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

Date - T me: 9-Ju -2023 5: 6:54 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:

11432595	11625182	13742948	15653875
18960812	19893595	19982084	20502096
20981958	21860708	22054077	22054115

Total Cases: 12

Total number of Inactive cases: *0

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

Case ID: 11432595

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** US **Event Date:** Aug-2015 **Outcomes:** DE **Application Type:**

FDA Rcvd Date: 28-Aug-2015 **Mfr Rcvd Date:** 20-Aug-2015 **Mfr Control #:** US-NOVOPROD-461651 **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		Product used for unknown indication		

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

Event Information:

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

Completed suicide

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Consumer via company representative as "suicide by hanging" beginning on (b)(6)**, and concerned a Female patient in her 50's who was treated with Saxenda (liraglutide) from unknown start date and ongoing due to "product used for unknown indication". Medical history included depression and previous unsuccessful suicide attempts. A patient's neighbor reported that the patient committed suicide by hanging herself while taking Saxenda in (b)(6)********** ********. The patient's body was found by her boyfriend. Action taken to Saxenda was reported as No Change. On(b)(6)*** the outcome for the event "suicide by hanging" was Fatal. The reporter declined to give their contact information. Health care professional information not provided. The batch number and product return were requested but were not available. Company Comment: Completed suicide is unlisted according to the Novo Nordisk CCDS for Saxenda. The patient's medical history of previous unsuccessful suicide attempts and depression provides an alternative explanation for the event. This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

Relevant Medical History:

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

Case ID: 11432595

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Depression			Yes
Suicide attempt			

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: 11625182

Case Information:

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

FDA Rcvd Date: 13-Oct-2015 **Mfr Rcvd Date:** 17-Sep-2015 **Mfr Control #:** US-NOVOPROD-464885 **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		Weight control		

#	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

Event/Problem Narrative:

This serious spontaneous case from the United States was reported by a nurse practitioner via a company representative as "suicidal thoughts" with an unspecified onset date, and concerned a female patient who was treated with Saxenda (liraglutide) from an unknown start date due to "weight control". Medical history was not provided. A nurse practitioner reported via a company representative that a patient experienced suicidal thoughts while on Saxenda. The product was discontinued and the patient recovered from the event. Action taken to Saxenda was reported as product discontinued. The outcome for the event "suicidal thoughts" was recovered. Comment: Company Comment: The event of suicidal ideation is unlisted according to the Novo Nordisk company core data sheet (CCDS) for Saxenda. Lack of information as related to suspect product therapy dates, medical history, social history (e.g. alcohol use, substance abuse, etc.), psychosocial circumstance, concomitant medications, and 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: 11625182

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: 13742948

Case Information:

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

FDA Rcvd Date: 11-Jul-2017 **Mfr Rcvd Date:** 15-May-2017 **Mfr Control #:** US-NOVOPROD-546316 **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		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 general physician as "suicidal ideation" with an unspecified onset date, and concerned a Female patient who was treated with Saxenda (liraglutide) from an unknown start date due to an unknown indication. Medical history was not provided. On an unspecified date, a patient receiving treatment with Saxenda experienced suicidal ideation. The physician stated the event began when Saxenda was started. In 2016, the patient was hospitalized twice for suicidal ideation. On an unspecified date, Saxenda was discontinued and the patient recovered. Action taken to Saxenda was reported as Product discontinued. The outcome for the event "suicidal ideation" was Recovered. A causal relationship between the event and therapy with Saxenda was not reported. Company Comment: "Suicidal ideation" is assessed as unlisted according to the Novo Nordisk CCDS for Saxenda. The temporal relationship cannot be assessed in the absence of the therapy and event onset dates. 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 Saxenda therapy, indication for use, medical history (e.g., depression, suicide threats or attempts, unusual changes in mood or behavior, drug or alcohol abuse), assessment of current medical conditions specifically psychiatric evaluation, negative change in life circumstances, family history of mental disorder, therapy and event onset dates, and concomitant medications. 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: 13742948

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: 15653875

Case Information:

Case Type : Direct **eSub:** N **HP:** Y **Country:** US **Event Date:** 23-Nov-2018 **Outcomes:** LT , HO , OT **Application Type:**

FDA Rcvd Date: 24-Nov-2018 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2018-107358 **Application #:**

Patient Information:

Age: 53 YR **Sex:** Male **Weight:** 102.9 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	LIRAGLUTIDE (SAXENDA) PEN		1.8 Mg Milligram(S) / QD			Diabetes-II and obesity. OBESITY	01-Aug-2018	24-Nov-2018

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	LIRAGLUTIDE (SAXENDA) PEN		Not Applicable	Not Applicable			00169 2800 15	NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Depression	NA
Suicide attempt	NA
Drug monitoring procedure not performed	NA

Event/Problem Narrative:

Describe Event, Problem, or Product Use Error: Patient has h/o depression, and PTSD which appears to be long standing. He recently has had worsening of depression and was admitted for a suicide attempt, OD of oxycodone and sertraline (old Rx for sertraline). Patient has more recently been taking escitalopram 20mg daily for depression and seeing a counselor. I don't know how long he's been using liraglutide, but I noticed that he/s been taking 1.8mg sq daily since at least Aug. 2018. I noticed that liraglutide has a warning to monitor for worsening of depression or suicidal behavior. A study of obese patients found an incidence of 0.3% in liraglutide patients versus 0.1% in placebo patients.

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

Case ID: 15653875

Relevant Medical History:

PTSD, depression (long standing), also wife states marital problems.

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Basic Details

Company Unit	CDER-CTU	Originating Account	FAERS
Source Medium	MWO (Drug)	Source Form Type	E2B XML 3500
Priority	Routine		
FDA Received Date	24-Nov-2018	CTU Received Date	24-Nov-2018
CTU Triage Date		CTU Data Entry Date	
Report Type	Spontaneous	Report Classification	Drug
Assign To	User		
User/Group			
Forward to Department	☑ CDER (CDER-OSE-RSS-CTU@fda.hhs.gov) (E2B)		
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	53 Year(s)
	Date of Birth	
	Sex	Male
	Weight	102.9 kg(s)
	Ethnicity (Check single best answer)	Hispanic/Latino
	Race (Check all that apply)	☐ Asian ☐ American Indian or Alaskan Native ☐ Black or African American ☑ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

	Check all that apply	☑ Adverse Event ☐ Product Use 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 (Important Medical Events) ☐ Disability/Permanent Damage ☐ Congenital Anomaly/Birth Defect ☐ Required Intervention to Prevent Permanent Impairment/Damage (Devices)
	Date of Death	

Date of Event	23-Nov-2018
Date of this Report	24-Nov-2018

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: Patient has h/o depression, and PTSD which appears to be long standing. He recently has had worsening of depression and was admitted for a suicide attempt, OD of oxycodone and sertraline (old Rx for sertraline). Patient has more recently been taking escitalopram 20mg daily for depression and seeing a counselor. I don't know how long he's been using liraglutide, but I noticed that he/s been taking 1.8mg sq daily since at least Aug. 2018. I noticed that liraglutide has a warning to monitor for worsening of depression or suicidal behavior. A study of obese patients found an incidence of 0.3% in liraglutide patients versus 0.1% in placebo patients.

Relevant Tests/Laboratory Data, Including Dates

Other Relevant History, Including Preexisting Medical Conditions

PTSD, depression (long standing), also wife states marital problems.

C. PRODUCT AVAILABILITY

Product Available for Evaluation? (Do not send product to FDA)	No
Returned to Manufacturer on	

D. PRODUCT(S) 1 of 1

Suspect	Yes		
Primary?	Yes		
Product Type	Drug/Biologic		
Product Name	Liraglutide (Saxenda) Pen		
Strength	1.8 mg milligram(s)	If Other	
Manufacturer/Compounder	Novo Nordisk		
NDC# or Unique ID	00169 2800 15		
Is the Product Compounded?			
Is the Product Over-the-Counter?			
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	1.8 mg milligram(s)	If Other	
Frequency	Daily	If Other	
Route		If Other	
Dosage Form			
Therapy Start Date	01-Aug-2018		
Therapy End Date	24-Nov-2018		
Therapy Duration		If Other	

Therapy Ongoing ?	
Lot Number	
Expiration Date	24-Nov-2019

Diagnosis or Reason for Use (indication) 1 of 1

Diabetes-II and obesity.

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 ☐ Lay User/Patient ☐ 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	

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	(b) (6)		
	Address			
	City			
	State/Province/Region			
	Country			
	ZIP/Postal Code			
	Phone			
	Email			
	Fax			
	Reporter Organization			
	Department			
	Reporter Speciality			
	Health Professional?	Yes		
	Occupation	Pharmacist	If Other	
	Also Reported to	☐ Manufacturer/Compounder ☐ User Facility ☐ Distributor/Importer		
	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: 18960812

Case Information:

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

FDA Rcvd Date: 02-Mar-2021 **Mfr Rcvd Date:** 01-Jul-2020 **Mfr Control #:** US-NOVOPROD-739659 **Application #:** 206321

Patient Information:

Age: 38 YR **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) / QD	Subcutaneous	1.8 mg, qd	Obesity	Apr-2017	May-2017

#	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

Depression

Event/Problem Narrative:

This serious spontaneous case from the UNITED STATES was reported by a medical doctor as "suicidal(Suicidal ideation)" beginning in APR-2017, "depression(Depression)" beginning in APR-2017, and concerned a 38 year old female patient, who was treated with Saxenda (liraglutide) from APR-2017 to MAY-2017 for severe morbid obesity. Current Condition: severe morbid obesity. A physician reported that a patient, who was receiving therapy with Saxenda 1.8 mg daily, experienced depression with symptoms of felt isolated and felt family disliked her and also felt suicidal in APR-2017. The patient did not receive treatment for the events. Action taken to Saxenda was reported as Product discontinued due to AE. In MAY-2017 the outcome for the event "suicidal(Suicidal ideation)" was Recovered. In MAY-2017 the outcome for the event "depression(Depression)" was Recovered. The physician felt that the events were related to therapy with Saxenda. On 20-AUG-2020, this case was reclassified from non-serious to serious as upon follow-up the physician reported patient was suicidal. 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 medical history aside from morbid obesity, 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.

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

Case ID: 18960812

Relevant Medical History:

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

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

Relevant Laboratory Data:

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

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: 19893595

Case Information:

Case Type : Non-Expedited **eSub:** Y **HP:** N **Country:** US **Event Date:** Jun-2021 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 20-Dec-2021 **Mfr Rcvd Date:** 20-Sep-2021 **Mfr Control #:** US-NOVOPROD-851090 **Application #:** 215256

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Wegovy		0.25 Mg Milligram(S) / /WK	Subcutaneous	0.25 mg, qw	Weight decreased	Jun-2021	Jul-2021
2	Wegovy		0.5 Mg Milligram(S) / / WK	Subcutaneous	0.5 mg, qw		Jul-2021	Aug-2021

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

Event Information:

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

Event/Problem Narrative:

This serious spontaneous case from the UNITED STATES was reported by a consumer as "suicidal ideation(Suicidal ideation)" beginning in JUN-2021, "whole lower body got numb(Numbness)" beginning in AUG-2021, "worsening depression(Depression worsened)" beginning in JUN-2021, and concerned an adult female patient, who was treated with Wegovy (semaglutide) from JUN-2021 to AUG-2021 for weight loss. Current Condition: depression Historical Drug: Saxenda (liraglutide). A patient, who was receiving therapy with Wegovy 0.25 mg, experienced worsening depression and suicidal ideation in JUN-2021. In AUG-2021, while on Wegovy 0.5 mg, the patient's whole lower body got numb for a minute or two on two separate occasions. Action taken to Wegovy was reported as Product

Case ID: 19893595

discontinued due to AE. On 18-AUG-2021 the outcome for the event "suicidal ideation(Suicidal ideation)" was Recovered. On 18-AUG-2021 the outcome for the event "worsening depression(Depression worsened)" was Recovered. In AUG-2021 the outcome for the event "whole lower body got numb(Numbness)" was Recovered. The patient felt that the events were possibly related to therapy with Wegovy. Patient declined to provide any further information including product batch number. Ths case is linked to non-serious Argus case 851092. Company Comment: Suicidal ideation and depression (worsened) are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Wegovy. A medical history of depression which may be associated with an increased risk for suicidal ideation considered a confounder for reported suicidal ideation and depression worsened. Limited information as related to concomitant medications, family/social history, and laboratory/diagnostic evaluations limits further medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Depression	Mar-2021		Yes

Medical History Product(s)	Start Date	End Date	Indications	Events
SAXENDA	Mar-2021	Jun-2021	Weight decreased	Depression

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: 19982084

Case Information:

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

FDA Rcvd Date: 20-Dec-2021 **Mfr Rcvd Date:** 13-Oct-2021 **Mfr Control #:** US-NOVOPROD-858578 **Application #:** 215256

Patient Information:

Age: 55 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Wegovy 2.4 mg		2.4 Mg Milligram(S) /	Subcutaneous	2.4 mg	Product used for unknown indication		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Wegovy 2.4 mg		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 ideations(Suicidal ideation)" with an unspecified onset date, and concerned a 55 Year old Female patient who was treated with Wegovy 2.4 mg (SEMAGLUTIDE) from unknown start date for "drug use for unknown indication". Medical history was not provided. A patient receiving therapy with Wegovy experienced suicidal ideations after first dose of 2.4 mg. Wegovy was discontinued and the event recovered. Action taken to Wegovy 2.4 mg was reported as Product discontinued. The outcome for the event "Suicidal ideations(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 Wegovy. Limited information as related to suspect product therapy dates and indication for use, 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: 19982084

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
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: 20502096

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-Jan-2021 **Mfr Control #:** US-NOVOPROD-784196 **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		NA	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 as "suicidal ideations(suicidal ideation)" 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 experienced suicidal ideations. The patient was also taking 4 other unspecified medications. The physician assistant discontinued use of all the patient's medications. Action taken to Saxenda was reported as Product discontinued due to AE. The outcome for the event "suicidal ideations(suicidal ideation)" was Unknown. 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: 20502096

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: 20981958

Case Information:

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

FDA Rcvd Date: 20-Jun-2022 **Mfr Rcvd Date:** 15-Apr-2022 **Mfr Control #:** US-NOVOPROD-912706 **Application #:** 215256

Patient Information:

Age: 21 YR **Sex:** Male **Weight:**

Suspect Products:

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

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Wegovy		NA	NA				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 consumer via social media as "suicidal thoughts(Suicidal ideation)" with an unspecified onset date, and concerned a 21 year-old male patient who was treated with Wegovy (semaglutide) from an unknown start date for an unknown indication. Medical history was not provided. A patient, receiving therapy with Wegovy, experienced suicidal thoughts and discontinued Wegovy. Action taken to Wegovy was reported as Product discontinued due to AE. The outcome for the event "suicidal thoughts(Suicidal ideation)" was Not Reported. Batch number will not be provided. Company Comment: Suicidal ideation is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Wegovy. 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: 20981958

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: 21860708

Case Information:

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

FDA Rcvd Date: 13-Jan-2023 **Mfr Rcvd Date:** 27-Oct-2022 **Mfr Control #:** US-NOVOPROD-975057 **Application #:** 215256

Patient Information:

Age: **Sex:** Female **Weight:** 72.562 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Wegovy 2.4 mg		2.4 Mg Milligram(S) / WK / Subcutaneous		2.4 mg, qw	Product used for unknown indication		

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Wegovy 2.4 mg		No	NA				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 with frequent thoughts about suicide(Suicidal ideation)" with an unspecified onset date, and concerned a female patient who was treated with Wegovy 2.4 mg (SEMAGLUTIDE) from unknown start date for an unknown indication. Patient's weight: 72.6 kg Medical history was not provided. A patient, who was receiving therapy with Wegovy 2.4 mg, had cut all alcohol out of her life at the same time that her weight dropped from starting weight of 160 pounds to 105 pounds. Later, the patient was suicidal and was having frequent thoughts about suicide. As treatment, the product was discontinued temporarily. Action taken to Wegovy 2.4 mg was reported as Drug discontinued temporarily. The outcome for the event "suicidal with frequent thoughts about suicide(Suicidal ideation)" was Not 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 Wegovy. Limited information as related to age, Wegovy therapy dates, event onset date, medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluations limits medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

Relevant Medical History:

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

Case ID: 21860708

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
BODY MASS INDEX	20	kg/m2			N
WEIGHT					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: 22054077

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:** 09-Aug-2022 **Mfr Control #:** US-NOVOPROD-948045 **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		NA	NA				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 thoughts(Suicidal ideation)" with an unspecified onset date, and concerned a 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 after starting on Saxenda. Action taken to Saxenda was reported as Product discontinued. The outcome for the event "Suicidal thoughts(Suicidal ideation)" was Not Reported. 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. Limited information as related to Ozempic therapy dates, event onset date, medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluations limits medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Case ID: 22054077

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: 22054115

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:** 20-Jul-2022 **Mfr Control #:** US-NOVOPROD-942724 **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 behaviour

Event/Problem Narrative:

This serious spontaneous case from the UNITED STATES was reported by an emergency medical technician via a company representative as "suicidal(Suicidal behavior)" 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. An emergency medical technician reported that a patient, who was receiving therapy with Saxenda, was suicidal. Action taken to Saxenda was reported as Product discontinued due to AE. The outcome for the event "suicidal(Suicidal behavior)" was Recovered. Product batch number was requested. Company Comment: Suicidal behavior is assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Saxenda. Limited information as related to Saxenda therapy dates, event onset date, medical history, concomitant medications, family/social history, and laboratory/diagnostic evaluations limits medical assessment. This single case report is not considered to change the current knowledge of the safety profile of the product.

Relevant Medical History:

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

Case ID: 22054115

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: