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

Date - Time: 13-Feb-2024 14:57:33 EST

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

Case ID(s) Printed:

20621593	20621907	20622063	20981863
20981933	20981970	20982290	20982546
20982614	22738610	22738907	

Total Cases: 11

Total number of Inactive cases: *0

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

Case ID: 20621593

Case Information:

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

FDA Rcvd Date: 22-Mar-2022 **Mfr Rcvd Date:** 16-Feb-2022 **Mfr Control #:** US-NOVOPROD-885288 **Application #:** 215256

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Wegovy		2.4 Mg Milligram(S) /	Subcutaneous	2.4 mg	Aug-2021	Dec-2021	Weight decreased

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

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Wegovy//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

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

Alopecia

Event/Problem Narrative:

This is an auto generated narrative This non-serious Spontaneous case from the UNITED STATES was reported by a Nurse as "significant hair loss(Hair loss)" beginning on NOV-2021, and concerned a Adult Female patient who was treated with Wegovy (SEMAGLUTIDE) from AUG-2021 to DEC-2021 for "16-FEB-2022", Dosage Regimens: Wegovy: ??-AUG-2021 to ??-DEC-2021; Medical history was not provided. Batch Numbers: Wegovy: ASKU Action taken to Wegovy was reported as Product discontinued due to AE. On DEC-2021 the outcome for the event "significant hair loss(Hair loss)" was Recovered. References

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

Case ID: 20621593

included: Reference Type: SIMS case number Reference ID#: ||US-Novo-20220105556 Reference Notes: Reference Type: Company Representative Reference ID#: Reference Notes: Reference Type: E2B Linked Report Reference ID#: US-NOVOPROD-885289 Reference Notes: Reference Type: E2B Linked Report Reference ID#: US-NOVOPROD-885290 Reference Notes: Reference Type: E2B Report Duplicate Reference ID#: US-Novo-20220105556 Reference Notes: Novo Reference Type: SIMS case number Reference ID#: 885288||US-Novo-20220105556 Reference Notes:

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Case ID: 20621907

Case Information:

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

FDA Rcvd Date: 22-Mar-2022 **Mfr Rcvd Date:** 13-Dec-2021 **Mfr Control #:** US-NOVOPROD-891762 **Application #:** 215256

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Wegovy 2.4 mg		2.4 Mg Milligram(S) /	Subcutaneous	2.4 mg	Jul-2021		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		NA	NA				NOVO NORDISK	

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Wegovy 2.4 mg//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

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

COVID-19

Alopecia

Event/Problem Narrative:

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

Case ID: 20621907

This is an auto generated narrative This non-serious Spontaneous case from the UNITED STATES was reported by a Other Health Care Professional as "hair loss while on Wegovy(Hair loss)" beginning on 2021, "covid(COVID-19)" beginning on 2021, and concerned a Female patient who was treated with Wegovy 2.4 mg (SEMAGLUTIDE) from JUL-2021 for "drug use for unknown indication", Dosage Regimens: Wegovy 2.4 mg: ??-JUL-2021 to Not Reported; Medical history was not provided. Batch Numbers: Wegovy 2.4 mg: UNK Action taken to Wegovy 2.4 mg was reported as No Change. The outcome for the event "hair loss while on Wegovy(Hair loss)" was Not recovered. The outcome for the event "covid(COVID-19)" was Not recovered. References included: Reference Type: SIMS case number Reference ID#: ||US-Novo-20211203449 Reference Notes: Reference Type: Company Representative Reference ID#: Reference Notes:

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Case ID: 20622063

Case Information:

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

FDA Rcvd Date: 22-Mar-2022 **Mfr Rcvd Date:** 13-Dec-2021 **Mfr Control #:** US-NOVOPROD-894323 **Application #:** 215256

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Wegovy 2.4 mg		/	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		NA	NA				NOVO NORDISK	

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Wegovy 2.4 mg//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

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

Alopecia

Event/Problem Narrative:

This is an auto generated narrative This non-serious Spontaneous case from the UNITED STATES was reported by a Physician as "Hair loss(Hair loss)" with an unspecified onset date, and concerned a Female patient who was treated with Wegovy 2.4 mg (SEMAGLUTIDE) from unknown start date and ongoing for

