VIA ELECTRONIC DELIVERY

May 6, 2025

Stephen Astle
Director, Defense Industrial Base Division
Office of Strategic Industries and Economic Security
Bureau of Industry and Security
United States Department of Commerce

Re: Comments on Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients [Docket No. 250414-0065, XRIN 0694-XC120]

Dear Director Astle:

Novo Nordisk appreciates the opportunity to provide comments in regard to the Section 232 National Security Investigation of Imports of Pharmaceuticals and Pharmaceutical Ingredients. Novo Nordisk is a global healthcare company with a 100-year history of innovation, committed to preventing, treating, and ultimately curing diabetes, and to improving the lives of those living with other serious chronic conditions, including hemophilia, growth disorders, and obesity. While we are a global healthcare company, we have made significant and strategic investments in the United States, ensuring that we serve the American market with American product or product from our European allies.

As a pharmaceutical company with existing U.S. manufacturing operations, Novo Nordisk recognizes the importance of promoting U.S. production in the pharmaceutical sector and ensuring patient access to innovative products. Consistent with those goals, we are committed to not only maintaining production in the United States but also growing our U.S. manufacturing operations in the future. Given the complex and highly specialized nature of pharmaceutical supply chains, as well as the particular manner in which country of origin determinations are made for pharmaceutical products, tariffs on imports of Novo Nordisk's products and the inputs on which its U.S. manufacturing operations rely will result in severe supply chain disruptions and market instability. Such disruptions will hinder patient access to medication, increase prices of medications, and—by requiring us to divert resources to account for new tariffs—could significantly hamper and delay our continued and future investments in the United States, threatening economic harm and lost U.S. jobs. Accordingly, we strongly urge the Department of Commerce not to recommend the imposition of tariffs on these products.

Instead, we encourage the Department to take action to address the national security threat posed by certain other imports. While Novo has invested in America to ensure a secure supply chain, our U.S. operations face a growing threat from the rampant influx of active pharmaceutical ingredients (APIs) for weight loss medications from foreign sources, including unauthorized semaglutide from China. Such imports impede investments in the United States and constitute a threat to national security that urgently requires the Administration's attention.

Novo Nordisk is an American Success Story

Novo Nordisk has made a commitment to grow our ability to produce current and future injectable and oral treatments for Americans with obesity and other serious chronic diseases in America since 1993, with the establishment of our first manufacturing site in Clayton, NC. Over the last 10 years, facilitated by the corporate tax policy implemented through the 2017 Tax Cuts and Jobs Act, we have invested over $24 billion in the U.S. to expand manufacturing capacity and fuel R&D in 9 U.S. states, totalling 5.4M sq ft, with new investments in North Carolina, Virginia, and Indiana. Novo Nordisk employs approximately 10,000 people throughout the country, marking a 70% full-time employee growth since 2016. While other drugmakers chose to move operations overseas to countries such as Ireland, we have chosen to double-down in America.

This continued investment in America means that Novo Nordisk is a net exporter from the U.S. We export two-times as much API from the U.S. than we import, and the majority of the fill and finishing manufacturing is done in the U.S. as well. As our manufacturing capacity expands, our ability to make the products in this country that are used by Americans will continue to grow.

Our commitment to the U.S. remains strong and we hope to be able to continue our investments; however, as the Administration considers tariffs on the pharmaceutical sector, we urge the Administration to recognize the strength of the pharmaceutical supply chain and the need to ensure strategic geographic diversity.

NNI Supply Chain Is Secure and Robust

While much of our API is developed in and our medications are filled and packaged in the U.S., our manufacturing facilities in Denmark also provide material for medications used by Americans. However, our closed loop supply chain has many stringent protocols in place to ensure the authenticity and security of our products.

All semaglutide API imported into the U.S. comes from our manufacturing site in Denmark and is shipped directly to our facilities in Clayton, NC and Bloomington, IN. The shipper and receiver addresses are always a Novo Nordisk facility, ensuring the authenticity of the product. To maintain the integrity of the shipments, the consignee number and importer number on the shipping documentation are consistent for every shipment per location. We use approved and designated freight companies with one specific importer of record.

