Reduced			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 7 of 13

Concomitant	Yes
Primary?	
Type	Drug/Biologic
This report involves:	

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

Product Name	hydrochlorathiazide		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		

	Event Abated After Use Stopped or Dose Reduced?				
	Event Reappeared after Reintroduction ?				

Drug Therapy 1 of 1

	Dose or Amount		If Other		
	Frequency		If Other		
	Route		If Other		
	Dosage Form				
	Start				
	Stop				
	Dose Reduced				
	Therapy Duration		If Other		
	Is therapy still on-going?				
	Lot Number				
	Expiration Date				

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 8 of 13

	Concomitant	Yes
	Primary?	
	Type	Drug/Biologic
	This report involves:	

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

	Product Name	amlodipine			
	Strength		If Other		
	Manufacturer/Compounder				
	NDC# or Unique ID				
	Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar			
	Event Abated After Use Stopped or Dose Reduced?				
	Event Reappeared after Reintroduction ?				

Drug Therapy 1 of 1

	Dose or Amount		If Other		
	Frequency		If Other		
	Route		If Other		
	Dosage Form				
	Start				

	Stop			
	Dose Reduced			
	Therapy Duration		If Other	
	Is therapy still on-going?			
	Lot Number			
	Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 9 of 13

	Concomitant	Yes
	Primary?	
	Type	Drug/Biologic
	This report involves:	

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

	Product Name	metformin		
	Strength		If Other	
	Manufacturer/Compounder			
	NDC# or Unique ID			
	Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
	Event Abated After Use Stopped or Dose Reduced?			
	Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

	Dose or Amount		If Other	
	Frequency		If Other	
	Route		If Other	
	Dosage Form			
	Start			
	Stop			
	Dose Reduced			
	Therapy Duration		If Other	
	Is therapy still on-going?			
	Lot Number			
	Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 10 of 13

Concomitant	Yes
Primary?	
Type	Drug/Biologic
This report involves:	

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

Product Name	lisinopril		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		
Event Abated After Use Stopped or Dose Reduced?			
Event Reappeared after Reintroduction ?			

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Dose Reduced			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 11 of 13

Concomitant	Yes
Primary?	
Type	Drug/Biologic
This report involves:	

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

Product Name	atorvastatin			
Strength		If Other		
Manufacturer/Compounder				
NDC# or Unique ID				
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar			
Event Abated After Use Stopped or Dose Reduced?				
Event Reappeared after Reintroduction ?				

Drug Therapy 1 of 1

Dose or Amount		If Other	
Frequency		If Other	
Route		If Other	
Dosage Form			
Start			
Stop			
Dose Reduced			
Therapy Duration		If Other	
Is therapy still on-going?			
Lot Number			
Expiration Date			

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 12 of 13

Concomitant	Yes
Primary?	
Type	Drug/Biologic
This report involves:	

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

Product Name	sildenafil		
Strength		If Other	
Manufacturer/Compounder			
NDC# or Unique ID			
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar		

	Event Abated After Use Stopped or Dose Reduced?				
	Event Reappeared after Reintroduction ?				

Drug Therapy 1 of 1

	Dose or Amount		If Other		
	Frequency		If Other		
	Route		If Other		
	Dosage Form				
	Start				
	Stop				
	Dose Reduced				
	Therapy Duration		If Other		
	Is therapy still on-going?				
	Lot Number				
	Expiration Date				

Diagnosis for Use (indication) 1 of 1

D. PRODUCT(S) 13 of 13

	Concomitant	Yes
	Primary?	
	Type	Drug/Biologic
	This report involves:	

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

	Product Name	ibuprofen			
	Strength		If Other		
	Manufacturer/Compounder				
	NDC# or Unique ID				
	Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar			
	Event Abated After Use Stopped or Dose Reduced?				
	Event Reappeared after Reintroduction ?				

