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

Date - T me: 09-Aug-2023 2:02:52 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:

16013385	16072382	16944171	21008159
21626703	21719396	21800949	22107520
22118110	22128240		

Total Cases: 10

Total number of Inactive cases: *0

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

Case ID: 16013385

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** US **Event Date:** 13-Aug-2018 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 27-Feb-2019 **Mfr Rcvd Date:** 15-Aug-2018 **Mfr Control #:** US-NOVOPROD-617240 **Application #:** 206321

Patient Information:

Age: 64 YR **Sex:** Male **Weight:** 142.4 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Saxenda		/	Subcutaneous	UNK	Weight decreased	31-Jul-2018	Aug-2018
2	Saxenda		1.2 Mg Milligram(S) / QD	Subcutaneous	1.2 mg, qd	Obesity	Aug-2018	17-Aug-2018

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Saxenda	13 Day	Yes	NA	UNKNOWN			NOVO NORDISK	
2	Saxenda	13 Day	Yes	NA	UNKNOWN			NOVO NORDISK	

Event Information:

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

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a General physician as "suicidal ideation" beginning on 13-AUG-2018, "Depression" beginning on 13-AUG-2018, "Abdominal pain" beginning on 13-AUG-2018, "Fatigue" beginning on 13-AUG-2018, and concerned a 64 Years old Male patient who was treated with Saxenda (liraglutide) from 31-JUL-2018 to 17-AUG-2018 for "Weight loss due to Obesity". Patient's height: 182.9 cm Patient's weight: 142.4 kg

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

Case ID: 16013385

Patient's BMI: 42.57. Medical history included obesity, pulmonary embolism, shortness of breath, hypoxia. Historical drugs included adipex Concomitant products included - flexeril(cyclobenzaprine hydrochloride), valium(diazepam), prozac(fluoxetine hydrochloride), neurontin(gabapentin), norco(hydrocodone bitartrate, paracetamol), xalatan(latanoprost), prilosec(omeprazole), DHEA(prasterone), pravachol(pravastatin sodium), cholecalciferol, coumadin(warfarin sodium) On 13-AUG-2018, a patient who was on the 1.2mg dose of Saxenda in the second week of therapy developed depression along with suicidal ideation. The patient additionally experienced abdominal pain and fatigue. On 17-AUG-2018, the patient discontinued taking Saxenda. The patient recovered from the suicidal ideation. Action taken to Saxenda was reported as Product discontinued. On AUG-2018 the outcome for the event "suicidal ideation" was Recovered. The outcome for the event "Depression" was Not Reported. The outcome for the event "Abdominal pain" was Not Reported. The outcome for the event "Fatigue" was Not Reported. The physician felt the event of "suicidal ideation" was related to the use of Saxenda. Product batch was requested but not provided. Since the last time this case was submitted the following has been updated: -New events of abdominal pain, fatigue and depression -Reporter causality for event of suicidal ideation -Onset date for suicidal ideation -Saxenda indication added; stop date updated for Saxenda -Patient height, weight and date of birth added -Concomitant medications added -Medical history updated -Lab data updated -Narrative updated accordingly -Company comment updated Company Comment: "Suicidal ideation" and "depression" are assessed as unlisted 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 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, and family history of mental disorder. This single case report is not considered to change the current knowledge of the safety profile of Saxenda.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Obesity			Yes
Pulmonary embolism			
Dyspnoea			
Hypoxia			

Medical History Product(s)	Start Date	End Date	Indications	Events
ADIPEX /00131701/	Apr-2018	2018	Obesity	

Relevant Laboratory Data:

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

Concomitant Products:

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

Case ID: 16013385

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	FLEXERIL /00428402/	10 Mg Milligram(S) / TID	Oral	10 mg, tid as needed	Product used for unknown indication			
2	VALIUM	5 Mg Milligram(S) / BID	Oral	5 mg, bid as needed	Product used for unknown indication			
3	PROZAC	80 Mg Milligram(S) / QD	Oral	80 mg, qd	Product used for unknown indication			
4	NEURONTIN	1200 Mg Milligram(S) / TID	Oral	1200 mg, tid	Product used for unknown indication			
5	NORCO	1 Dosage Form /	Oral	1 Tab (10mg/325mg) q6h as needed	Product used for unknown indication			
6	XALATAN	1 Gtt Drop(S) / QD	Ophthalmic	1 Gtt, qd into both eyes at bedtime	Product used for unknown indication			
7	PRILOSEC /00661201/	20 Mg Milligram(S) / QD	Oral	20 mg, qd at bedtime	Product used for unknown indication			
8	DHEA	15 Mg Milligram(S) / QD	Oral	15 mg, qd	Product used for unknown indication			
9	PRAVACHOL	20 Mg Milligram(S) / QD	Oral	20 mg, qd	Product used for unknown indication			
10	CHOLECALCIFEROL	5000 Dosage Form / QD	Oral	5000 U, qd	Product used for unknown indication			
11	COUMADIN	5 Mg Milligram(S) / QD	Oral	5 mg, qd	Product used for unknown indication			

Reporter Source:

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

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

Case ID: 16013385

Literature Text:

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

Case ID: 16072382

Case Information:

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

FDA Rcvd Date: 14-Mar-2019 **Mfr Rcvd Date:** 07-Mar-2019 **Mfr Control #:** BR-NOVOPROD-651658 **Application #:** 206321

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Saxenda		/	Unknown	0.6 mg	Overweight		
2	Saxenda		/	Unknown	UNK			
3	Saxenda		/	Unknown	1.8 mg			

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

Event Information:

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

Event/Problem Narrative:

This serious spontaneous case from BRAZIL was reported by a Physician as "suicidal thinks" with an unspecified onset date, "mental confusion (feeling lost on the time and space)" with an unspecified onset date, and concerned a Male patient(age not reported) who was treated with Saxenda (liraglutide) from unknown start date due to "overweight", Patient's height and body mass index were not reported. Medical history included Major depression, Overweight, Anxiety disorder and Fybromyalgia. Concomitant products included - lyrica(pregabalin), cebrilin(paroxetine hydrochloride), stavigile(modafinil) On an unknown date patient complained about suicidal thinks and became totally mental confused (feeling lost on the time and space). Batch number requested. Action taken to Saxenda was Not reported.

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

Case ID: 16072382

The outcome for the event "suicidal thinks" was Unknown. The outcome for the event "mental confusion (feeling lost on the time and space)" was Unknown. Company comment: Suicidal ideation and mental confusion is assessed as unlisted according to the Novo Nordisk CCDS for Saxenda. The circumstances and situations that has led to the suicidal ideation and confusion is not known. However, the underlying history of major depression and anxiety disorder could have contributed to the above said events. The concomitant medication Paroxetine hydrochloride has also been associated with suicidal ideation and behaviour. 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?
Major depression			Yes
Anxiety disorder			Yes
Fibromyalgia			Yes
Overweight			Yes

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

Relevant Laboratory Data:

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	LYRICA	/		UNK				
2	CEBRILIN	/		UNK				
3	STAVIGILE	/						

Reporter Source:

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

Case ID: 16072382

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: 16944171

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** **Country:** US **Event Date:** 07-Oct-2019 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 22-Oct-2019 **Mfr Rcvd Date:** 10-Oct-2019 **Mfr Control #:** US-NOVOPROD-690762 **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	Weight decreased		07-Oct-2019

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

Event Information:

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

Self-injurious ideation

Abnormal behaviour

Ill-defined disorder

Event/Problem Narrative:

This serious Spontaneous case from the UNITED STATES was reported by a Consumer as "urge to drive off the road(Thoughts of self harm)" beginning on 07-OCT-2019, "changes in behavior(Abnormal behavior)" with an unspecified onset date, "several unspecified health issues(ill-defined disorder)" with an unspecified onset date, and concerned a Female patient who was treated with Saxenda (liraglutide) from unknown start date to 07-OCT-2019 for "Weight Loss". Medical history was not provided. A patient receiving therapy with Saxenda for weight loss was extremely happy with the results. However, the patient experienced changes in behavior beginning on an unspecified date. On 07-OCT-2019, the patient had the urge to drive off the road, but did not do so. The patient stated she had "several health issues". The patient did not feel the events of "changes in behavior" and "urge to drive off the road" were related to Saxenda therapy. Action taken to Saxenda was reported as Product discontinued due to AE. On OCT-2019 the outcome for the event "urge to drive off the road(Thoughts of self harm)" was Recovered. On OCT-2019 the outcome for the event "changes in behavior(Abnormal behavior)" was Recovered. The outcome for the event "several unspecified health issues(ill-defined disorder)" was Not Reported. Batch number not available. Company Comment: Self-injurious ideation and Abnormal behavior

are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Saxenda. Limited information as related to the date of events onset in relation to the product, 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?