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

Case ID: 20622063

"Drug use for unknown indication", Dosage Regimens: Wegovy 2.4 mg: Medical history was not provided. Batch Numbers: Wegovy 2.4 mg: ASKU Action taken to Wegovy 2.4 mg was reported as No Change. The outcome for the event "Hair loss(Hair loss)" was Not recovered. References included: Reference Type: SIMS case number Reference ID#: ||US-Novo-20211203288 Reference Notes:

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Case ID: 20981863

Case Information:

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

FDA Rcvd Date: 20-Jun-2022 **Mfr Rcvd Date:** 31-May-2022 **Mfr Control #:** US-NOVOPROD-907609 **Application #:** 215256

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Wegovy 2.4 mg		/	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 2.4 mg		NA	NA				NOVO NORDISK	

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Wegovy 2.4 mg//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

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

Alopecia

Event/Problem Narrative:

This is an auto generated narrative This non-serious Spontaneous case from the UNITED STATES was reported by a Nurse as "hair falling out(Hair loss)" with an unspecified onset date, and concerned a patient who was treated with Wegovy 2.4 mg (SEMAGLUTIDE) from unknown start date and ongoing for "drug

Case ID: 20981863

use for unknown indication", Dosage Regimens: Wegovy 2.4 mg: Medical history was not provided. Batch Numbers: Wegovy 2.4 mg: ASKU Action taken to Wegovy 2.4 mg was reported as No Change. The outcome for the event "hair falling out(Hair loss)" was Not Reported. References included: Reference Type: E2B Report Duplicate Reference ID#: US-Novo-20220401180 Reference Notes: Novo Reference Type: SIMS case number Reference ID#: ||US-Novo-20220401180 Reference Notes:

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Case ID: 20981933

Case Information:

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

FDA Rcvd Date: 20-Jun-2022 **Mfr Rcvd Date:** 31-May-2022 **Mfr Control #:** US-NOVOPROD-910861 **Application #:** 215256

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Wegovy 0.5 mg		/	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 0.5 mg		NA	NA				NOVO NORDISK	

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Wegovy 0.5 mg//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

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

Alopecia

Event/Problem Narrative:

This is an auto generated narrative This non-serious Spontaneous case from the UNITED STATES was reported by a Nurse as "Hair loss(Hair loss)" with an unspecified onset date, and concerned a Female patient who was treated with Wegovy 0.5 mg (SEMAGLUTIDE) from unknown start date and ongoing for

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

Case ID: 20981933

"drug use for unknown indication", Dosage Regimens: Wegovy 0.5 mg: Medical history was not provided. Batch Numbers: Wegovy 0.5 mg: ASKU Action taken to Wegovy 0.5 mg was reported as No Change. The outcome for the event "Hair loss(Hair loss)" was Not Reported. References included: Reference Type: SIMS case number Reference ID#: US-Novo-20220107285 Reference Notes:

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Case ID: 20981970

Case Information:

Case Type : Non-Expedited **eSub:** Y **HP:** Y **Country:** US **Event Date:** 01-Dec-2021 **Outcomes:** **Application Type:**

FDA Rcvd Date: 20-Jun-2022 **Mfr Rcvd Date:** 04-Mar-2022 **Mfr Control #:** US-NOVOPROD-916208 **Application #:** 215256

Patient Information:

Age: 49 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Wegovy		1.7 Mg Milligram(S) / / Unknown WK		1.7 mg, qw	21-Sep-2021	14-Feb-2022	Obesity

#	Product Name:	Interval 1st Dose to Event	DeC	ReC	Lot#	Exp Date	NDC #	MFR/Labeler	OTC
1	Wegovy	71 Day	No	NA				NOVO NORDISK	

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Wegovy//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

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

Alopecia

Event/Problem Narrative:

This is an auto generated narrative This non-serious Spontaneous case from the UNITED STATES was reported by a Medical Doctor as "Hair loss(Hair loss)" beginning on 01-DEC-2021, and concerned a 49 Years old Female patient who was treated with Wegovy (SEMAGLUTIDE) from 21-SEP-2021 to 14-FEB-2022 for