For air shipments, each pallet is wrapped, strapped, and edge-protected. The pallets are taken directly from the warehouse facility by the approved transport company and handed to trained airport handling staff, who place them securely in the aircraft. Upon arrival in the U.S., the containers are retrieved by the same transport company and sealed into a truck for delivery to our U.S. production facility. Similarly, for sea shipments, the transport company takes a sealed, temperature-controlled shipping container from our warehouse facility directly to the seaport, where it is loaded onto the freight carrier. The seal remains intact until it reaches our U.S. facility.

All pallets are wrapped, strapped, and edge-protected and placed in sealed seafreight containers to prevent tampering. If any damages occur during shipping, the product is quarantined until an investigation can determine where and how the damage took place. Customs & Border Protection generally reviews the shipping documentation, but occasionally opens a pallet, breaking the seal. The transport company reports any such incidents to Novo Nordisk, allowing us to ensure secured transport without risk of tampering.

Furthermore, all shipping seafreight containers and pallets on airfreight are temperature controlled and monitored by a tracker. Notable changes in temperature alert us to potential tampering or mishandling of pallets. **Our raw materials for API are sourced from vendors in Europe or the U.S., with only the finished API being imported into the U.S. No pharmaceutical ingredients are sourced from China or other foreign adversaries.**

While the Administration has expressed concern that U.S. citizens could be at risk of unsafe products or a disruption in access due to a national security threat, Novo Nordisk has implemented stringent security measures for all products shipped into the U.S. and can safely supply our products, either through our import process or through production in the U.S.

Our supply chain is not only secure but also robust and we are transitioning more production to the United States. Our U.S. investments to enhance our production capacity are yielding positive results, ensuring that our products remain readily available. However, additional tariffs imposed on pharmaceuticals transported through approved channels would hinder our investments, affecting our capacity and ultimately impacting patients' ability to access their medications.

At Novo Nordisk, we are committed to maintaining the uninterrupted availability of our medications. We understand that any disruption in access can have severe consequences for patients, affecting their health outcomes and quality of life. Our investments in secure and efficient supply chain systems are part of our broader commitment to the American market and to ensuring that patients receive the medications they need, when they need them.

Therefore, as the administration evaluates its tariff policies, we urge consideration of the ramifications on patient access. Protecting the integrity of our supply chain is crucial to ensuring that Americans continue to benefit from our high-quality pharmaceutical products without interruption. We strive to be a reliable partner in the healthcare system, dedicated to supporting the health and well-being of patients across the nation.

Foreign Illicit API Is the Real Threat to National Security and Should Be Prohibited

Novo Nordisk appreciates the Department's effort to assess the impact of API imports on national security. For this effort, we aim to inform the Department about a concern regarding American health and safety – the significant increase of illegal semaglutide that is not made by Novo Nordisk, not approved by the Food and Drug Administration (FDA), and is not intended for use in humans entering the country from foreign sources, such as China and being made widely available to U.S. citizens through unregulated compounding practices. [1]

[1] Marta Wosińska, "the Wild East of Semaglutide." Brookings. April 21 2025. The Wild East of semaglutide

Semaglutide is the foundational molecule that serves as the primary ingredient for Novo Nordisk's well-known, prescription only medicines: Rybelsus® (semaglutide) tablets to improve glycemic control in adults with type 2 diabetes, Ozempic® (semaglutide) injection to improve glycemic control in adults with type 2 diabetes and to reduce the risk of major adverse cardiovascular events ("MACE") in adults with type 2 diabetes and established cardiovascular disease, and Wegovy® (semaglutide) injection to reduce the risk of MACE in adults with established cardiovascular disease and either obesity or overweight or for chronic weight management in patients with obesity or adults with overweight.

Due to the groundbreaking health benefits of these products made possible through years of costly and innovative R&D, the demand for the semaglutide injection medications led to an FDA-declared shortage of Ozempic® and Wegovy® from March 2022 to February 2025. During this period, FDA permitted compounding pharmacies and outsourcing facilities to operate and produce fake versions of Novo Nordisk's brand name drugs. FDA's announcement of the shortage led to a significant increase of foreign companies marketing semaglutide in the U.S., "with little indication that they [were] doing so in support of generic drug applications".[2] Novo Nordisk is the only company that makes semaglutide, and any other version of it currently being marketed and used in the U.S. is from unapproved, unauthorized sources. From 2018 to 2020, two other companies, one European and one Chinese, entered the market with fake versions of semaglutide. As of September 2024, over 30 companies were marketing fake semaglutide, 60% of which are based in China.[3]

Novo Nordisk is the only manufacturer of semaglutide with FDA-approved applications and we manufacturer our API in the U.S. and import additional semaglutide API from Denmark. However, when the Brookings Institute reviewed the FDA's Import Trade Auxiliary Communication System (ITACS), they found that "[b]etween March 2023 and September 2024, 16 companies shipped semaglutide bulk to the U.S. across 159 shipments, of which 134 were allowed entry …The median shipment size was 51g, which might seem small, but 1g is equivalent to 4,000 starting doses of semaglutide."[4] The largest volume shipments were as high as 50kg."[5] As noted above, our semaglutide supply chain is a closed loop system. This trend has continued into 2025: as of April 15, 2025, at least 373.8kg of semaglutide API for use in compounding has been exported from China to the U.S. since the start of FY 2024, which is sufficient to make approximately 1.5 billion starting doses of semaglutide injection.[6] Therefore, shipments with an importer number different from Novo Nordisk are not for FDA-approved products and the product was never tested for use in humans.

FDA lacks sufficient oversight of manufacturers of semaglutide API in China that export to the U.S. Of the 19 establishments in China that have shipped semaglutide API to the U.S.

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[2] Partnership for Safe Medicines, Knockoff Weight Loss Drugs From Illegal Foreign Sources: An Analysis of Unauthorized Semaglutide and Tirzepatide Shipments Entering the U.S. With Urgent Recommendations to Protect the Safety Of Americans, *available at*: https://www.safemedicines.org/wp-content/uploads/2019/09/PSM-White-Paper-v1-PUBLIC-VERSION.pdf [hereinafter, "Partnership for Safe Medicines GLP-1 Report"].

[3] *Supra note 2*

[4] *Supra note 2*

[5] *Supra note 2*

[6] Food & Drug Admin., Import Trade Auxiliary Communications System, https://www.access.fda.gov/itacs/#/ (last visited Apr. 23, 2025).

for use in compounding or further manufacture between the start of FY 2024 and April 15, 2025, five are not even registered with FDA, and six of the establishments that are registered have not had a surveillance inspection by FDA. Additional reporting by the Partnership for Safe Medicines, found that 239 semaglutide and tirzepatide API shipments originated from unregistered facilities, 82% of which were allowed into the United States, and 18% of which "were explicitly marked as either 'Rx API for Compounding' or indicated for 'Further Manufacturing.'"[7] None of these shipments should have been allowed into the country for use in compounding. Compounded drugs using API from unregistered establishments is unlawful for good reason: the quality and safety of such APIs cannot be guaranteed. If FDA does not know that a foreign establishment is manufacturing APIs for the U.S. market, FDA will not know to inspect the establishment and monitor their compliance with current good manufacturing practices (CGMPs) and other requirements.[8]

Additionally, the Partnership for Safe Medicines found that product codes and paperwork accompanying foreign, non-Novo Nordisk sourced API presented for entry into our country contained numerous "red flags." For example, shipments listed unlikely manufacturers, such as a major hotel chain, a fitness center, and a public school in Canada.[9] Novo Nordisk's independent test purchases have revealed that most semaglutide is being imported into the country from Chinese API suppliers and these findings also highlight the unlawful tactics employed by these entities to mislead consumers regarding the nature and origin of their products. Test purchases have identified mislabeled items such as "White Pigment" on packaging or "Adhesive" on import documents. Novo Nordisk has even obtained illegal shipments from China claiming to be "semaglutide" that are deceptively packaged as kitten food and facial masks. These imports into the country continue despite not meeting federal requirements for API shipments.

Oversight by China regulators of manufacturers that export semaglutide API to the U.S. is also insufficient. Of the 19 companies in China that shipped semaglutide API to the U.S. for use in compounding or for further manufacture between the start of FY 2024 and April 15, 2025, only seven had drug manufacturing licenses for semaglutide API. Said differently, 12 of the 19 companies are considered not in compliance with GMP for semaglutide manufacturing and would not be able to distribute the semaglutide API they manufacture for use in human drugs within China—yet they are exporting to the U.S. In addition, six of the 19 companies have no public evidence of drug manufacturing licenses at all in China.[10]

This broad lack of oversight regarding semaglutide API imported into the U.S. for use in compounding, or directly to consumers for self-injection,[11] is concerning given the significant safety risks posed by these products to patients. Because this imported API is manufactured by chemical synthesis—rather than through recombinant DNA technology in yeast cells like the API in Novo Nordisk's FDA-approved drugs—different impurity profiles abound. Through testing, Novo Nordisk has identified peptide-related impurities, as well as unknown

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[7] *Supra note 2*

[8] GAO, Drug Safety: FDA Should Take Additional Steps to Improve Its Foreign Inspection Program (Jan. 2022) at 14, https://www.gao.gov/assets/720/718363.pdf.

[9] Partnership for Safe Medicines GLP-1 Report, *supra* note 5, at 14–16

[10] Nat'l Med. Prods. Admin., Data Search, https://www.nmpa.gov.cn/datasearch/home-index.html (last visited Apr. 15, 2025).

[11] See Novo Nordisk, Inc. v. Aesthetic Maison LLC, No. 4:24-cv-2036 (S.D. Tex., filed May 30, 2024).

impurities, in imported semaglutide API.[12] FDA has recognized that peptide-related impurities in peptide APIs and products can pose significant safety and immunogenicity risks to patients.[13] Major safety concerns with immunogenicity include anaphylaxis, cytokine release syndrome, and non-acute immune reactions.[14]

As the Partnership for Safe Medicines said, "Our analysis makes clear that President Trump's concerns about Chinese chemical companies going to great lengths to evade law enforcement and import illicit substances into the U.S. marketplace should extend beyond fentanyl to API that is being used in diabetes and weight-loss products sold to Americans every day."[15] Guided by our fundamental values that prioritize patient safety, we ask the Department to focus its investigation on imported semaglutide APIs from unauthorized sources to determine whether these illegal imports constitute a threat to national security. We expect the Department will reach a determination in the affirmative, finding that such imports pose serious risks to U.S. patients, violate U.S. trade laws, and undermine the U.S. manufacturing base. In that case, we would urge the Department to recommend action under Section 232 to properly identify and prohibit such imports.

Conclusion

We appreciate the Department's consideration of our comments and wish to reiterate Novo Nordisk's commitment to the American market and to ensuring Americans have access to our products. Nonetheless, there are significant threats that may hinder future investments in manufacturing CAPEX, people and research. We are particularly concerned about the impact of illicit semaglutide API on both our company and the safety of the American public. Individuals are injecting substances of questionable origin, resulting in emergencies due to overdoses or adverse reactions. This poses a serious threat to public health. We urge the Department to examine these entities importing API into the country and place tariffs on these entities or ban this practice altogether.

We look forward in working with the Department to further investigate these entities. For any additional information please feel free to contact me at JEDK@novonordisk.com.

Sincerely,

Jennifer Duck, Esq.
Vice President, Public Affairs

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[12] Morten Hach et al., Impact of Manufacturing Process and Compounding on Properties and Quality of Follow-on GLP-1 Polypeptide Drugs, Pharm. Rsch., Table IV at 7-8 (Oct. 8, 2024), https://link.springer.com/article/10.1007/s11095-024-03771-6.

[13] Food & Drug Admin., ANDAs for Certain Highly Purified Synthetic Peptide Drug Products that Refer to Listed Drugs of rDNA Origin: Guidance for Industry, at 7 (May 2021), https://www.fda.gov/media/107622/download; FDA, Immunogenicity Assessment for Therapeutic Protein Products, Guidance for Industry (Aug. 2014), https://www.fda.gov/media/85017/download

[14] Food & Drug Admin., Immunogenicity Assessment for Therapeutic Protein Products, Guidance for Industry (Aug. 2014), https://www.fda.gov/media/85017/download.

[15] *Id.* at 8.