

Compounding the Joy of Living*

November 18, 2024

Robert Califf, MD Commissioner

Valerie Jensen Director, Drug Shortage Staff

Gail Bormel, JD
Director, Office of Compounding Quality and Compliance
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Subject: Formal Comment Submission Regarding the Ongoing Shortage of FDA-Approved Semaglutide Injection Products, **Docket No. FDA-2015-N-0030-0001**

Dear Commissioner Califf, Ms. Jensen, and Dr. Bormel:

Thank you for your attention to my letter submitted on November 15 regarding the persistent shortage of FDA-approved semaglutide injection products. Since that submission, we have received additional reports from our members, which further underscore the critical role compounded semaglutide products continue to play in addressing patient needs during this shortage.

Attached are the latest screenshots from wholesalers indicating continued limited availability of FDA-approved semaglutide products. Additionally, we have gathered dispensing data from 15 additional compounders, which collectively account for nearly 40,000 compounded semaglutide prescriptions per month. This volume highlights the substantial patient reliance on compounded products to fill the gap created by insufficient supply of FDA-approved medications.

Below is a breakdown of prescriptions dispensed monthly by these 15 additional pharmacies:

Pharmacy Prescriptions/Month

AA 830

BB 1,700

CC 8,800

Pharmacy Prescriptions/Month

DD 250

EE 475

FF 2,700

GG 6,000

HH 2,400

1,000

JJ 3,500

KK 1,700

LL 6,200

MM 3,000

NN 350

00 600

Total 39,505

These numbers emphasize the need for a robust supply chain of FDA-approved semaglutide products. We urge the agency to address manufacturing shortages promptly to ensure adequate availability for patients who depend on these therapies.

We remain committed to supporting the FDA in addressing this issue and are available to provide any additional data or insights that may aid in resolving these shortages effectively.

Thank you for your continued attention and consideration.