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

Case ID: 20981970

"obesity", Dosage Regimens: Wegovy: 21-SEP-2021 to 14-FEB-2022; Current Condition: obesity. Batch Numbers: Wegovy: ASKU Action taken to Wegovy was reported as Product discontinued. The outcome for the event "Hair loss(Hair loss)" was Not recovered. References included: Reference Type: SIMS case number Reference ID#: US-Novo-20220301460 Reference Notes:

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

Reporter Source:

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

Literature Text:

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

Case ID: 20982290

Case Information:

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

FDA Rcvd Date: 20-Jun-2022 **Mfr Rcvd Date:** 18-May-2022 **Mfr Control #:** US-NOVOPROD-924950 **Application #:** 215256

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Wegovy 1 mg		/	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 1 mg		Unknown	NA				NOVO NORDISK	

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Wegovy 1 mg//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

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

Fatigue

Alopecia

Event/Problem Narrative:

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

Case ID: 20982290

This is an auto generated narrative This non-serious Spontaneous case from the UNITED STATES was reported by a as "Fatigue(Fatigue)" with an unspecified onset date, "hair loss(Hair loss)" with an unspecified onset date, and concerned a Female patient who was treated with Wegovy 1 mg (SEMAGLUTIDE) from unknown start date for "drug use for unknown indication", Dosage Regimens: Wegovy 1 mg: Medical history was not provided. Batch Numbers: Wegovy 1 mg: ASKU Action taken to Wegovy 1 mg was Not reported. The outcome for the event "Fatigue(Fatigue)" was Recovered. The outcome for the event "hair loss(Hair loss)" was Recovered. References included: Reference Type: E2B Report Duplicate Reference ID#: US-Novo-20220505801 Reference Notes: Novo Reference Type: SIMS case number Reference ID#: US-Novo-20220505801 Reference Notes:

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Case ID: 20982546

Case Information:

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

FDA Rcvd Date: 20-Jun-2022 **Mfr Rcvd Date:** 01-Apr-2022 **Mfr Control #:** US-NOVOPROD-917822 **Application #:** 215256

Patient Information:

Age: 70 YR **Sex:** Female **Weight:**

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Wegovy 2.4 mg		/	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 2.4 mg		Unknown	NA				NOVO NORDISK	

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Wegovy 2.4 mg//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

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

Alopecia

Event/Problem Narrative:

This is an auto generated narrative This non-serious Spontaneous case from the UNITED STATES was reported by a Nurse as "Hair loss(Hair loss)" with an unspecified onset date, and concerned a 70 Years old Female patient who was treated with Wegovy 2.4 mg (SEMAGLUTIDE) from unknown start date for

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

Case ID: 20982546

"drug use for unknown indication", Dosage Regimens: Wegovy 2.4 mg: Medical history was not provided. Batch Numbers: Wegovy 2.4 mg: ASKU Action taken to Wegovy 2.4 mg was Not reported. The outcome for the event "Hair loss(Hair loss)" was Unknown. References included: Reference Type: SIMS case number Reference ID#: US-Novo-20220400318 Reference Notes:

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Case ID: 20982614

Case Information:

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

FDA Rcvd Date: 20-Jun-2022 **Mfr Rcvd Date:** 28-Mar-2022 **Mfr Control #:** US-NOVOPROD-918756 **Application #:** 215256

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Wegovy 2.4 mg		/	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 2.4 mg		Unknown	Unknown				NOVO NORDISK	

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Wegovy 2.4 mg//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

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

Alopecia

Event/Problem Narrative:

This is an auto generated narrative This non-serious Spontaneous case from the UNITED STATES was reported by a Physician as "alopecia(Alopecia)" with an unspecified onset date, and concerned a Adult Female patient who was treated with Wegovy 2.4 mg (SEMAGLUTIDE) from unknown start date for "drug use

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

Case ID: 20982614

for unknown indication", Dosage Regimens: Wegovy 2.4 mg: Medical history was not provided. Batch Numbers: Wegovy 2.4 mg: ASKU Action taken to Wegovy 2.4 mg was Not reported. The outcome for the event "alopecia(Alopecia)" was Not Reported. References included: Reference Type: SIMS case number Reference ID#: US-Novo-20220309000 Reference Notes: Reference Type: Company Representative Reference ID#: Reference Notes:

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Case ID: 22738610

Case Information:

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

FDA Rcvd Date: 21-Jul-2023 **Mfr Rcvd Date:** 03-May-2023 **Mfr Control #:** US-NOVOPROD-1065307 **Application #:** 215256

Patient Information:

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

Suspect Products:

#	Product Name:	Compounded Drug ?	Dose/Frequency	Route	Dosage Text	Start Date	End Date	Indication(s)
1	Wegovy 0.5 mg		/	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 0.5 mg		Unknown	NA				NOVO NORDISK	

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Wegovy 0.5 mg//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

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

Weight decreased

Alopecia

Event/Problem Narrative:

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

Case ID: 22738610

This is an auto generated narrative This non-serious Spontaneous case from the UNITED STATES was reported by a Physician as "lost significant amount of weight, 20lbs quickly(Weight loss)" with an unspecified onset date, "hair loss(Hair loss)" with an unspecified onset date, and concerned a Female patient who was treated with Wegovy 0.5 mg (SEMAGLUTIDE) from unknown start date for "drug use for unknown indication", Dosage Regimens: Wegovy 0.5 mg: Medical history was not provided. Lab Data included: Lab Data Test as Reported: Weight Test Name: Weight Comments: On an unknown date, patient experienced lost significant amount of weight, 20lbs quickly. Batch Numbers: Wegovy 0.5 mg: ASKU Action taken to Wegovy 0.5 mg was Not reported. The outcome for the event "lost significant amount of weight, 20lbs quickly(Weight loss)" was Not recovered. The outcome for the event "hair loss(Hair loss)" was Not recovered. References included: Reference Type: SIMS case number Reference ID#: US-Novo-20230502993 Reference Notes:

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
WEIGHT					Y

Concomitant Products:

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

Reporter Source:

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

Literature Text:

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

Case ID: 22738907

Case Information:

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

FDA Rcvd Date: 21-Jul-2023 **Mfr Rcvd Date:** 30-May-2023 **Mfr Control #:** US-NOVOPROD-1076534 **Application #:** 215256

Patient Information:

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

Suspect Products:

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

Device Products:

#	Brand Name / Common Device Name / Product Code	Similar Device?	Malfunction ?	Device Lot#	Device Usage/ Operator of Device	Remedial Action	Device Problem	Manufacturer Name
1	Wegovy//	No			/Other		Adverse Event Without Identified Device or Use Problem	Novo Nordisk A/S

Event Information:

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

Gastrointestinal disorder

Alopecia

Gastrooesophageal reflux disease

Event/Problem Narrative:

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

Case ID: 22738907

This is an auto generated narrative This non-serious Spontaneous case from the UNITED STATES was reported by a Nurse as "GI symptoms(Gastrointestinal disorder)" with an unspecified onset date, "Excessive hair loss(Hair loss)" with an unspecified onset date, "Gastrooesophageal reflux disease(Gastrooesophageal reflux disease)" with an unspecified onset date, and concerned a Female patient who was treated with Wegovy (SEMAGLUTIDE) from unknown start date for "Product used for unknown indication", Dosage Regimens: Wegovy: Medical history was not provided. Batch Numbers: Wegovy: ASKU Action taken to Wegovy was reported as Product discontinued. The outcome for the event "GI symptoms(Gastrointestinal disorder)" was Recovered. The outcome for the event "Excessive hair loss(Hair loss)" was Recovered. The outcome for the event "Gastrooesophageal reflux disease(Gastrooesophageal reflux disease)" was Recovered. References included: Reference Type: SIMS case number Reference ID#: US-Novo-20230517540 Reference Notes:

Relevant Medical History:

Disease/Surgical Procedure	Start Date	End Date	Continuing?

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

Relevant Laboratory Data:

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

Concomitant Products:

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

Reporter Source:

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

Literature Text: