DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 (973)331-4900	1/13/2025-2/7/2025* FEI NUMBER 2244771

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Anna L. Windle, PhD, Senior Vice President

FIRM NAME	STREET ADDRESS
Novo Nordisk Inc.	800 Scudders Mill Rd
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Plainsboro, NJ 08536-1606	Corporate Headquarters

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Not all adverse drug experiences that are both serious and unexpected have been reported to FDA within 15 calendar days of initial receipt of the information.

Specifically,

a)More than 300 15-Day Alert reports had not been submitted to the FDA prior to this inspection.

On 29Apr2024, you identified a “failure to transmit safety events to global safety database” (deviation DV0166369) which began on 21Sep2020 and erroneously excluded reportable 15-Alert reports from evaluation and reporting. You reported the deviation was completed on 19Dec2024. However, we found not all serious and unexpected individual case safety reports (ICSRs) related to this deviation had not been submitted.

For example, the following ICSRs were submitted during this inspection or placed in submission pending status following our identification of cases pending medical review.

Argus Case #	Initial Receipt Date	Due Date	Submission Date	# Days Late
1320918	10Sep2021	24Sep2021	Not submitted	Pending submission
1317485	12Apr2021	27Apr2021	30Jan2025	1374
851316	20Sep2021	05Oct2021	03Feb2025	1217

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Tyanna N Hadley, Investigator Mayar M Mussa, Investigator X Tyanna N Hadley Investigator Signed By: Tyanna N. Hadley -S Date Signed: 02-07-2025 17:32:25	2/7/2025

1331385	10Oct2022	25Oct2022	05Feb2025	834
1320208	26Oct2022	10Nov2022	04Feb2025	817
1234211	12Aug2024	27Aug2024	04Feb2025	161
1241370	03Sep2024	18Sep2024	04Feb2025	139
1334278	08Nov2024	22Nov2024	04Feb2025	74

In addition to deviation DV0166369, we identified serious and unexpected events which were reported with the four minimum criteria but were evaluated as invalid.

For example, we identified the following reports have not been submitted.

Argus Case #	Initial Receipt Date	Preferred Term	Due Date	Submission Date
1180543	07Jun2023	Seizure	22Jun2023	Not submitted
1138656	07Nov2023	Liver injury	22Nov2023	Not submitted
1162091	09Jan2024	Death	24Jan2024	Not submitted
1171264	30Jan2024	Death	14Feb2024	Not submitted
1194540	20Mar2024	Death	04Apr2024	Not submitted
1342548	20Dec2024	Death	04Jan2025	Not submitted

b)There were more than 700 15-Day Alert reports submitted late to FDA.

You expanded a vendor's responsibilities to include surveillance of adverse events through the call center between 16May2023 and 13Oct2023 after identifying inadequacies in vendor training. More than 480 reports of serious and unexpected events received during that time were submitted late to the FDA.

For example,

Argus Case #	Initial Receipt Date	Due Date	Date Submitted	# Days Late
1194206	25May2023	09Jun2023	17Apr2024	313
1189423	08Jun2023	23Jun2023	10May2024	322
1193345	22Jun2023	07Jul2023	17Apr2024	285
1202152	26Jun2023	11Jul2023	06May2024	300
1202442	07Jul2023	21Jul2023	02May2024	286
1163151	26Jul2023	10Aug2023	17Jan2024	160
1208214	03Aug2023	18Aug2023	08May2024	264
1192674	16Aug2023	31Aug2023	17May2024	260
1207730	11Oct2023	26Oct2023	02May2024	189
1165295	12Oct2023	27Oct2023	25Jan2024	90

Deviation DV0166369 resulted in more than 300 additional late 15-Day Alert submissions to the FDA.

c)You failed to report serious and unexpected events as 15-Day Alert reports instead of periodic individual case reports (ICSRs). Not all events reported in these ICSRs were initially evaluated for appropriate seriousness and expectedness resulting in late submissions to the FDA.

For example,

Argus Case #	Initial Receipt Date	Due Date	15-Day Alert ICSR Submission Date	# Days Late
786425	02Feb2021	17Feb2021	30Jan2025	1443
842794	27Aug2021	10Sep2021	31Jan2025	1239
1161983	17Aug2023	01Sep2023	30Jan2025	517

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OBSERVATION 2

Adverse drug experiences that were the subject of post marketing 15-day reports were not investigated.

Specifically, you failed to promptly investigate reports of serious and unexpected events by conducting two follow-up attempts with the reporter according to your procedures to obtain minimum criteria for a valid report and/or serious reports of death or hospitalization.

For example,

Argus case #	Initial Receipt Date	Product	Preferred term	Follow-up Date(s)
1079792	13Jun2023	Ozempic	Completed suicide, Depression	Not conducted
1171264	30Jan2024	Ozempic	Death	Not conducted
1342548	20Dec2024	Ozempic	Death	Not conducted

OBSERVATION 3

You failed to submit an ICSR for the reporting period.

Specifically, you failed to submit at least 10 ICSRs for serious and listed events.

For example,

Argus Case #	Initial Receipt Date	Product	Submitted Periodic Reporting Period	Periodic Report Due Date

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1350012	09Nov2023	Ozempic (NDA 209637)	01Jun2023 – 30Nov2023	08Feb2024
1142066	15Nov2023	Ozempic (NDA 209637)	01Jun2023 – 30Nov2023	08Feb2024
1317727	15Feb2024	Ozempic (NDA 209637)	01Jun2023 – 31May2024	09Aug2024

OBSERVATION 4

Written procedures have not been developed for the surveillance, receipt and reporting to FDA of post marketing adverse drug experiences.

Specifically, you are required to investigate and evaluate reports of adverse events subject to 15-Day Alert reports, but your written procedures inhibit these activities.

SOP Q0360683, "Case Management Workflow at Novo Nordisk Inc. (NNI) Patient Safety," states no outbound follow up should be attempted if consent was not obtained and reporter is a non-HCP." The SOP also states "non-case reports are to be rejected" from intake into the safety database but the procedure does not define a "non-case."

There were serious and unexpected events reported but not investigated due to documentation that reporter consent had not been obtained. There were serious and unexpected ICSRs submitted late which had initially been rejected by your case processors between Sep2020 and Aug2024.

***DATES OF INSPECTION**

1/13/2025(Mon), 1/14/2025(Tue), 1/15/2025(Wed), 1/16/2025(Thu), 1/17/2025(Fri), 1/21/2025(Tue), 1/22/2025(Wed), 1/23/2025(Thu), 1/24/2025(Fri), 1/27/2025(Mon), 1/28/2025(Tue), 1/29/2025(Wed),

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Tyanna N Hadley, Investigator Mayar M Mussa, Investigator	X Tyanna N Hadley Investigator Signed By: Tyanna N. Hadley -S Date Signed: 02-07-2025 17:32:25	2/7/2025

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1/30/2025(Thu), 1/31/2025(Fri), 2/03/2025(Mon), 2/04/2025(Tue), 2/05/2025(Wed), 2/06/2025(Thu), 2/07/2025(Fri)

X Mayar M Mussa
Investigator
Signed By: 2003950881
Date Signed: 02-07-2025 17:32:43

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EMPLOYEE(S) SIGNATURE

Tyanna N Hadley, Investigator
Mayar M Mussa, Investigator

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Investigator
Signed By: Tyanna N. Hadley -S
Date Signed: 02-07-2025
17:32:25

DATE ISSUED
2/7/2025

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."