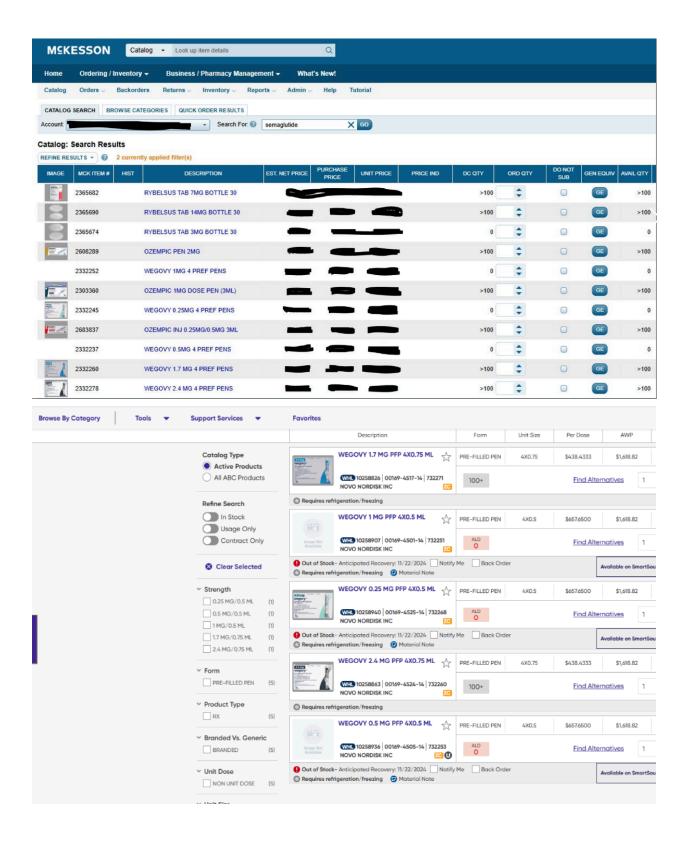
Sincerely,

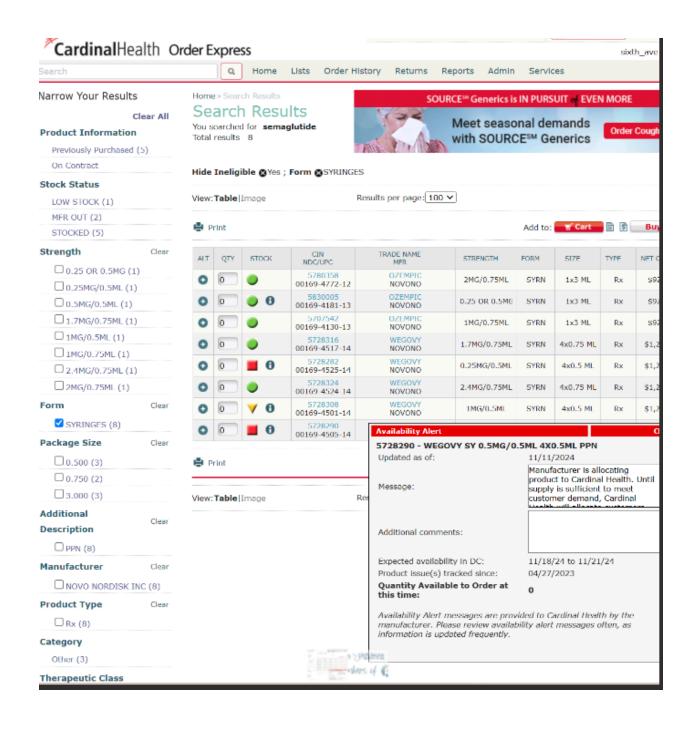
Tenille Davis, PharmD, RPh, BCSCP, FAPC

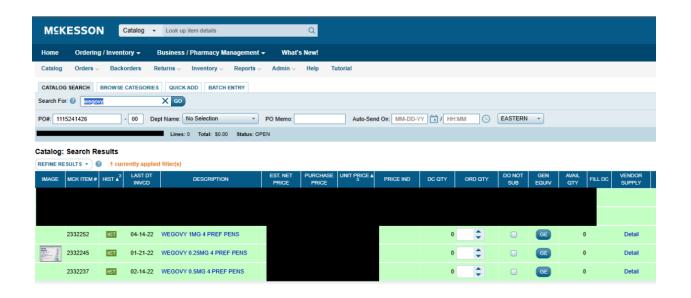
Chief Advocacy Officer

Alliance for Pharmacy Compounding

tenille@a4pc.org







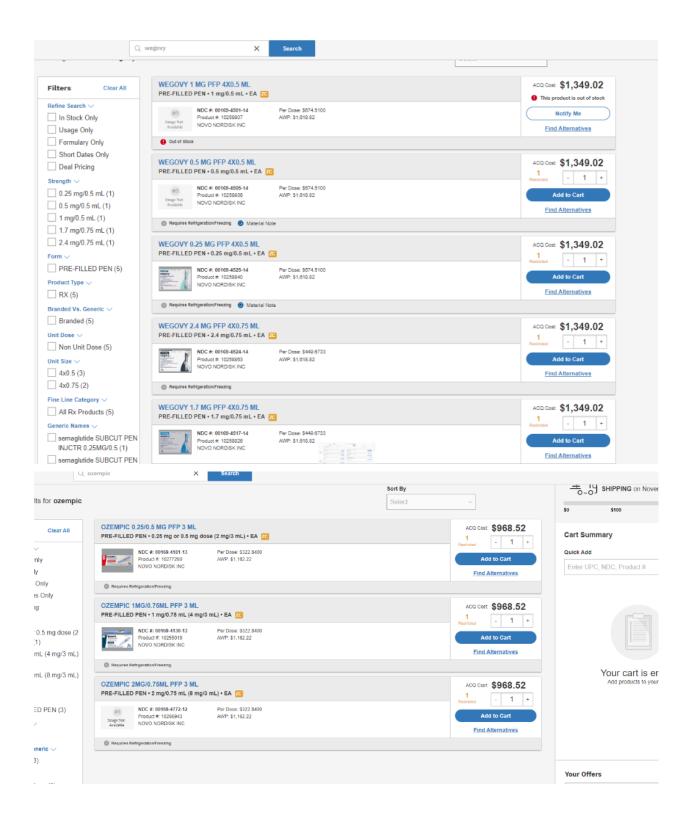


Catalog: Search Results



11/15/24

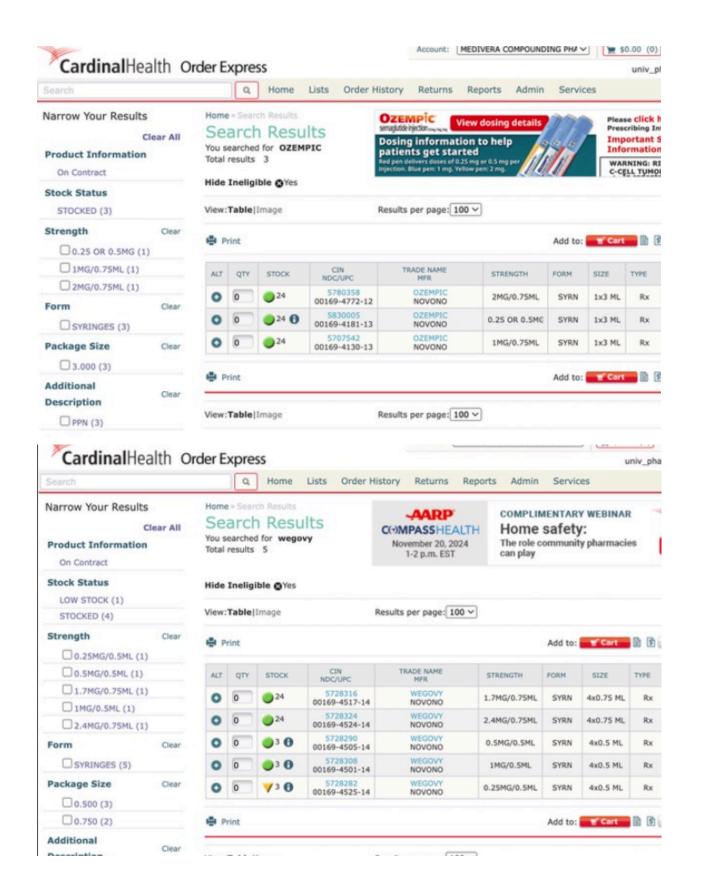
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earch	Requires refrigeration/freezing Material Note	
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	NOVO NORDISK INC	100+
Product Type	Requires refrigeration/freezing	



