The Partnership for SAFEMEDICINES®

March 14, 2025

U.S. Customs and Border Protection
Office of Trade
Regulations and Rulings
90 K Street NE, 10th Floor
Washington, DC 20229-1177

Re: Docket Nos. USCBP-2025-0002 & USCBP-2025-0003

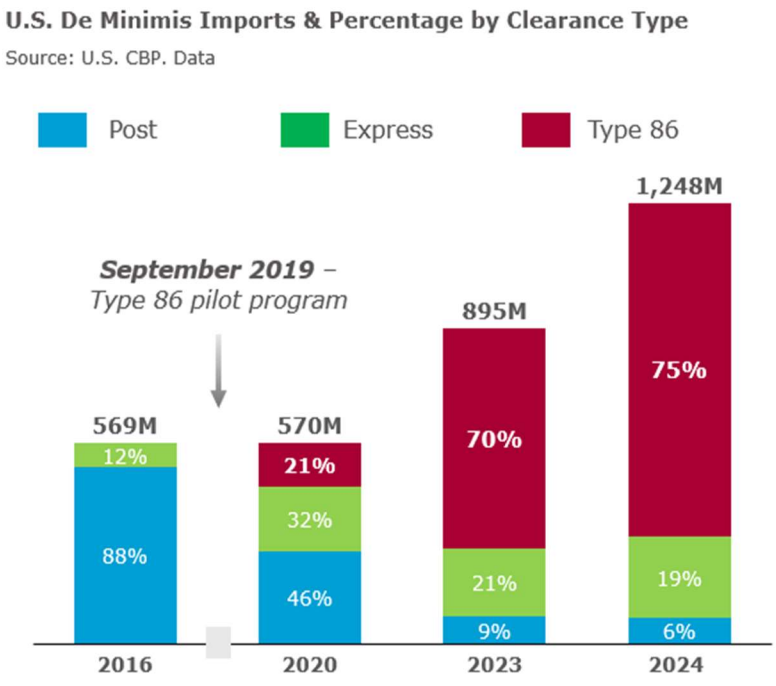
Dear Sir/Madam:

The Partnership for Safe Medicines (PSM) appreciates the opportunity to comment on Customs and Border Patrol's (CBP) proposed rules USCBP-2025-0003 and USCBP-2025-0002, which seek to enhance trade enforcement, prevent tariff evasion, and improve security screening for low-value shipments. Both rules address critical gaps in De Minimis shipment processing and are essential for protecting U.S. trade policies, national security, and legitimate businesses. However, certain refinements are necessary to maximize the effectiveness of enforcement while minimizing undue burdens on compliant trade participants.

PSM is a public health coalition committed to the safety of prescription drugs and protecting consumers against counterfeit, substandard, and otherwise unsafe medicines. We work with a broad coalition of stakeholders to promote policies that **prioritize American patient safety, promote the integrity of our American pharmaceutical supply chains and protect our pharmaceutical border security**.

The current regulations for De Minimis shipments and the Type 86 Entry Pilot have resulted in a flood of uninspected low value shipments into the United States. As CBP points out in its rule-making proposal, De Minimis shipments have increased from 139 million in 2015 to nearly 1.3 billion of small De Minimis parcels mostly facilitated by Type 86 entry environment.

The growth in De Minimis, Type 86 entries, raises significant concerns about increases in the entry of counterfeit medicines. Counterfeit medicines pose a serious threat to public health and safety, and to national security, as they often contain incorrect ingredients, improper dosages, or harmful substances. Combatting illicit criminal networks and drug cartels peddling counterfeit medicines and fake pills to Americans is critical to **protecting our pharmaceutical border security.**



Figure

Counterfeiting growth has been spurred by several things, including an increasing volume of drugs, longer supply chains, drug shortages, the development of technologies that make it easier to counterfeit drugs, and the involvement of international organized crime. This growth is exacerbated by the relatively low criminal penalties

for distribution of adulterated, unapproved or misbranded drugs under the Federal Food, Drug and Cosmetic (FD&C) Act compared to other types of crime.

These illicit products often contain incorrect or harmful ingredients, are improperly dosed, or are falsely labeled. In the United States, counterfeit drugs have infiltrated our secure supply chain, endangering patients and undermining trust in the healthcare system. Mexican drug cartels smuggle millions of these pills over the border, and the U.S. also has homegrown traffickers who import ingredients and pill presses from China and manufacture their own deadly pills. While Americans are unfortunately familiar with deaths related to counterfeit pills laced with fentanyl, other counterfeit medicines (such as counterfeit oncology, HIV, blood thinners, and diabetes and obesity medicines) also pose significant threats to public health.

We believe the proposed rules are a step in the right direction to address this issue and offer several suggestions for your consideration to enhance the enforcement against counterfeit medicines stemming from De Minimis and the Type 86 entry environment.

PATIENT SAFETY DANGERS POSED BY WEAK PHARMACEUTICAL BORDER SECURITY

Every day, Americans are protected by seizures conducted by CBP, FDA, and DEA staff. Counterfeit, adulterated, and substandard medical goods and medicines trafficked into the U.S. via De Minimis shipments and Type 86 entry pose a serious threat to consumer and patient safety, and seizures of these dangerous goods are the pinnacle of protection of Americans.

PSM often celebrates these seizures in our coverage of counterfeit and unapproved medical products. Beyond the obvious danger of illicit opioids and controlled substances, the dangerous products identified below explain why these reforms are so important to the safety of American patients.

Counterfeit therapeutic medicines

Fake therapeutic medicines are not just dangerous because of what's in them; they are often dangerous because of what isn't in them. Below are examples of counterfeit anticoagulants purchased in Mexican pharmacies and brought to the U.S. These medicines didn't contain fentanyl or any other dangerous substance. They were deadly to the Americans that bought them because the purchasers needed medicine to prevent blood clots.

These medicines were placebos that contained no medicine at all. The counterfeits were good enough that patients would not have been able to detect their fake nature without lab testing. Americans sometimes attempt to buy these illegally from foreign websites, but medicines that treat serious conditions like this should never be allowed to be imported to the U.S. by individuals.

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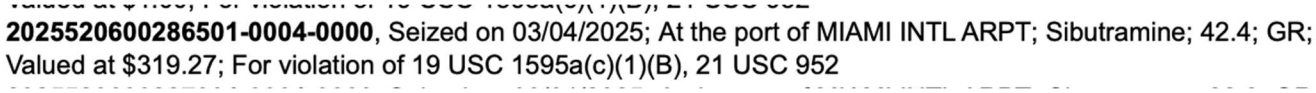
Unapproved, Dangerous Medicines

In March 2025, CBP inspectors working at the Miami International Airport seized sibutramine, an unapproved medicine withdrawn from the market in 2010 because it increased the risk of cardiovascular events. Americans are protected when the FDA's post-market pharmacovigilance programs detect dangerous side effects in medicine on the market.



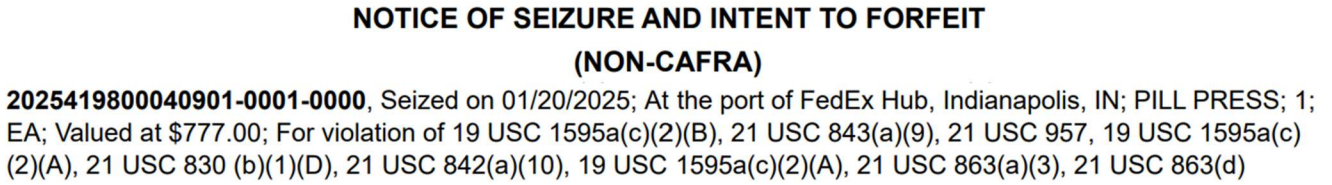
2025520600286501-0004-0000, Seized on 03/04/2025; At the port of MIAMI INTL ARPT; Sibutramine; 42.4; GR; Valued at $319.27; For violation of 19 USC 1595a(c)(1)(B), 21 USC 952

Excerpt from public seizure notice

Americans taking these medicines have been sold them by illegal vendors practicing pharmacy without a license and endangering Americans for their own profit.

Machinery used in the manufacturing of fake medicines, both controlled and non-controlled

While pill presses are well-known as tools for making illegal opioids, they are also critical for making counterfeit therapeutic medications. These machines are very difficult to detect and we are grateful when CBP intercepts them, as they did at the FedEx Hub in Indianapolis, in January 2025.



NOTICE OF SEIZURE AND INTENT TO FORFEIT

(NON-CAFRA)

2025419800040901-0001-0000, Seized on 01/20/2025; At the port of FedEx Hub, Indianapolis, IN; PILL PRESS; 1; EA; Valued at $777.00; For violation of 19 USC 1595a(c)(2)(B), 21 USC 843(a)(9), 21 USC 957, 19 USC 1595a(c)(2)(A), 21 USC 830 (b)(1)(D), 21 USC 842(a)(10), 19 USC 1595a(c)(2)(A), 21 USC 863(a)(3), 21 USC 863(d)

Excerpt from public seizure notice

All these examples show just how important CBP's work is, and how increasing resource support and tightening regulations as we recommend below will protect American patients.

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COMMENTS ON PROPOSED DRAFT RULE CBP-2025-003:

1. New Entry Process for Low-Value Shipments
We support the rule's overall goal to improve CBP's ability to **target high-risk shipments**, particularly those containing **illicit fentanyl and synthetic opioids**. We especially support the introduction and requirement of Advanced Electronic Data (AED) requirements for all shipments, including small parcels and De Minimis shipments. We think it will be crucial to require these **additional / new data collection requirements** to ensure compliance with all laws and regulations of low-value shipments.

As an improvement, we recommend requiring receipt of the same pre-arrival AED collection across all entry methods to enable interdiction and targeting of illicit goods and fentanyl. This needs to include small parcel shipments and De Minimis shipments. No packages should enter the United States without Advanced Electronic Data.

We oppose and are concerned that CBP appears to want to expand on the Entry Type 86 Test, since it has single-handedly resulted in a significant increase in low-value shipments (see Figure 1). We think Type 86 needs serious reform. In our opinion Type 86 entry, since it is a pilot program, never went through the proper rule-making process and should be suspended until it can be re-evaluated through regular rule making.

We recommend **suspending the Type 86 test program and reverting to previous practices** until it can be evaluated with proper rule making process. CBP should return to screening and clearing goods as it did four years ago, which will prevent foreign e-commerce platforms from using this channel for shipments that do not comply with laws and regulations. Most importantly, it will suppress the entry of counterfeit products, including and especially counterfeit medicines. This would ensure that imports from foreign e-commerce platforms go through the informal/formal entry process to ensure consumer safety and compliance.

2. Additional Data Requirements for Low-Value Shipments
We support CBP's attempt to **enhance screening** of shipments by collecting more **detailed shipment data** in advance through submission of AED **requiring importers to provide more information about the contents, origin, and destination** of shipments to better assess risk. This data needs to include **product identifiers** and a **security screening report number**.

We recommend that CBP require **verifiable transactional data** from sellers and platforms to prevent **manipulated shipment values**. We also recommend that AED requirements should expand product descriptions to include **detailed SKU, brand, and classification verification**.

Furthermore, CBP has an opportunity to implement **AI-driven technologies and audits** to expedited screening processes and detect counterfeits more easily, which will also allow for additional analysis for suspicious undervaluation trends.

CBP also has an opportunity to require and ensure **real-time data exchange** between CBP and Partner Government Agencies (PGA) for better tracking. CBP should require **advanced electronic PGA data submission** for regulated products, as it does in cargo shipping environments. This will allow CBP to flag **high-risk shipments for manual review** before release.

3. Crackdown on Misuse of Duty-Free Exemptions

We support CBPs requirement to prevent **splitting orders** into multiple shipments to avoid duties. We think this will allow for better detection of shipments of higher value items used for counterfeit medicines, such as pill press / tableting machines. We also support CBPs clarification and re-establishment of the one-to-one relationship for all De Minimis shipments, so that **if one person imports multiple low-value shipments exceeding $800 in one day**, all shipments must be **formally entered** and will not qualify for duty-free treatment. We reiterate our call to suspend Type 86 entry, since it will be nearly impossible to enforce this requirement in the Type 86 entry requirement, where bundled shipments are entered en masse.

4. Stronger Screening for E-Commerce & Express Shipments
We are elated that CBP recognizes that a significant portion of low-value shipments are **e-commerce** purchases, which may be exploited for illegal importation. We support CBPs requirements to **track e-commerce transactions and participants (sellers, buyers, and delivery parties)** more closely.

In addition, we recommend maintaining a **Restricted Importer List** for repeat violators, as well as requiring detailed **seller identification for e-commerce shipments** to increase accountability. Finally, CBP has an opportunity to propose and enforce **stricter penalties** for fraudulent misclassification.

5. Targeting High-Risk Shipments
PSM is appreciative of and agrees with CBPs assessment that transnational criminal organizations **exploit** the current rules to smuggle illicit drugs and counterfeit goods. As PSM has extensively documented, counterfeit medicines virtually exclusively enter the United States in the small parcel environment, utilize the De Minimis loophole, and are likely often cleared through the Type 86 entry method.

We support CBPs proposal for CBP to have the authority to **deny duty-free entry** if:

- The shipment lacks sufficient data.
- It is deemed high-risk for containing **illegal substances, counterfeit goods, or non-compliant products**.

6. Updated Compliance & Enforcement Rules
We support CBPs proposal to clarify **who is responsible for compliance**, ensuring that importers, brokers, and carriers are properly identified. We believe that CBP should mandate that all shipments adhere to the high compliance standards currently in place for cargo environments and commercial express carriers. This should extend to all entry methods, including the United States Postal Service.

We also support CBPs proposal to **deny or revoke exemptions** if there is evidence of abuse or fraud.

7. Improve Processing Efficiency & Risk-Based Screening
Reviewing the rule, we believe CBP has an opportunity to leverage technological advancements and implement **AI-driven targeting** to focus resources on **high-risk shipments**. This would likely drastically increase the number of shipments that can be screened and inspected and flagging of suspicious shipments for secondary inspections.

We recommend that CBP establishes a **Trusted Importer Program** for small parcel shipments to expedite compliant shipments. Such a program, which would mirror the one in the Cargo environment with CTPAT, would allow certified shippers to quickly import small parcel and compliant De Minimis shipments. Such a program would likely need to be a foundation for any Type 86 program; only Trusted Importers could utilize Type 86 entry.

COMMENTS ON PROPOSED DRAFT RULE CBP-2025-002

PSM is not an economics expert, so we will limit our comments on the impact of the proposed rule on counterfeit products.

1. Exclusion of Certain Goods from De Minimis

We support the recommendation to exclude goods subject to Section 232, 201, and 301 tariffs from De Minimis eligibility. The De Minimis rule **was never intended to exempt goods subject to national security or trade measures**. Traffickers of counterfeit medicines have exploited the De Minimis loophole through misdeclaration. Given that counterfeit medicines pose a threat to public health and safety, and therefore national security, we strongly support this measure.

We believe that the requirement for a 10-digit HTSUS classification is an important step in ensuring proper enforcement, and that CBP should provide transition guidance and compliance assistance to small businesses and importers.

2. Addressing USPS & International Mail Challenges:

CBP has requested comments on whether USPS and international mail carriers should be included in these new requirements. We strongly believe they should be. In 2018, the Senate passed the STOP Act to require AED for all mail shipments coming into the United States. From conversations with CBP officials and reports, it is our understanding that this requirement is still not fully implemented.

This rule making is CBPs opportunity to correct this issue and require immediate compliance with AED requirements, which USPS has had nearly ten years to implement. CBP should propose and require an aggressive phased plan that ensures full compliance within the year and refuses entry for all shipments lacking the required AED.

Additionally, CBP should collaborate with USPS to establish a risk-based screening framework that prioritizes high-risk shipments from certain countries, areas, and shippers similar to targeting efforts executed in the cargo environment.

FURTHER CONSIDERATIONS:

As CBP considers stakeholder feedback on the proposed rule to improve its ability to protect Americans from counterfeit and illicit substances entering via international mail shipments, PSM urges you to keep in mind the following key concerns:

1. **Increased Risk of Counterfeit Medicines:** Counterfeit medicines currently enter the United States at unprecedented rates in the De Minimis, small parcel and postal environment facilitated by Type 86 entry. Any loosening of requirements or continuation of the flawed Type 86 pilot endanger everyday Americans. Counterfeit medicines often contain harmful substances such as toxic chemicals, incorrect doses, or no active ingredients at all. They can cause severe health complications, including poisoning, treatment failure, and even death.

2. **Public Health Implications:** The presence of counterfeit drugs in the market undermines public trust in the healthcare system and poses a substantial risk to patient safety. CBP should rapidly implement these more stringent requirements and suspend the Type 86 pilot immediately to lessen potential impacts on public health. CBP needs to be very concerned about rules or programs that increase the volume of low-value shipments that enter the country with less oversight.

The economic burden of counterfeit medicines is also significant, as they cause ineffective treatments, increased healthcare costs, and loss of productivity. Moreover, counterfeit medicines can contribute to the development of antimicrobial resistance, making it harder to treat infections and diseases.

3. **Need for Enhanced Screening and Enforcement:** We urge CBP to implement robust screening and enforcement mechanisms to prevent the entry of counterfeit medicines. The proposed rule introduces an enhanced entry process that requires additional data elements for low-value shipments.

   We also recommend leveraging advanced technologies and data analytics to enhance the detection of counterfeit shipments. Enhanced screening protocols are essential to ensure that counterfeit medicines are identified and intercepted before they reach consumers, thereby protecting public health and safety.

4. **Illegal Pill Presses:** The proliferation of illegal pill presses is a significant concern in the context of counterfeit medicines. Criminals used these machines, which can be easily purchased online, to manufacture counterfeit pills that often contain dangerous substances like fentanyl. We believe that the implementation of both rules, paired with a suspension of Type 86 Entry, could dramatically improve detection, seizure and destruction of illegally imported pill presses and related equipment. Illegal pill presses enable counterfeiters to produce large quantities of fake medicines quickly and cheaply, increasing the risk to public health.

ADDITIONAL RECOMMENDATIONS:

- **Strengthen Drug Supply Chain Security and Screening Protocols:** Enhance screening protocols for low-value shipments to ensure that counterfeit medicines are identified and intercepted before they reach consumers. This may include more stringent tracking and verification requirements for pharmaceutical products, random sampling, targeted inspections, and the use of advanced detection technologies.

- **Increase Penalties for Counterfeit Drug Offenses:** Congress should impose harsher penalties on individuals and organizations involved in the manufacture, distribution, and sale of counterfeit medicines. This includes imposing stricter penalties for those found in possession of illegal pill presses used to manufacture and distribute mass quantities of counterfeit pills. By increasing penalties, CBP can help prevent the importation and use of illegal pill presses, reduce the production of counterfeit medicines, and protect public health.

- **Increase Collaboration:** Foster greater collaboration between CBP, FDA, and other relevant agencies to share information and resources for identifying and preventing the entry of counterfeit medicines. Joint efforts can significantly improve the effectiveness of enforcement actions. Collaboration allows the pooling of resources and expertise, leading to more effective identification and interception of counterfeit medicines.

- **Public Awareness Campaigns:** Launch public awareness campaigns to educate consumers about the risks of counterfeit medicines and the importance of purchasing medications from reputable sources. Increased awareness can help reduce the demand for counterfeit drugs and protect public health. Public awareness campaigns are vital because they inform consumers about the dangers of counterfeit medicines and encourage them to make safer purchasing decisions.

In conclusion, we support CBP's proposed rules and have offered considerations, recommendations and improvements, as it is imperative to stop De Minimis shipments and Type 86 entries from compromising the safety of the U.S. drug supply. We urge CBP to consider the potential risks associated with counterfeit medicines

and to implement the proposed and recommended measures to safeguard public health and strengthen **our pharmaceutical border security**.

By protecting the efficacy of our pharmaceutical supply chain, the Administration has an opportunity to bolster our p**harmaceutical border security**, protect Americans from illicit Chinese actors and Mexican drug cartels who traffic in illicit drugs and counterfeit pharmaceuticals, and put America first by ending reliance on foreign adversaries for our own health and safety.

Thank you for considering our comments. We look forward to continued collaboration to ensure the safety and integrity of the U.S. prescription drug supply chain.

Sincerely,

Shabbir Safdar
Executive Director
The Partnership for Safe Medicines

About Us: PSM is a public health group committed to the safety of prescription drugs and protecting consumers against counterfeit, substandard or otherwise unsafe medicines. Comprised of more than 45 non-profit organizations, PSM studies counterfeit drug crime, threats to American patients, and educates the public, policymakers, and health care professionals about threats to the safety of the U.S. drug supply.

cc: Pam Bondi, Attorney General, Department of Justice
The White House Office of National Drug Control Policy
The U.S. Drug Enforcement Administration