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: 21008159

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** N **Country:** ES **Event Date:** 09-May-2022 **Outcomes:** LT , OT **Application Type:**

FDA Rcvd Date: 27-Jun-2022 **Mfr Rcvd Date:** 14-Jun-2022 **Mfr Control #:** ES-NOVOPROD-929108 **Application #:** 213051

Patient Information:

Age: 56 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Rybelsus 3 mg		3 Mg Milligram(S) / QD	Oral	3 mg, qd	Weight control	09-May-2022	06-Jun-2022

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

Event Information:

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

Event/Problem Narrative:

This serious Spontaneous case from SPAIN was reported by a Consumer as "suicidal thoughts(Suicidal ideation)" beginning on 13-MAY-2022, "insomnia(Insomnia)" beginning on 13-MAY-2022, "anxiety(Anxiety)" beginning on 13-MAY-2022, "off label use (Rybelsus for weight loss) (Off label use in unapproved indication)" beginning on 09-MAY-2022, and concerned a 56 Years old Female patient who was treated with Rybelsus 3 mg (SEMAGLUTIDE) from 09-MAY-2022 to 06-JUN-2022 for "weight loss", Patient's height,weight and Body mass index was not reported. Dosage Regimens: Rybelsus 3 mg: 09-MAY-2022 to 06-JUN-2022; Medical history was not provided. Concomitant products included - ESCITALOPRAM On 09-MAY-2022, the patient started usinf Rybulsus for weight loss.On 13-MAY-2022, the patient had Suicidal ideation, Insomnia, Anxiety. On 06-Jun-2022, the patient recovered from the events. Batch Number

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

Case ID: 21008159

Rybelsus 3 mg was requested. Action taken to Rybelsus 3 mg was reported as Product discontinued due to Adverse Event. On 06-JUN-2022 the outcome for the event "suicidal thoughts(Suicidal ideation)" was Recovered. On 06-JUN-2022 the outcome for the event "insomnia(Insomnia)" was Recovered. On 06-JUN-2022 the outcome for the event "anxiety(Anxiety)" was Recovered. On 06-JUN-2022 the outcome for the event "off label use (Rybelsus for weight loss) (Off label use in unapproved indication)" was Recovered. Company comment: 'Suicidal ideation' (life threatening), 'Insomnia' and 'Anxiety' are assessed as unlisted events according to Novo Nordisk current CCDS on Rybelsus. Information on detailed clinical course of events, concomitant medications (SSRIs, benzodiazepines, etc.), complete medical history (previous history of similar episode, treatment with sleep medications, etc.), family history, social or environmental circumstances and final diagnosis will aid in comprehensive assessment of the case. This single case report is not considered to change the current knowledge of the safety profile of Rybelsus.

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
1	ESCITALOPRAM	/	Unknown	UNK	Product used for unknown indication			

Reporter Source:

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

Literature Text:

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

Case ID: 21626703

Case Information:

Case Type : Expedited (15-Day) **eSub:** Y **HP:** Y **Country:** PT **Event Date:** 05-Nov-2022 **Outcomes:** HO , OT **Application Type:**

FDA Rcvd Date: 30-Dec-2022 **Mfr Rcvd Date:** 21-Dec-2022 **Mfr Control #:** PT-NOVOPROD-980058 **Application #:** 209637

Patient Information:

Age: 48 YR **Sex:** Female **Weight:** 61 KG

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic 1.0 mg		/		1.5 mg	Weight control	05-Nov-2022	05-Nov-2022

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic 1.0 mg	3 Day	Yes	NA				NOVO NORDISK	