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orm Gran	0 0	5728 Kr8 00169-4501-14	WEGLIVY	1MG/0.5MS	SYRN	4x0,5 ML	Rv	-		100
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	Usage	Daily Max	Item	NDC/UPC	TE	Description ≑	Size ≑	Unit Cost ≑	Cost ≑	Avail ‡
•		4	940775	00169452514	NR	WEGOVY .25MG PREFILL PENS REFRIGERATED	4X.5 ML SOA	674.51	\$1,349.02	50+
•		4	940783	00169450514	NR	WEGOVY .5MG PREFIL PENS REFRIGERATED	4X.5 ML SOA	674.51	\$1,349.02	0
•		4	940759	00169451714	NR	WEGOVY 1.7MG PREFIL PENS REFRIGERATED	4X.75 ML SOA	449.6733	\$1,349.02	25+
•		4	940767	00169450114	NR	WEGOVY 1MG PREFIL PEN REFRIGERATED	4X.5 ML SOA	674.51	\$1,349.02	0
•		2	940742	00169452414	NR	WEGOVY 2.4MG PREFILL PENS REFRIGERATED	4X.75 ML SOA	449.6733	\$1,349.02	75+

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		12	977132	00169418113	NR	OZEMPIC .25MG PEN INJ 3ML REFRIGERATED	1X3 ML SOP	322.84	\$968.52	100+
•		15	935023	00169413013	NR	OZEMPIC 1MG SOL PEN INJ 4MG REFRIGERATED	1X3 ML SOP	322.84	\$968.52	100+
•		12	955617	00169477212	NR	OZEMPIC 8MG/3ML 1X3ML 2MG DOSE REFRIGERATED	1X3 ML SOP	322.84	\$968.52	0

	ITEM DESCRIPTION \$		SIZE \$	INV PR	RICE \$	PER UNIT	QTY
MAGE COMING SOON	WEGOVY SINGLE DOSE PENS 0.5MG NDC: 00169450514 Item: 805168 MFR: NOVO NORDISK	INJECTABLE PREFILLED PEN NET ■ * ■ ②	4	1	J		Notify me when this item is in stock
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MAGE COMING SOON	WEGOVY SINGLE DOSE PENS 1MG NDC: 00169450114 Item: 805170 MFR: NOVO NORDISK	INJECTABLE PREFILLED PEN NET □ ★ ☑ ②	4	-		=	Notify me when this item is in stock
wegoy wegoy companies companies companies by	WEGOVY SINGLE DOSE PENS 1.7MG NDC: 00169451714 Item: 805171 MFR: NOVO NORDISK	INJECTABLE PREFILLED PEN NET B * 200	4	J= "	-1	-	1 ADD Refrigerated Item: Ships Monday

Daily Max	Item	NDC/UPC	TE	Description \$	Size \$	Unit Cost\$	Cost \$	Avail \$	Note	Contract \$	Sched Class
4	940775	00169452514	NR	WEGOVY .25MG PREFILL PENS REFRIGERATED	4X.5 ML SOA			0	* c		B-RX
4	940783	00169450514	NR	WEGOVY .5MG PREFIL PENS REFRIGERATED	4X.5 ML SOA			0	* c		B-RX
4	940759	00169451714	NR	WEGOVY 1.7MG PREFIL PENS REFRIGERATED	4X.75 ML SOA			1	* c		B-RX
4	940767	00169450114	NR	WEGOVY 1MG PREFIL PEN REFRIGERATED	4X.5 ML SOA			0	* c		B-RX

Availability Alert 5728308 - WEGOVY SY 1MG/0.5ML 4X0.5ML PPN

Close X

Updated as of: 11/11/2024

Manufacturer is allocating product to

Message: Cardinal Health. Until supply is sufficient to meet customer demand,

Cardinal Health will allocate

customers based on a percentage of

Additional comments:

Expected availability in DC: 11/18/24 to 11/21/24

Product issue(s) tracked since: 05/03/2023

Quantity Available to Order at

this time:

0

Availability Alert messages are provided to Cardinal Health by the manufacturer. Please review availability alert messages often, as information is updated frequently.

Availability Alert Close X 5830005 - OZEMPIC SY0.25 OR 0.5MG 3ML PPN Updated as of: Product is in stock or in transit to Cardinal Health. Current Message: inventory may expire in less than 12 months as the manufacturer was previously shipping shorter dated Additional comments: Expected availability in DC: 11/05/24 to 11/19/24 Product issue(s) tracked since: 08/26/2024 Quantity Available to Order at 24 this time: Availability Alert messages are provided to Cardinal Health by the manufacturer. Please review availability alert messages often, as information is updated frequently.

The state of the s

Availability Alert Close X

5728282 - WEGOVY SY 0.25MG/0.5ML4X0.5ML PPN

Updated as of: 11/11/2024

Manufacturer is allocating short dated product to Cardinal Health.
Until supply is sufficient to meet customer demand, Cardinal Health

will allocate customers based on a

Best dating available is 05/31/2025

Additional comments:

Expected availability in DC: 11/18/24 to 11/21/24

Product issue(s) tracked since: 05/04/2023

Quantity Available to Order at

this time:

Message:

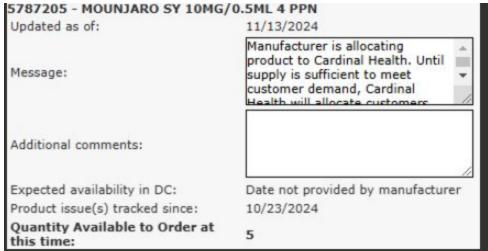
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Availability Alert messages are provided to Cardinal Health by the manufacturer. Please review availability alert messages often, as information is updated frequently.

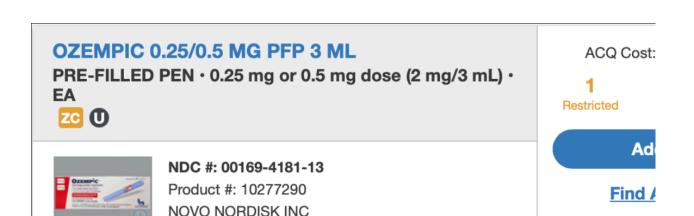
Availability Alert	Close X
5728290 - WEGOVY SY 0.5MG/0.	5ML 4X0.5ML PPN
Updated as of:	11/11/2024
Message:	Manufacturer is allocating product to Cardinal Health. Until supply is sufficient to meet customer demand, Cardinal Health will allocate
Additional comments:	
Expected availability in DC:	11/18/24 to 11/21/24
Product issue(s) tracked since:	04/27/2023
Quantity Available to Order at this time:	0
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728290 - WEGOVY SY 0.5MG/0					
Jpdated as of:	11/11/2024				
dessage:	Manufacturer is allocating product to Cardinal Health. Until supply is sufficient to meet customer demand, Cardinal Health will allocate customers				
Additional comments:					
expected availability in DC:	11/18/24 to 11/21/24				
Product issue(s) tracked since:	04/27/2023				
Quantity Available to Order at this time:	3				
Availability Alert messages are prov manufacturer. Please review availab					
5728308 - WEGOVY SY 1MG/0.	5ML 4X0.5ML PPN				
Updated as of:	11/11/2024				
Message:	Manufacturer is allocating product to Cardinal Health. Until supply is sufficient to meet customer demand, Cardinal Health will allocate customers				
Additional comments:					
Expected availability in DC:	11/18/24 to 11/21/24				
Product issue(s) tracked since:	05/03/2023				
Quantity Available to Order at this time:	3				
Availability Alert messages are no	wided to Cardinal Health hy the				
787197 - MOUNJARO SY 7.5MG					
Jpdated as of:	11/13/2024				
1essage:	Manufacturer is allocating product to Cardinal Health. Until supply is sufficient to meet customer demand, Cardinal				
Additional comments:					
expected availability in DC:	Date not provided by manufacturer				
Product issue(s) tracked since:	01/17/2024				
Quantity Available to Order at his time:	3				







OZEMPIC 1MG/0.75ML PFP 3 ML

PRE-FILLED PEN · 1 mg/0.75 mL (4 mg/3 mL) · EA



1 Restricted



NDC #: 00169-4130-13 Product #: 10255019

NOVO NORDISK INC

Ad

ACQ Cost:

Find A

ACQ Cos

OZEMPIC 2MG/0.75ML PFP 3 ML

PRE-FILLED PEN · 2 mg/0.75 mL (8 mg/3 mL) · EA ZC

4

Image Not Available NDC #: 00169-4772-12 Product #: 10266943

NOVO NORDISK INC

Restricted