Drug Therapy 1 of 1

	Dose or Amount		If Other		
	Frequency		If Other		
	Route		If Other		
	Dosage Form				
	Start				

	Stop			
	Dose Reduced			
	Therapy Duration		If Other	
	Is therapy still on-going?			
	Lot Number			
	Expiration Date			

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

	Brand Name	
	Common Device Name	
	Procode	
	Manufacturer Name	
	City	
	State	
	Model #	
	Lot #	
	Catalog #	
	Expiration Date	
	Serial #	
	Unique Identifier (UDI)#	
	Operator of Device	☐ Health Professional ☐ Patient/Consumer ☐ Other
	Other	
	If Implanted, Give Date	
	If Explanted, Give Date	
	Is this a single-use device that was reprocessed and reused on a patient?	
	If Yes for the above field, Enter Name and Address of Reprocessor	
	Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER

1 of 1

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

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

Case ID: 21979556

Case Information:

Case Type : Direct **eSub:** N **HP:** **Country:** US **Event Date:** 16-Jan-2023 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 09-Feb-2023 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2023-11602 **Application #:**

Patient Information:

Age: 42 YR **Sex:** Female **Weight:** 99 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Mounjaro		Other / 999	Subcutaneous	OTHER QUANTITY : 1 Injection(s); OTHER FREQUENCY : Weekly;	Type 2 diabetes	18-Dec-2022	16-Jan-2023

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Mounjaro		Yes	Not Applicable	D552770C	20-Oct-2024	0002149580	ELI LILLY AND CO	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Depressed mood	NA
Apathy	NA
Fatigue	NA
Suicidal ideation	NA
Panic attack	NA

Event/Problem Narrative:

Tell us what happened and how it happened : Upon starting mounjaro 2.5 mg weekly I noted new onset sadness, lack of motivation, and fatigue. Took 2.5 mg weekly for 4 weeks. On 1/15/2023 prior to bed took increased dose of mounjaro 5 mg. Within 12 hours the fatigue and decreased motivation were significantly

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

Case ID: 21979556

worse and I started having suicidal ideation and panic attacks. I saw my health care provider on 1/17/23. Mounjaro was discontinued and sertraline was started. Within 1 week all symptoms were improved.;

Relevant Medical History:

List known medical conditions : Diabetes;

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	Progesterone only birth control	/						
2	famotidine	/						
3	sertraline	/						

Reporter Source:

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

Literature Text:

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500B
Priority	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	09-Feb-2023	CTU Received Date	09-Feb-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
Date the problem occurred	16-Jan-2023
Serious	Yes
Did any of the following happen? (Check all that apply)	☐ Hospitalization - admitted or stayed longer ☐ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☑ Other serious/important medical incident(Please Describe Below)
Other serious/important medical incident(Please Describe Below)	

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Upon starting mounjaro 2.5 mg weekly I noted new onset sadness, lack of motivation, and fatigue. Took 2.5 mg weekly for 4 weeks. On 1/15/2023 prior to bed took increased dose of mounjaro 5 mg. Within 12 hours the fatigue and decreased motivation were significantly worse and I started having suicidal ideation and panic attacks. I saw my health care provider on 1/17/23. Mounjaro was discontinued and sertraline was started. Within 1 week all symptoms were improved.

Relevant Test/Laboratory Data 1 of 1

Test Name		Test Date	
Test Result		Test Unit	

Low Test Range		High Test Range		
More Information Available?				

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	Yes
Do you have a picture of the product? (check yes if you are including a picture)	No

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Other		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Mounjaro		
Name of the company that makes (or compounds) the product	Lilly		
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength	5mg mg milligram(s)	If Other	
NDC number	0002149580		
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	20-Oct-2024		
Lot number	D552770C		
Dosage Form			
Quantity	Other	If Other	1 Injection(s)
Frequency	Other	If Other	Weekly
How was it taken or used	Subcutaneous	If Other	
Date the person first started taking or using the product	18-Dec-2022		

Date the person stopped taking or using the product	16-Jan-2023	
Date the person reduced dose of the product		
Give best estimate of duration		
Is therapy still on-going?		

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

Type 2 diabetes

Returned to Manufacturer On	

Section D - About the Medical Device

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

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

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

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

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

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Female
Gender	Cisgender woman/girl
Please Specify Other Gender	
Age (specify unit of time for age)	42 Year(s)
Date of Birth	
Weight	99 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander

	☐ Asian ☑ White ☐ Black or African American

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

Diabetes

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

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.

Progesterone only birth control, famotidine 20 mg, sertraline 50 mg

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

Section F - About the Person Filling Out This Form 1 of 1

Primary?	Yes
Reporter is Patient?	
Title	
Last name	(b) (6)
Middle Name	
First name	
Number/Street	
City	
State/Province	
Country	
ZIP or Postal code	
Telephone number	
Email address	

	Fax		
	Reporter Organization		
	Department		
	Reporter Speciality		
	Today's date	09-Feb-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	No	

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

Case ID: 22040650

Case Information:

Case Type : Direct **eSub:** N **HP:** **Country:** US **Event Date:** 26-Dec-2022 **Outcomes:** HO , RI **Application Type:**

FDA Rcvd Date: 25-Feb-2023 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2023-15879 **Application #:**

Patient Information:

Age: 57 YR **Sex:** Male **Weight:** 119.25 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Mounjaro		/			Weight loss, diabetes diabetes	01-Nov-2022	30-Dec-2022

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Mounjaro		Yes	Not Applicable				ELI LILLY AND CO	

Event Information:

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

Event/Problem Narrative:

Tell us what happened and how it happened : Mounjaro caused panic attacks and thoughts of suicide;

Relevant Medical History:

List known medical conditions : Diabetes obesity depression; List any other important information about the person : Non smoker

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Case ID: 22040650

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	Routine		
Override Auto Calculation Rule	No		
FDA Received Date	25-Feb-2023	CTU Received Date	25-Feb-2023
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑		
Case Priority	Direct		

Contact

Case Reporter	First Name	Last Name	Email Address	Phone
☑	(b) (6)	(b) (6)	(b) (6)	(b) (6)

Section A - About the Problem

	What kind of problem was it? (Check all that apply)	☑ Were hurt or had a bad side effect (including new or worsening symptoms) ☐ Used a product incorrectly which could have or led to a problem ☐ Noticed a problem with the quality of the product ☐ Had problems after switching from one product maker to another maker
	Date the problem occurred	26-Dec-2022
	Serious	Yes
	Did any of the following happen? (Check all that apply)	☑ Hospitalization - admitted or stayed longer ☑ Required help to prevent permanent harm ☐ Disability or health problem ☐ Birth defect ☐ Life-threatening ☐ Death ☐ Other serious/important medical incident(Please Describe Below)

4.Tell us what happened and how it happened (Include as many details as possible FDA may reach out to you for any additional documents if necessary)

Mounjaro caused panic attacks and thoughts of suicide

Relevant Test/Laboratory Data 1 of 1

	Test Name		Test Date	
	Test Result		Test Unit	
	Low Test Range		High Test Range	
	More Information Available?			

Additional Comments

Section B - Product Availability

Do you still have the product in case we need to evaluate it?	No
Do you have a picture of the product? (check yes if you are including a picture)	No

Section C - About the Products 1 of 1

Suspect	Yes		
Primary?	Yes		
Type	Drug/Biologic		
This report is about	Other		
Name of the product as it appears on the box, bottle, or package (Include as many names as you see)	Mounjaro		
Name of the company that makes (or compounds) the product	Eli lilly and co		
Product Type(check all that apply)	☐ Over-the-Counter ☐ Compounded by a Pharmacy or an Outsourcing Facility ☐ Generic ☐ Biosimilar		
Strength		If Other	
NDC number			
Did the problem stop after the person reduced the dose or stopped taking or using the product?	Yes		
Did the problem return if the person started taking or using the product again?	Doesn't Apply		

Drug Therapy 1 of 1

Expiration date			
Lot number			
Dosage Form			
Quantity		If Other	
Frequency		If Other	
How was it taken or used		If Other	
Date the person first started taking or using the product	01-Nov-2022		
Date the person stopped taking or using the product	30-Dec-2022		
Date the person reduced dose of the product			

Give best estimate of duration	
Is therapy still on-going?	

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

Weight loss, diabetes

Returned to Manufacturer On	

Section D - About the Medical Device

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

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

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

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

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

Section E - About the Person Who Had the Problem

Person's Initials	(b) (6)
Sex	Male
Gender	Cisgender man/boy
Please Specify Other Gender	
Age (specify unit of time for age)	57 Year(s)
Date of Birth	
Weight	119.25 kg
Ethnicity (Choose only one)	Not Hispanic/Latino
Race (Check all that apply)	☐ American Indian or Alaska Native ☐ Native Hawaiian or Other Pacific Islander ☐ Asian ☑ White ☐ Black or African American

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

Diabetes obesity depression

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

List any other important information about the person (such as smoking, pregnancy, alcohol use, etc.)

Non smoker

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.

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	25-Feb-2023	
	Did you report this problem to the company that makes the product (the manufacturer/compounder)?	No	
	If you do NOT want your identity disclosed to the manufacturer, please mark this box (Confidentiality Requested):	Yes	