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

Date - T me: 0-Aug-2023 4:32:5 EDT

Run by: KIA BAZEMORE@FDA HHS GOV

Disclaimer:

Submission of a safety report does not constitute an admission that medical personnel, user facility, importer, distr butor, manufacturer or product caused or contributed to the event. The information in these reports has not been scientifically or otherwise verified as to a cause and effect relationship and cannot be used to estimate the incidence of these events.

Data provided in the Quarterly Data Extract (QDE) or a FAERS FOIA report are a snapshot of FAERS at a given time. There are several reasons that a case captured in this snapshot can be marked as inactive and not show up in subsequent reports. Manufacturers are allowed to electronically delete reports they submitted if they have a valid reason for deletion. FDA may merge cases that are found to describe a single event, marking one of the duplicate reports as inactive. The data marked as inactive are not lost but may not be available under the original case number.

The cover page will display all Case ID(s) included in the Batch Printing Report and FOIA case report information may include both Electronic Submissions (Esubs) and MedWatch Reports (Non-Esubs).

Cover page Case ID(s) with an asterisk ('*') indicate an invalid status and are not captured in the body of the report.

Cover page Case ID(s) with an asterisk ('**') indicate an failed status and are not captured in the body of the report.

Case ID(s) Printed:

12271797	13742984	14402770	14988618
16014521	20502265	20502267	20502322
20882038	21854592	21933415	22054156

Total Cases: 12

Total number of Inactive cases: *0

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

Case ID: 12271797

Case Information:

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

FDA Rcvd Date: 15-Apr-2016 **Mfr Rcvd Date:** 02-Mar-2016 **Mfr Control #:** US-NOVOPROD-482732 **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		3 Mg Milligram(S) / QD	Subcutaneous	3 mg daily	Drug use for unknown indication		

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

Event Information:

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

Suicidal ideation

Event/Problem Narrative:

This serious spontaneous case from the United States was reported by a physician assistant via a company representative as "suicidal thoughts" with an unspecified onset date, and concerned a female patient (in her early 50s) who was treated with Saxenda (liraglutide) from an unknown start date to an unknown stop date due to an unknown indication. Medical history was not provided. A physician assistant reported that a patient receiving therapy with Saxenda had experienced suicidal thoughts. Upon discontinuation of Saxenda, the suicidal thoughts had subsided. Action taken to Saxenda was reported as product discontinued. The outcome for the event "suicidal thoughts" was recovered. A causal relationship between the event and therapy with Saxenda was not reported.
Batch number and product return was not available at the time of the initial report. Company Comment: "Suicidal thoughts (PT=Suicidal ideation)" is assessed as unlisted according to the Novo Nordisk CCDS for Saxenda. Since the event, "suicidal thoughts" occurred after initiation of the product in question, a contributory role of the drug cannot be ruled out; however, it is unknown if the patient currently suffers from depression. Further relevant information regarding sudden, unexpected negative change in life circumstances, history of depression, previous suicide threats or attempts, drug or alcohol abuse, psychiatric evaluation, and concomitant medications would prove helpful for complete assessment of the event. This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

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

Case ID: 12271797

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: 13742984

Case Information:

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

FDA Rcvd Date: 11-Jul-2017 **Mfr Rcvd Date:** 25-May-2017 **Mfr Control #:** US-NOVOPROD-548062 **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		/	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		Yes	NA	UNKNOWN			NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Abdominal pain	
Nausea	

Event/Problem Narrative:

This serious spontaneous case from the United States was reported by a physician assistant via a company representative, as "suicidal thoughts" with an unspecified onset date, "severe gastrointestinal (GI) abdominal pain" with an unspecified onset date, "severe gastrointestinal (GI) nausea" with an unspecified onset date, and concerned a 46 Year old Female patient who was treated with Saxenda (liraglutide) from unknown start date due to an unknown indication". Medical history was not provided. On an unspecified date, a patient being treated with Saxenda developed severe gastrointestinal (GI) nausea, severe gastrointestinal (GI) abdominal pain, and suicidal thoughts. The patient discontinued therapy with Saxenda and reported that the severe GI nausea, severe GI abdominal pain, and suicidal thoughts went away. Action taken to Saxenda was reported as Product discontinued. The outcome for the event "suicidal thoughts" was Recovered. The outcome for the event "severe gastrointestinal (GI) abdominal pain" was Recovered. The outcome for the event "severe gastrointestinal (GI) nausea" was Recovered. A causal relationship between the event and therapy with Saxenda was not reported. Comment: 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 suspect product therapy

dates, medical history including psychological history, concomitant medications, family/social history, and laboratory/diagnostic evaluations precludes medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

Relevant Medical History:

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: 14402770

Case Information:

Case Type : Non-Expedited **eSub:** Y **HP:** **Country:** US **Event Date:** 2017 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 17-Jan-2018 **Mfr Rcvd Date:** 13-Dec-2017 **Mfr Control #:** US-NOVOPROD-577580 **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	Drug use for unknown indication		2017
2	Saxenda		/	Subcutaneous	UNK		2017	2017

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

Event Information:

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

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a physician's assistant as "Suicidal thoughts" with an unspecified onset date, "Suicidal thoughts" beginning in 2017, and concerned a Female patient who was treated with Saxenda (liraglutide) from unknown start date to 2017 and again from 2017 to 2017 due to "Drug use for unknown indication". Medical history included depression. On an unspecified date a patient began to have suicidal thoughts after taking Saxenda for 4 days. The patient then stopped Saxenda and recovered. The patient decided to try Saxenda again. On an unspecified date in 2017, the patient began to have suicidal thoughts again. Saxenda was stopped afterwards, and the patient recovered. Action taken to Saxenda was reported as Product discontinued. On 2017 the outcome for the event "Suicidal thoughts" was Recovered. On 2017 the outcome for the event "Suicidal thoughts" was Recovered. Company Comment: "Suicidal thoughts (PT=Suicidal ideation)" is assessed as unlisted according to the NN current reference safety information on Saxenda. Although there is an apparent temporal association, the patient's medical history of depression provides an alternative explanation towards the onset of the

event. Further information regarding the patient's health status prior to Saxenda therapy, indication for use, assessment of current medical conditions specifically psychiatric evaluation, negative change in life circumstances, previous suicide threats or attempts, family history of mental disorder, drug or alcohol abuse, and concomitant medications would be necessary for complete assessment of 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?
Depression			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: 14988618

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** CA **Event Date:** 16-May-2018 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 08-Jun-2018 **Mfr Rcvd Date:** 28-May-2018 **Mfr Control #:** CA-NOVOPROD-603445 **Application #:** 206321

Patient Information:

Age: 47 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	Subcutaneous	0.6 mg, qd	Weight control	16-May-2018	17-May-2018
2	Saxenda		.6 Mg Milligram(S) / QD	Subcutaneous	0.6 mg, qd		19-May-2018	23-May-2018

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

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Depression	
Hallucination	
Nausea	
Abdominal pain upper	
Headache	
Asthenia	

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

Case ID: 14988618

Event/Problem Narrative:

This serious spontaneous case from Canada was reported by a consumer as "suicide thoughts" beginning on 16-MAY-2018, "depression" beginning on 16-MAY-2018, "hallucination" beginning on 16-MAY-2018, "nausea" beginning on 19-MAY-2018, "stomach pain" beginning on 19-MAY-2018, "headaches" beginning on 19-MAY-2018, "felt weak " beginning on 17-MAY-2018, and concerned a 47 years old female patient who was treated with Saxenda (liraglutide) from 16-MAY-2018 to 23-MAY-2018 due to "Weight loss". Patient's height, weight and BMI (body mass index) were not reported. Medical history was not provided. On 16-MAY-2018, patient developed depression, hallucination and suicidal thoughts. On 17-MAY-2018, patient was not able to get out of bed, felt weak and could not walk. On 18-MAY-2018, patient had decided not to take Saxenda. On 19-MAY-2018, patient had restarted and decided to take injections at night in order to check if it makes any difference in the side effects, but however it was reported to be worse the next day. Patient was also nausea, stomach pains and headache. Patient continued to take Saxenda until 23-MAY-2018 and then decided to stop completely on 24- MAY-2018. After discontinuing Saxenda patient stated that side effects continued for 2-3 days before it completely resolved. Action taken to Saxenda was reported as Product discontinued. On 26-MAY-2018 the outcome for the event "suicide thoughts" was Recovered. On 26-MAY-2018 the outcome for the event "depression" was Recovered. On 26-MAY-2018 the outcome for the event "hallucination" was Recovered. On 26-MAY-2018 the outcome for the event "nausea" was Recovered. On 26-MAY-2018 the outcome for the event "stomach pain" was Recovered. On 26-MAY-2018 the outcome for the event "headaches" was Recovered. On 26-MAY-2018 the outcome for the event "felt weak " was Recovered. No further information available. Company Comment: The events Suicidal ideation, Depression, Hallucination and Headache are assessed as unlisted; Nausea, Stomach pain and Feelings of weakness- are assessed as listed events according to the Novo Nordisk current CCDS on Saxenda. The information regarding the concomitant medications, investigations done, treatment provided and other risk factors for suicidal ideation, depression and hallucination such as history of neurological or psychiatric illness, social circumstances, substance use, prior history of suicide attempt- are currently unavailable for a complete medical assessment of 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?

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

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

Case ID: 14988618

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: 16014521

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** AU **Event Date:** 20-Jul-2016 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 08-May-2019 **Mfr Rcvd Date:** 30-Apr-2019 **Mfr Control #:** AU-NOVOPROD-647871 **Application #:** 206321

Patient Information:

Age: 45 YR **Sex:** Female **Weight:** 119 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Saxenda		/	Unknown	3 mg	Weight control	25-May-2016	22-Jul-2016

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Saxenda	56 Day	Yes	Unknown				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Paranoia	
Anxiety	
Depressed mood	
Suicidal ideation	
Thinking abnormal	

Event/Problem Narrative:

This serious Spontaneous case from AUSTRALIA was reported by a General practitioner as "Acutely anxious" beginning on 22-JUL-2016, "paranoid" beginning on 20-JUL-2016, "Acute deterioration of mood" beginning on 22-JUL-2016, "irrational thinking" beginning on 22-JUL-2016, "Suicidal ideation (passive ideation only)" beginning on 22-JUL-2016, and concerned a 45 Years old Female patient who was treated with Saxenda (liraglutide) from 25-MAY-2016 to 22-JUL-2016 due to "Weight loss", Patient's height: 164 cm Patient's weight: 119 kg Patient's BMI: 44.2440. Medical history included history of depression (Past history of depression but was stable and off medication. Continued to see psychologist for maintenance), eating disorder (previous), anxiety (Long history of depression and anxiety). Drug history included Zoloft. Treatment included - zoloft(sertraline hydrochloride), seroquel(quetiapine fumarate) On an unknown date the patient

Case ID: 16014521

became paranoid. On 22-JUL-2016 the patient became acutely anxious and experienced acute deterioration of mood, became teary and irrational in her thought process (not a previous feature) and had a Suicidal ideation. The patient was at A+E (Accident and Emergency) (for not more than 24 hrs) and was administered with an antipsychotic Seroquel and restarted Zoloft. Later the patient was followed up with Crisis Assessment team as outpatient. The patient had a falling out with friend in the days before the acute deterioration. Had not had irrational thinking in previous exacerbations of mood disorder. The patient remained in treatments for underlying depression- medication. Upon follow-up ,it was reported that patient was not hospitalized, just seen and given medication then followed up by ACAT team. it was also reported regarding medical history, that patient had Llng history of depression and anxiety, previous eating disorder. Conditions were stable at onset of Saxenda. Fluctuating worse over the years. Batch number unavailable. Action taken to Saxenda was reported as Product discontinued. On 26-JUL-2016 the outcome for the event "paranoid" was Recovered. The outcome for the event "Acutely anxious" was Recovering/resolving. On SEP-2016 the outcome for the event "Acute deterioration of mood" was Recovered. On 26-JUL-2016 the outcome for the event "irrational thinking" was Recovered. On 26-JUL-2016 the outcome for the event "Suicidal ideation (passive ideation only)" was Recovered. Since last submission following information has been added: - patient medical history - stop dates of the events,event outcome - case seriousness was updated from hospitalization to medically significant - Narrative was updated accordingly. Company comment: 'Acutely anxious', 'paranoid', 'suicidal ideation', 'acute deterioration of mood' and 'irrational thinking' is assessed as unlisted according to the Novo Nordisk current CCDS information on Saxenda. The patient's underlying history of long-standing depression, anxiety, eating disorder along with the presence of the stressor (fall out with friend) could have contributed to the above said events. 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?
Depression			
Eating disorder			
Anxiety			

Medical History Product(s)	Start Date	End Date	Indications	Events
ZOLOFT			No adverse event	Product used for unknown indication

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

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

Case ID: 16014521

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: 20502265

Case Information:

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

FDA Rcvd Date: 22-Feb-2022 **Mfr Rcvd Date:** 26-May-2021 **Mfr Control #:** US-NOVOPROD-817380 **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		Yes	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 nurse practitioner as "depression with suicidal ideation(suicidal ideation)(depression)" with an unspecified onset date, and concerned a female patient, who was treated with Saxenda (liraglutide) from an unknown start date for an unknown indication. Medical history was not provided. A nurse practitioner reported that a patient, who was taking Saxenda, experienced depression with suicidal ideation. Saxenda was discontinued and the event recovered. Action taken to Saxenda was reported as Product discontinued. The outcome for the event "depression with suicidal ideation(suicidal ideation)(depression)" was Recovered. Batch number was requested upon follow-up. Company Comment: Suicidal ideation and depression are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Saxenda. Limited information as related to weight, BMI, Saxenda therapy 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.

Relevant Medical History:

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

Case ID: 20502265

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: 20502267

Case Information:

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

FDA Rcvd Date: 22-Feb-2022 **Mfr Rcvd Date:** 25-May-2021 **Mfr Control #:** US-NOVOPROD-816177 **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		1.8 Mg Milligram(S) /	Subcutaneous	1.8 mg	Product used for unknown indication		

#	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**

Suicidal ideation

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Physician as "suicidal thoughts(Suicidal ideation)" with an unspecified onset date, and concerned a Adult Female patient who was treated with Saxenda (liraglutide) from unknown start date for "drug use for unknown indication". Medical history was not provided. A patient receiving therapy with Saxenda experienced suicidal thoughts. Action taken to Saxenda was reported as Product discontinued due to AE. The outcome for the event "suicidal thoughts(Suicidal ideation)" was Recovered. Batch number requested in follow up. 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 suspect product therapy dates, medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluations precludes medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Case ID: 20502267

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: 20502322

Case Information:

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

FDA Rcvd Date: 22-Feb-2022 **Mfr Rcvd Date:** 23-Jul-2021 **Mfr Control #:** US-NOVOPROD-833662 **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		Yes	NA				NOVO NORDISK	

Event Information:

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

Suicidal ideation

Crying

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Medical Doctor as "suicidal ideation(Suicidal ideation)" with an unspecified onset date, "crying bouts(Crying)" with an unspecified onset date, and concerned an Adult Female patient who was treated with Saxenda (liraglutide) from unknown start date for "drug use for unknown indication". Medical history was not provided. A patient receiving therapy with Saxenda had crying bouts and suicidal ideation. Action taken to Saxenda was reported as Product discontinued. The outcome for the event "suicidal ideation(Suicidal ideation)" was Recovered. The outcome for the event "crying bouts(Crying)" was Recovered. Batch number requested in follow up. 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 suspect product therapy dates, medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluations precludes medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

Relevant Medical History:

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

Case ID: 20502322

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: 20882038

Case Information:

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

FDA Rcvd Date: 27-Jul-2022 **Mfr Rcvd Date:** 20-Jul-2022 **Mfr Control #:** BR-NOVOPROD-921593 **Application #:** 206321

Patient Information:

Age: 53 YR **Sex:** Male **Weight:** 138 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Saxenda		/	Unknown	3 mg			
2	Saxenda		/	Unknown	UNK	Obesity		

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

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Depression suicidal	
Furuncle	
Hunger	
Nausea	
Constipation	
Diarrhoea	

Event/Problem Narrative:

This serious Spontaneous case from BRAZIL was reported by a Physician as "Feeling depressive and have mild suicide thinking(Depression suicidal)" beginning on 2020, "appearance of boils on the arms(Boil on arm)" beginning on 2020, "Uncontrolled hungry during the night.(Hunger)" beginning on 2020, "nauseas

during morning(Nausea)" beginning on 2020, "bowel malfunction (constipation) and dry stools(Constipation)" beginning on 2020, "Diarrhea (two days)(Diarrhea)" beginning on 2020, and concerned a 53 Years old Male patient who was treated with Saxenda (liraglutide) from unknown start date for "Obesity", Patient's height: 172 cm Patient's weight: 138 kg Patient's BMI: 46.64683610. Current Condition: Obesity Family History: Obesity, leukemia, multiple myeloma, Hypertension Historical Drug: Atacand, Ablok, Pressat, Galvus Met, Glicazide, Alopurinol, Melatonin. Procedure: uncontrolled diet habits during the dinner Treatment included - BRINTELLIX(VORTIOXETINE HYDROBROMIDE) On an unknown date, the physician prescribed saxenda and on 05-OCT (unknown year), patient returned using saxenda and reporting the appetite was decreased. The medical conduct was keep the saxenda 3 mg dose. On an unknown date, in year 2020 the patient reported the appearance of boils on the arms which were considered an isolated episode and the doctor believes it has nothing to do with the use of Saxenda. Patient’s Intestine was already very problematic before the use of saxenda due to low water intake and poor diet. patient experienced nauseas during morning, bowel malfunction (constipation) and dry stools. Additionally, the patient was feeling depressive and had mild suicide thinking due to the social isolation of the pandemic and lack of physical activity in this period, it was just a mild and transient depressive condition. patient has returned to the doctor several times and is without depression. The patient stopped the saxenda use. The medical conduct was to immediately reintroduce saxenda and recommend the use of oral antiemetic drugs 30 minutes before the application. Also, advises fiber to his diet and to drink more water to improve bowel function. Prescribed the antibiotics(unspecified) and a procedure to solve the boils on the arms. It was also prescribed antidepressant drug Brintellix (vortioxetine). - Selective serotonin reuptake inhibitors. On 11-JAN-2022, the patient returned using the saxenda and antidepressant treatment, working out and assuming being less depressive. However, he reports to feels hungrier (uncontrolled)during the night. Patient was recommended ketogenic diet. On 17-MAr-2022, patient reports to feel more energy On an unknown date, the patient also experienced nauseas and two days diarrhea. Batch Number of Saxenda was requested. Action taken to Saxenda was reported as Drug discontinued temporarily. The outcome for the event "Feeling depressive and have mild suicide thinking(Depression suicidal)" was Unknown. The outcome for the event "appearance of boils on the arms(Boil on arm)" was Recovered. The outcome for the event "Uncontrolled hungry during the night.(Hunger)" was Unknown. The outcome for the event "nauseas during morning(Nausea)" was Unknown. The outcome for the event "bowel malfunction (constipation) and dry stools(Constipation)" was Recovered. The outcome for the event "Diarrhea (two days)(Diarrhea)" was Unknown. Since last submission the case has been updated with the following: Height was added Treatment drug was added Treatment for diarrhea and constipation was updated Events start date was added Causality was added Narrative was updated accordingly References included: Reference Type: E2B Company Number Reference ID#: BR-NOVOPROD-921593 Reference Notes: COMPANY COMMENT - The events, “depression suicidal”, "boil on arm", "hunger" are assessed as unlisted events and "nausea", "constipation", "diarrhea" are listed events according to the Novo Nordisk CCDS on Saxenda. As only limited information has been obtained so far, it is difficult to perform a thorough medical evaluation of the case. The following important information is lacking: patient’s health status prior to suspect drug therapy, medical history on mental health and environmental factors influencing suicide ideation, baseline laboratory and diagnostic tests results. The underlying obesity, concomitant medications and elderly age may be contributory. This single case report is not considered to change the current knowledge of the safety profile Saxenda.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Obesity			
Obesity			No
Leukaemia			No
Plasma cell myeloma			No
Hypertension			No
Inadequate diet			

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

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

Case ID: 20882038

ATACAND	Product used for unknown indication	No adverse event
ABLOK	Product used for unknown indication	No adverse event
PRESSAT	Product used for unknown indication	No adverse event
GALVUS MET	Product used for unknown indication	No adverse event
GLICLAZIDE	Product used for unknown indication	No adverse event
ALOPURINOL	Product used for unknown indication	No adverse event
MELATONIN	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	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: 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: 21933415

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** N **Country:** DK **Event Date:** 21-Jan-2023 **Outcomes:** HO , DS , OT **Application Type:**

FDA Rcvd Date: 31-Jan-2023 **Mfr Rcvd Date:** 21-Jan-2023 **Mfr Control #:** DK-NOVOPROD-1018173 **Application #:** 206321

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Saxenda		/		lowest dose again (dose not reported)		2022	
2	Saxenda		/		UNK			03-Aug-2022
3	Saxenda		/		UNK (dose increased)		2022	
4	Saxenda		/		lowest dose (dose not reported)	Overweight	May-2022	

#	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	
3	Saxenda		No	NA				NOVO NORDISK	
4	Saxenda		No	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Back pain	
Suicidal ideation	
Loss of consciousness	

Paralysis

Seizure

Anxiety

Feeling abnormal

Mood altered

Depressed mood

Decreased appetite

Nausea

Dry mouth

Dizziness

Fatigue

Event/Problem Narrative:

This serious Spontaneous case from DENMARK was reported by a Consumer as "back pain(Back pain)" with an unspecified onset date, "suicidal thoughts(Suicidal ideation)" with an unspecified onset date, "head was black(Blackout)" with an unspecified onset date, "feeling paralyzed in bed(Paralyzed)" with an unspecified onset date, "seizures(Seizures)" beginning on 21-JAN-2023, "anxiety(Anxiety)" with an unspecified onset date, "feels mentally bad(Feeling bad)" with an unspecified onset date, "changes in her mood(Mood change)" with an unspecified onset date, "depression/feeling overwhelming sad(Feeling sad)" with an unspecified onset date, "lack of appetite(Appetite lost)" with an unspecified onset date,"Nausea(Nausea)" with an unspecified onset date, "dry mouth(Dry mouth)" with an unspecified onset date, "dizziness(Dizziness)" with an unspecified onset date, "endlessly tired(Tired all the time)" with an unspecified onset date and concerned a 48 Years old Female patient who was treated with Saxenda (liraglutide) from MAY-2022 to 03-AUG-2022 for "overweight". Dosage Regimens: Saxenda: ??-MAY-2022 to Not Reported, ??-???-2022 to Not Reported, ??-???-2022 to Not Reported, Not Reported to 03-AUG-2022; Current Condition: overweight Procedure: diet. Treatment included - OXAZEPAM, SERTRALIN SERTRALINE On an unknown date in OCT-2021 the patient had some blood work done in relation to the metabolism, these showed some tests with slight fluctuations (not specified). On an unknown date patient's New blood tests were performed(not specified) no results provided Since an unknown date the patient had nausea, dry mouth, back pain and a little dizziness, but otherwise nothing. It was reported that patient tried massage to treat the back pain with no effect. On 06-JUL-2022 the patient needed a physiotherapist to get some treatment. The patient received 1 hour of treatment but back pain remained. The day after the treatment the patient still had back pain and experienced changes in her mood, and feels completely down, feel mentally super bad and experienced waves of anxiety and felt completely off course. The patient then suddenly felt everything in her head was "black" and experiences the ugliest thoughts of disaster. The patient was not able to get out of bed because of the back pain but also her mental state. On 08-JUL-2022 the patient received another physiotherapy treatment, and wéxplains to the physiotherapist about her mental state. It was reported that the physiotherapist did not think that the mental state was related to the back pain. The patient stopped taking Saxenda, had no appetite and was just lying in bed. On an unknown date the patient experienced feeling paralyzed in bed, sleeping, crying and being really scared of being alone suddenly tormented by suicidal thoughts. The pack pain then increased so the patient went to the hospital (hospitalization details not reported) where they put in a block in the back with effect after a few days on the back pain, but the patient was still overwhelmed with sadness, emptiness and the catastrophic thoughts. On 02-AUG-2022 the patient suddenly felt super bad mentally again. The patient again experienced, cannot get out of bed, cannot be alone, felt really bad mentally, felt like "losing" sanity. On 07-AUG-2022 after going home from vacation, the patient talks to a therapist after waking up in the morning and experiencing increasingly mentally unbalanced. It was reported that the patient had to call in sick at her job. On 29-AUG-2022 the patient has several blood tests(unspecified) performed at the doctors, that showed nothing. The patient also felt endlessness tired and cries most of the time and have to cancel all appointments as could not figure out

anything else but lying in bed. And thereby had to miss out on several planned events. The patient also had seen a specialist in relations to hormones, but nothing was found in any tests. On 21-JAN-2023 the patient still felt tires, but did not have any “black darkness” in her mind. On the same day the patient experienced some "shock"/dizziness "seizures" in brain. However not back to her ownself yet an was still on sick leave from work. The patient reported that she felt Saxenda "poisoned" her body. It was reported that the patient did not dare not contact the doctor at home, as the patient was afraid that they would "label" her as being "crazy”. The patient had never had contact with the psychiatry, and did not know of anything in this regard-and was usually just an ordinary positive person. Batch Number for Saxenda has been requested. Action taken to Saxenda was reported as Product discontinued. The outcome for the event "back pain(Back pain)" was Unknown. The outcome for the event "suicidal thoughts(Suicidal ideation)" was Unknown. The outcome for the event "head was black(Blackout)" was Not Reported. The outcome for the event "feeling paralyzed in bed(Paralyzed)" was Not Reported. The outcome for the event "seizures(Seizures)" was Not Reported. The outcome for the event "anxiety(Anxiety)" was Unknown. The outcome for the event "feels mentally bad(Feeling bad)" was Unknown. The outcome for the event "changes in her mood(Mood change)" was Not Reported. The outcome for the event "depression/feeling overwhelming sad(Feeling sad)" was Unknown. The outcome for the event "lack of appetite(Appetite lost)" was Unknown. The outcome for the event "Nausea(Nausea)" was Unknown. The outcome for the event "dry mouth(Dry mouth)" was Unknown. The outcome for the event "dizziness(Dizziness)" was Unknown. The outcome for the event "endlessly tired(Tired all the time)" was Not Recovered. COMPANY COMMENT - The events, “back pain”, "suicidal ideation", "paralyzed", "blackout", "seizures", "anxiety", "feeling bad", "mood change", "feeling sad" are assessed as unlisted and "appetite lost", "nausea", "dry mouth", "dizziness", "fatigue" are listed events according to the Novo Nordisk CCDS on Saxenda. As only limited information has been obtained so far, it is difficult to perform a thorough medical evaluation of the case. The following important information is lacking: event onset date and product start date (to assess the temporal relationship), patient’s health status prior to suspect drug therapy, medical history on risk factors, baseline laboratory and diagnostic tests results, and concomitant medications. The overweight of the patient may be contributory. 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?
Overweight			
Medical diet			

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

Relevant Laboratory Data:

Test Name	Result	Unit	Normal Low Range	Normal High Range	Info Avail
BLOOD TEST					Y
BLOOD TEST					Y
BLOOD TEST					Y

Concomitant Products:

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

Case ID: 21933415

#	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: 22054156

Case Information:

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

FDA Rcvd Date: 02-Mar-2023 **Mfr Rcvd Date:** 12-May-2022 **Mfr Control #:** US-NOVOPROD-919560 **Application #:** 206321

Patient Information:

Age: 26 YR **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		
2	Saxenda		1.2 Mg Milligram(S) /	Subcutaneous	1.2 mg			11-May-2022

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

Event Information:

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

Suicidal ideation

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Other Health Care Professional as "suicidal ideations(Suicidal ideation)" with an unspecified onset date, and concerned a 26 Years old Female patient who was treated with Saxenda (liraglutide) from unknown start date to 11-MAY-2022 for "Drug use for unknown indication". Historical Condition: suicidal ideations. Concomitant products included - LEXAPRO(ESCITALOPRAM OXALATE), ESTRADIOL A patient receiving therapy with Saxenda experienced suicidal ideations. Action taken to Saxenda was reported as Product discontinued due to AE. The outcome for the event "suicidal ideations(Suicidal ideation)" was Recovered. Batch number was requested in follow up. Company Comment: Suicidal ideation is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Saxenda. A medical history of suicidal ideations suggests an alternative etiology. In addition, the US package insert for concomitant medication Lexapro lists suicidal ideation as a side effect observed on post-marketing period. Limited information as related to event onset date, family/social history, and laboratory/diagnostic evaluations limits further medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

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

Case ID: 22054156

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Suicidal ideation			

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	/		UNK	Product used for unknown indication			
2	ESTRADIOL	/		UNK	Product used for unknown indication			

Reporter Source:

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

Literature Text: