Congress of the United States

Washington, DC 20515

January 14, 2026

Fujian Genohope Biotech Ltd.
No. 288, Renyang, Binglun Village,
Hushi Town, Xiuyu District, Putian City,
351146 Fujian Province,
P.R. China

Dear Mr. Helton Chang:

I write to inquire about illicit glucagon-like peptide 1s (GLP-1s) and associated active pharmaceutical ingredients (APIs) that are being manufactured in the People's Republic of China (PRC) and then shipped into the U.S. These drug products are commonly being used to make compounded GLP-1 injectable weight loss drugs that mimic Ozempic and Wegovy. This letter requests information regarding your company's manufacturing, exporting, and sale of GLP-1s, and the extent to which these activities may contribute to threats to public health. Counterfeit PRC injectable weight loss drugs not only compromise the security of the U.S. drug supply, but may put consumers at risk. PRC-based companies do not, and should not, enjoy an exemption from U.S. regulation.

The need for vigilance is clear. The FDA has received hundreds of reports of illicit compounded GLP-1s causing severe harm in patients.[1] It is possible that these reported cases are just the tip of the iceberg, as federal law does not require state-licensed pharmacies that are not outsourcing facilities to submit adverse events to FDA.[2] In February, the FBI issued a warning about the safety risks and significant health consequences associated with fraudulent compounded weight loss drugs, which include "gastrointestinal disorders, nervous system disorders, cardiac disorders, psychiatric disorders, and death."[3]

GLP-1 injectable weight loss drugs are used by millions of Americans in the United States. The demand for these treatments has at times exceeded supply, leading to national supply shortages. In March 2022, semaglutide injectable products (Ozempic and Wegovy) were added to the U.S. FDA Drug Shortages List, permitting pharmacies to create compounded products which are falsely marketed as exact copies of the patent-protected FDA-approved drugs.[4] PRC-based manufacturers have exploited these circumstances to market dangerous unregulated GLP-1 products that put unsuspecting American patients at risk.

It is estimated that millions of Americans are currently taking compounded GLP-1s that are not subject to the FDA's approval process, and a subset of these are counterfeits.[5] On April 14, 2025, the FDA confirmed the

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[1] U.S. Food and Drug Administration, "FDA's Concerns with Unapproved GLP-1 Drugs Used for Weight Loss," September available at: https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/fdas-concerns-unapproved-glp-1-drugs-used-weight-loss

[2] *Id*.

[3] Internet Crime Complaint Center (IC3). "Safety Concerns Related to Fraudulent Compounding Practices Associated with Weight Loss Drugs." Public Service Announcement I-022825-PSA, February 28, 2025 https://www.ic3.gov/PSA/2025/PSA250228.

[4] U.S. Food and Drug Administration, "Declaratory Order: Resolution of Shortages of Semaglutide Injection Products (Ozempic and Wegovy)." Declaratory Order, February 21, 2025. https://www.fda.gov/media/185526/download.

[5] Kate Knibbs, "The Crackdown on Compounded GLP-1 Meds Has Begun," Wired, October, 10, 2024, https://www.wired.com/story/crackdown-compounded-glp-1-lilly-mounjaro-zepbound/

presence of such semaglutide products in the U.S. supply chain.[6] These versions of GLP-1 injectable weight-loss drugs often contain unauthorized semaglutide and tirzepatide, or their component APIs, that were produced and exported from the PRC. A recent study found that following the FDA's 2022 declaration of a semaglutide and tirzepatide shortage, there was a massive increase in PRC-based companies manufacturing semaglutide and tirzepatide to be imported into the U.S.[7] This study also found that less than a quarter of all PRC facilities marketing semaglutide bulk have been inspected by FDA since they began manufacturing the product, and approximately 60 percent of such PRC facilities were not registered with the FDA at all prior to the 2022 semaglutide and tirzepatide shortage announcements.[8] Some have expressed the additional concern that certain PRC manufacturers are intentionally misrepresenting their semaglutide, tirzepatide, and API products as having obtained certifications which they have not obtained, and are deliberately mislabeling products to bypass importation inspections.

Despite the FDA declaring an end to the semaglutide shortage on February 21, 2025, the presence of PRC GLP-1s in the U.S. continues to grow. Ensuring that Americans have access to safe and reliable medicines is a top priority for Congress and any PRC manufacturing that potentially puts patients at risk deserves scrutiny. As such, please respond to the following questions and produce all responsive documents by no later than January 31, 2026.

1. Please provide a full list detailing all semaglutide and tirzepatide products and associated APIs you manufacture, sell, and ship to customers in the U.S.
2. Please provide a comprehensive list of retailers in the U.S. that you supply (including any retailers supplied by your customers).
3. Please describe your business relationship(s) with U.S.-based compounding companies and other U.S.-based customers.
4. Please describe your company's practices used for labeling semaglutide and tirzepatide products and associated API that are imported into the U.S.
    a. Have you ever labeled any of your semaglutide and tirzepatide products "for research use only," "not for human use," "animal-grade," or any other sort of similar labels that might indicate the product is not intended for human consumption?
    b. If yes, how many instances are you aware of such labeling?
    c. Please provide a full list of orders from the past 12 months that contain semaglutide or tizepatide products and/or associated APIs that were labeled with any of the aforementioned labels.
5. Please describe any agreements made with U.S.-based compounding companies regarding labeling of semaglutide and tirzepatide shipped into the U.S.
6. Please describe the manufacturer safety assurance procedures your company uses to monitor any and all facilities where semaglutide and tirzepatide and associated APIs are manufactured.

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[6]U.S. Food and Drug Administration, "FDA Warns Consumers Not to Use Counterfeit Ozempic (semaglutide) Found in U.S. Drug Supply Chain." News Release, April 14, 2025. https://www.fda.gov/drugs/drug-safety-and-availability/fda-warns-consumers-not-use-counterfeit-ozempic-semaglutide-found-us-drug-supply-chain. FDA warns consumers not to use counterfeit Ozempic (semaglutide) found in U.S. drug supply chain | FDA

[7] Marta Wosińska, "The Wild East of semaglutide," Brookings, April 21, 2025, https://www.brookings.edu/articles/the-wild-east-of-semaglutide/.

[8] *Id*.

7. Please describe the safety and quality testing procedures your company uses for all manufactured semaglutide and tirzepatide products and associated APIs.
8. Please produce your company's drug manufacturing license in the PRC.
9. Please produce your company's registration, if applicable, with the U.S. FDA.
    a. In the preceding 36 months, how many times has the U.S. FDA inspected your facilities?
    b. Please provide any U.S. FDA issued Form 483s or U.S. FDA warning letters your company has received.
10. Please describe any subsidies, funding, or other benefits your company receives from any government entity in the PRC.

Thank you for your attention to this matter.

Sincerely,

Raja Krishnamoorthi
Ranking Member
House Select Committee on the CCP