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicidal ideation	
Psychotic disorder	
Hepatitis toxic	
Headache	
Palpitations	
Nausea	
Vomiting	
Dizziness	
Product use in unapproved indication	
Inappropriate schedule of product administration	
Prescription drug used without a prescription	

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

Case ID: 21626703

Event/Problem Narrative:

This serious Spontaneous case from PORTUGAL was reported by a Pharmacist as "Suicidal ideation(Suicidal ideation)" beginning on 08-NOV-2022, "psychotic condition - feelings of sadness and anxiety(Psychotic disorder)" beginning on 08-NOV-2022, "Hepatitis toxic(Hepatitis toxic)" beginning on 08-NOV-2022, "Headache (pressure in the head)(Headache)" beginning on 05-NOV-2022, "palpitations(Palpitations)" beginning on 05-NOV-2022, "Nausea(Nausea)" beginning on 05-NOV-2022, "Vomiting(Vomiting)" beginning on 05-NOV-2022, "Dizziness(Dizziness)" beginning on 05-NOV-2022, "ozempic used for weight loss(Product use in unapproved indication)" beginning on 05-NOV-2022 "ozempic used without titration(Inappropriate schedule of product administration)" beginning on 05-NOV-2022, patient did not have a medical prescription for Ozempic (Prescription drug used without a prescription)" beginning on 05-NOV-2022 and concerned a 48 Years old Female patient who was treated with Ozempic 1.0 mg (SEMAGLUTIDE) from 05-NOV-2022 to 05-NOV-2022 for "weight loss", Patient's height: 167 cm Patient's weight: 61 kg Patient's BMI: 21.87242280. Dosage Regimens: Ozempic 1.0 mg: 05-NOV-2022 to 05-NOV-2022; Current condition: Gilbert's Syndrome Concomitant products included - SEDOXIL(MEXAZOLAM) On (b)(6)*****, patient without prescription administered ozempic in the aim of weight loss and without any titration at 1.5 mg dose and experienced nausea, Headache (pressure in head) and Palpitation and was admitted to the emergency room. The patient also experienced vomiting and dizziness. On (b)(6)*****, patient had psychotic condition with feelings of sadness and anxiety, suicidal thoughts (negative thoughts with depressed mood), and toxic hepatitis with lab values Alanine aminotransferase (ALT) 508 U/L, Aspartate aminotransferase (AST) 123 U/L, Bilirubin direct 0.45 mg/dL, Alkaline phosphatase 55 U/L, Bilirubin total 3.10 mg/dL and Gamma glutamyl transpeptidase 54 U/L and was hospitalized (admitted for observation and not given any treatment) on the same day due to these events with no improvements except for the hepatic enzymatic values. In the hospital, the patient was only in Internal Medicine care. Further referral to the general and family practice. Refused help from a psychiatrist during hospitalization. On unknown date patient performed abdominal ultrasound and results were not reported. On unknown date patient performed Serology test and results found to be negative for Anticorpo anti-SS-A, SS-B, RNP, Sm, SCL-70, PM-Scl-, Centromero, Histonas, Nucleossoma, PCNA and Jo-1. On (b)(6)*****, the patient was discharged from the hospital. On 22-DEC-2022, patient lab findings reported as Alanine aminotransferase (ALT) 39 U/L, Albumin globulin ratio 1.93, Alpha 1 globulin 3.2 %, Alpha 2 globulin 6.3 %, Aspartate aminotransferase (AST) 9 U/L, Beta 2 globulin 3.6 %, Bilirubin direct 0.27 mg/dL, Albumin 65.9 %, Alkaline phosphatase 50 U/L, Bilirubin total 1.64 mg/dL, Lactate dehydrogenase 124 U/L, Gamma glutamyl transpeptidase 25 U/L, Gamma globulin 15.9 % and Serum total protein 7 g/dL. Batch Number of Ozempic 1.0 mg has been requested Action taken to Ozempic 1.0 mg was reported as Product discontinued due to AE. The outcome for the event "Suicidal ideation(Suicidal ideation)" was Recovering/resolving. The outcome for the event "psychotic condition - feelings of sadness and anxiety(Psychotic disorder)" was Recovering/resolving. The outcome for the event "Hepatitis toxic(Hepatitis toxic)" was Recovering/resolving. The outcome for the event "Headache (pressure in the head)(Headache)" was Recovering/resolving. The outcome for the event "palpitations(Palpitations)" was Recovering/resolving. The outcome for the event "Nausea(Nausea)" was Recovering/resolving. The outcome for the event "Vomiting(Vomiting)" was Not Reported. The outcome for the event "Dizziness(Dizziness)" was Not Reported. On (b)(6)***** the outcome for the event "ozempic used for weight loss(Product use in unapproved indication)" was Recovered. On (b)(6)***** the outcome for the event " ozempic used without titration (Inappropriate schedule of product administration)" was Recovered. On (b)(6)***** the outcome for the event " patient did not have a medical prescription for Ozempic (Prescription drug used without a prescription)" was Recovered. Since last submission the case has been updated with the following: - Medical history added - All lab data updated. - Suspect product indication added. - New concomitant medication SEDOXIL added. -Outcome of event hepatitis toxic updated -Dechallenge for hepatitis toxic updated - Event Head pressure updated to Headache. - New events vomiting, Dizziness, Product use in unapproved indication, Inappropriate schedule of product administration and Prescription drug used without a prescription added - Narrative updated accordingly. Company Comment: "Suicidal ideation", "Psychotic disorder", "Hepatitis toxic", "Headache", "Palpitations" are assessed as unlisted and "Nausea", "Vomiting", "Dizziness" as listed according to current NovoNordisk CCDS information on Ozempic. Information on relevant medical history like previous episodes of suicidal thoughts, substance abuse, social circumstance definitive diagnosis are missing. However feeling sad and anxiety would be a confounding factor for suicidal thoughts. Definitive diagnosis for palpitation and headache were not provided. Relevant concomittant medications, infections and comordidities were not available to assess toxic hepatitis. Medical history of Gilbert's syndrome is a risk factor for toxic hepatitis. Limited information precludes meaningful assessment. This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

