

United States Senate

WASHINGTON, DC 20510

October 14, 2026

Kyle Diamantas
Acting Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Mr. Diamantas:

Online drug and active pharmaceutical ingredient (API) vendors are increasingly exploiting the “for research use only” labeling authority to make illicit profits selling drugs that have not been approved or even evaluated yet by the FDA. We are concerned that “for research use only” has become a dangerous loophole that undermines the FDA’s authority.

As you know, “for research use only” drug compounds are intended solely for laboratory research and are not intended for human therapeutic or clinical use. They are not FDA-approved for human use, are not subject to usual Current Good Manufacturing Practices, and not subject to quality-control or stability-testing requirements. As a result, they are vulnerable to contamination, impurity, mislabeling, and misuse.

Misuse of “for research use only” labeling authority is fostering gray and black markets on the internet. The wide availability of knockoff retatrutide illustrates the risks. Retatrutide is an investigational drug, currently in phase 3 clinical trials, that has demonstrated potential to promote weight loss and improve knee pain, lower back pain, and sleep apnea, among other ailments. It has not been approved by the FDA. Yet, many online vendors are already selling poor-quality retatrutide to Americans, and many of these companies source their APIs from unregulated manufacturers in China. This has dangerous consequences. America’s Poison Centers reported a 265% increase in poisonings related to illicit retatrutide in the first four months of 2026 compared to the last four months of 2025.

The FDA has issued warning letters to at least seven companies for marketing retatrutide “for research use only” while simultaneously promoting it to the general public to treat obesity, diabetes, and other human uses on their websites and social media. The FDA has also issued warning letters to more than a dozen other companies for selling unapproved retatrutide, lacking adequate directions for use, and making false or misleading claims. In some cases, products marketed as retatrutide contain no retatrutide at all, evidenced by federal charges against a Florida seller earlier this year.

We commend the FDA’s enforcement efforts, but we urge you to work more closely with U.S. Customs & Border Protection and other law enforcement agencies to take these illicit drugs off the market and hold the companies selling them accountable. Their foreign supply chains rely on concealment, falsified paperwork, and deliberately mislabeled shipments to evade customs detection. These are all crimes in their own right. Stronger security at ports of entry, more investigations of affiliated companies, and prosecutions are badly needed.

We respectfully request a briefing on the “for research use only” labeling authority and the FDA’s enforcement strategy, covering the following topics:

- 1) The FDA’s assessment of the extent of use, misuse, and trends in the “for research use only” labeling authority.
- 2) The FDA’s coordination with Customs & Border Protection and other federal, state, and local law enforcement agencies to identify and interdict illicit drugs and APIs.
- 3) The FDA’s capacity to identify, investigate, and take enforcement action against API and drug vendors that evade or break the law.

Thank you for your leadership on this important issue.

Sincerely,



Jim Banks
U.S. Senator for Indiana



Martin Heinrich
United States Senator



Ted Budd
United State Senator



Adam B. Schiff
United States Senator



Tom Cotton
United States Senator



Andy Kim
United States Senator



David H. McCormick
United States Senator



Jon Husted
United States Senator



Todd Young
United States Senator