Relevant Medical History:

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FOIA Case Report Information

Case ID: 21626703

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Gilbert's syndrome			

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
ALANINE AMINOTRANSFERASE	508	U/L	14	59	N
ALANINE AMINOTRANSFERASE	39	U/L	14	59	N
ALBUMIN GLOBULIN RATIO					Y
ALPHA 1 GLOBULIN	3.2	%			N
ALPHA 2 GLOBULIN	6.3	%			N
ASPARTATE AMINOTRANSFERASE	123	U/L	15	37	N
ASPARTATE AMINOTRANSFERASE	9	U/L	15	37	N
BETA 2 GLOBULIN	3.6	%			N
BILIRUBIN CONJUGATED	0.45	mg/dL	0.00	0.20	N
BILIRUBIN CONJUGATED	0.27	mg/dL	0.00	0.20	N
BLOOD ALBUMIN	65.9	%			N
BLOOD ALKALINE PHOSPHATASE	55	U/L	46	116	N
BLOOD ALKALINE PHOSPHATASE	50	U/L	46	116	N
BLOOD BILIRUBIN	3.10	mg/dL	0.2	1.00	N
BLOOD BILIRUBIN	1.64	mg/dL	0.2	1.00	N
BLOOD LACTATE DEHYDROGENASE	124	U/L	81	234	N
GAMMA-GLUTAMYLTRANSFERASE	54	U/L	5	55	N
GAMMA-GLUTAMYLTRANSFERASE	25	U/L	5	55	N
IMMUNOGLOBULINS	15.9	%			N
PROTEIN TOTAL	7	g/dL			N

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

Case ID: 21626703

SEROLOGY TEST	Y
ULTRASOUND ABDOMEN	Y
ANTINUCLEAR ANTIBODY	Y
ANTINUCLEAR ANTIBODY	Y
ANTINUCLEAR ANTIBODY	Y

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	SEDOXIL	/		UNK SOS	Product used for unknown indication			

Reporter Source:

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

Literature Text:

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

Case ID: 21719396

Case Information:

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

FDA Rcvd Date: 13-Dec-2022 **Mfr Rcvd Date:** 02-Dec-2022 **Mfr Control #:** US-NOVOPROD-990572 **Application #:** 22341

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Victoza		0.6 Mg Milligram(S) / QD	Subcutaneous	0.6 mg, qd	Weight control	25-Jun-2022	30-Jun-2022

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Victoza		Yes	NA	MS6FN02			NOVO NORDISK	

Event Information:

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

Event/Problem Narrative:

This serious Spontaneous case from the United states was reported by a Health Care Professional as "suicidal ideation(suicidal ideation)" with an unspecified onset date, "Seevere depression(Depression)" beginning on JUN-2022, "fatigue(Fatigue)" beginning on JUL-2022, "HCP prescribed for weight loss (Off label)(Off label use in unapproved indication)" beginning on JUN-2022, and concerned a Adult Female patient who was treated with Victoza (liraglutide) from JUN-2022 to 30-JUN-2022 for "Weight loss", Historical Condition: Post-traumatic stress disorder. On an unknown date in JUN-2022, the patient had experienced depression On an unknown date in JUL-2022, the patient had experienced fatigue. It was reported that, the patient was prescribed Victoza for weight loss On an unknown date, the patient went to Emergency department for Suicidal ideation and was said to stop medications Batch Numbers: Victoza: MS6FN02 Action taken to Victoza was

Case ID: 21719396

reported as Product discontinued due to adverse event. The outcome for the event "suicidal ideation(suicidal ideation)" was Unknown. On JUL-2022 the outcome for the event "Seevere depression(Depression)" was Recovered. The outcome for the event "fatigue(Fatigue)" was Not recovered. On 2022 the outcome for the event "HCP prescribed for weight loss (Off label)(Off label use in unapproved indication)" was Recovered. On 02-DEC-2022, the case was upgraded from non-serious to serious due to the addition of event Suicidal ideation with Medically significant criteria Company comment: Suicidal ideation, depression and fatigue are assessed as unlisted events according to the Novo Nordisk current Company Core Data Sheet (CCDS) on Victoza. Medical history of post-traumatic stress disorder in the past and current condition of depression assessed as risk factors for suicidal ideation. Information such as social circumstances, prior suicidal attempts/ideations is missing which makes thorough medical assessment difficult. This single case report is not considered to change the current knowledge of the safety profile of Victoza.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?
Post-traumatic stress disorder			

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: 21800949

Case Information:

Case Type : Direct **eSub:** N **HP:** Y **Country:** US **Event Date:** 19-Dec-2022 **Outcomes:** OT **Application Type:**

FDA Rcvd Date: 29-Dec-2022 **Mfr Rcvd Date:** **Mfr Control #:** FDA-CDER-CTU-2022-103604 **Application #:**

Patient Information:

Age: 59 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	OZEMPIC PEN 1MG DOSE		1 Mg/Mg - Milligrams/ Milligrams / QW	Subcutaneous	Frequency : Weekly;		19-Dec-2022	19-Dec-2022

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	OZEMPIC PEN 1MG DOSE		Yes	Not Applicable	00301694132122		00169413013	NOVO NORDISK	

Event Information:

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

Suicidal ideation NA

Event/Problem Narrative:

Tell us what happened and how it happened : Describe Event, Problem, or Product Use Error: SUICIDAL IDEATION W INCREASE DOSE FROM 0.25/0.5MG TO 1MG;

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Case ID: 21800949

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		
Override Auto Calculation Rule	No		
FDA Received Date	29-Dec-2022	CTU Received Date	29-Dec-2022
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)

A. PATIENT INFORMATION

	Patient Identifier (In Confidence)	(b) (6)
	Age	59 Year(s)
	Date of Birth	
	Sex	Female
	Gender	Not selected
	Please Specify Other Gender	
	Weight	
	Ethnicity (Check single best answer)	Not Hispanic/Latino
	Race (Check all that apply)	☐ Asian ☐ American Indian or Alaska Native ☐ Black or African American ☑ White ☐ Native Hawaiian or Other Pacific Islander

B. ADVERSE EVENT, PRODUCT PROBLEM

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

	☐ Congenital Anomaly/Birth Defects ☐ Required Intervention to Prevent Permanent Impairment/Damage
Date of Death	
Date of Event	19-Dec-2022
Date of this Report	29-Dec-2022

Describe Event, Problem or Product Use Error

Describe Event, Problem, or Product Use Error: SUICIDAL IDEATION W INCREASE DOSE FROM 0.25/0.5MG TO 1MG

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

Other Relevant History, Including Preexisting Medical Conditions

C. PRODUCT AVAILABILITY

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

D. PRODUCT(S) 1 of 1

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

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

Product Name	OZEMPIC PEN 1MG DOSE		
Strength	1MG mg/mg - milligrams/ milligrams	If Other	
Manufacturer/Compounder	NOVO NORDISK		

NDC# or Unique ID	00169413013
Product Type(check all that apply)	☐ OTC ☐ Compounded ☐ Generic ☐ Biosimilar
Event Abated After Use Stopped or Dose Reduced?	Yes
Event Reappeared after Reintroduction ?	Doesn't Apply

Drug Therapy 1 of 1

Dose or Amount	1 mg/mg - milligrams/ milligrams	If Other	
Frequency	Other	If Other	WEEKLY
Route	Subcutaneous	If Other	
Dosage Form			
Start	19-Dec-2022		
Stop	19-Dec-2022		
Dose Reduced			
Therapy Duration		If Other	
Is therapy still on-going?	No		
Lot Number	00301694132122		
Expiration Date			

Diagnosis for Use (indication) 1 of 1

E. SUSPECT MEDICAL DEVICE

Brand Name	
Common Device Name	
Procode	
Manufacturer Name	
City	
State	
Model #	
Lot #	
Catalog #	
Expiration Date	
Serial #	
Unique Identifier (UDI)#	
Operator of Device	☐ Health Professional ☐ Patient/Consumer ☐ Other
Other	

If Implanted, Give Date	
If Explanted, Give Date	
Is this a single-use device that was reprocessed and reused on a patient?	
If Yes for the above field, Enter Name and Address of Reprocessor	
Was this device serviced by a third party?	

F. OTHER (CONCOMITANT) MEDICAL PRODUCTS

CONCOMITANT MEDICAL PRODUCT DESCRIPTION

G. REPORTER 1 of 1

Primary?	Yes		
Reporter is Patient?			
Title			
Last Name	(b) (6)		
Middle Name			
First Name	(b) (6)		
Address			
City			
State/Province/Region	--		
Country	UNITED STATES	If Other	
ZIP/Postal Code			
Phone	(b) (6)		
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	No		

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

Case ID: 22107520

Case Information:

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

FDA Rcvd Date: 17-Mar-2023 **Mfr Rcvd Date:** 08-Mar-2023 **Mfr Control #:** US-NOVOPROD-1037280 **Application #:** 209637

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		/	Subcutaneous	UNK	Product used for unknown indication		
2	Ozempic		0.5 Mg Milligram(S) /	Subcutaneous	0.5 mg			
3	Ozempic		1 Mg Milligram(S) /	Subcutaneous	1 mg			

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Ozempic		No	NA				NOVO NORDISK	
2	Ozempic		No	NA				NOVO NORDISK	
3	Ozempic		No	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 Nurse as "suicide ideation(Suicidal ideation)" with an unspecified onset date, "increased depression(Depression)" with an unspecified onset date, and concerned a Adult patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for "drug use for unknown indication", Current Condition: mental illness. The patient on therapy with Ozempic was reported to have suicidal ideation

Case ID: 22107520

and increased depression when the dose was increased to 1 mg. When the dose was decreased to 0.5 mg the patient was stabilized. Batch number is requested in follow up. Action taken to Ozempic was reported as Dose Decreased. The outcome for the event "suicide ideation(Suicidal ideation)" was Not recovered. The outcome for the event "increased depression(Depression)" was Not recovered. Company Comment: Suicidal ideation and depression are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. A medical history of mental illness may suggest an alternative etiology. Limited information as related to age, Ozempic therapy dates, event onset date, more specifics on the medical history of mental illness, 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?
Mental disorder			Yes

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

Relevant Laboratory Data:

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

Concomitant Products:

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

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: 22118110

Case Information:

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

FDA Rcvd Date: 21-Mar-2023 **Mfr Rcvd Date:** 08-Mar-2023 **Mfr Control #:** US-NOVOPROD-1037279 **Application #:** 209637

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date
1	Ozempic		0.5 Mg Milligram(S) /	Subcutaneous	0.5 mg			
2	Ozempic		0.5 Mg Milligram(S) /	Subcutaneous	0.5 mg	Product used for unknown indication		
3	Ozempic		1 Mg Milligram(S) /	Subcutaneous	1 mg			

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

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 and office staff as "suicide ideation(Suicidal ideation)" with an unspecified onset date, "increased depression(Depression)" with an unspecified onset date, and concerned an Adult patient who was treated with Ozempic (SEMAGLUTIDE) from unknown start date for an unknown indication. Current Condition: mental health illness. A nurse practitioner reported that a patient receiving therapy with

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

Case ID: 22118110

Ozempic 1 mg experienced suicide ideation or depression. Action taken to Ozempic was reported as Dose Decreased. The outcome for the event "suicide ideation(Suicidal ideation)" was Recovered. The outcome for the event "increased depression(Depression)" was Recovered. Company Comment: Suicidal ideation and depression are assessed as unlisted according to the Novo Nordisk company core data sheet (CCDS) for Ozempic. A medical history of mental health illness may suggest an alternative etiology. Limited information as related to age, Ozempic therapy dates, event onset date, more specifics on the medical history of mental health illness, 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?
Mental disorder			Yes

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

Relevant Laboratory Data:

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

Concomitant Products:

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

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: 22128240

Case Information:

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

FDA Rcvd Date: 03-Apr-2023 **Mfr Rcvd Date:** 23-Mar-2023 **Mfr Control #:** LB-NOVOPROD-1038887 **Application #:** 209637

Patient Information:

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

Suspect Products:

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

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

Event Information:

Preferred Term (MedDRA Version: v.26.0)	ReC
Suicide attempt	
Intentional overdose	

Event/Problem Narrative:

This serious Spontaneous case from LEBANON was reported by a Physician as "attempted to commit suicide(Suicide attempt)" with an unspecified onset date, "taking 1 full pen of Ozempic 1mg in one day(Intentional overdose)" with an unspecified onset date, and concerned a Female patient (age not reported) who was treated with Ozempic 1.0 mg (SEMAGLUTIDE) from unknown start date for "Drug use for unknown indication". Patient's height weight and body mass index were not reported Medical history was not provided. Concomitant products included - Xanax(Alprazolam), Stilnox(Zolpidem Tartrate) On an unspecified date, the patient tried to commit suicide by taking 1 full pen of Ozempic 1mg in one day, in addition to Xanax and Stilnox. The patient was hospitalized to the ER. The blood tests were normal. (Test name, values and units were not reported). After that left the hospital. Batch Numbers: Ozempic 1.0 mg: not reported. Action taken to Ozempic 1.0 mg was Not reported. The outcome for the event "attempted to commit suicide(Suicide attempt)" was Not Reported. The outcome for the event "taking 1 full pen of Ozempic 1mg in one day(Intentional overdose)" was Not Reported. No further information available. Since last submission case updated with the following information: New lab data has been added NFI updated Narrative updated accordingly. Company comment: Suicide attempt is assessed as unlisted event and

Case ID: 22128240

intentional overdose is assessed as listed event according to NovoNordisk current reference safety information on Ozempic. Information on demographic details of the patient, history of any risk factors like psychiatric disorders, psychological disorders, anxiety, depression, social and family behavior, relevant medical history, relevant clinical and investigation results, action taken with the suspect, event onset dates with outcome, exposure details of the suspect are unavailable for thorough medical assessment. This single case report is not considered to change the current knowledge of the safety profile of Ozempic.

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

#	Product Name:	Dose/Frequency	Route	Dosage Text	Indication(s)	Start Date	End Date	Interval 1st Dose to Event
1	XANAX	/		UNK	Product used for unknown indication			
2	STILNOX	/		UNK	Product used for unknown indication			

Reporter Source:

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

Literature Text: