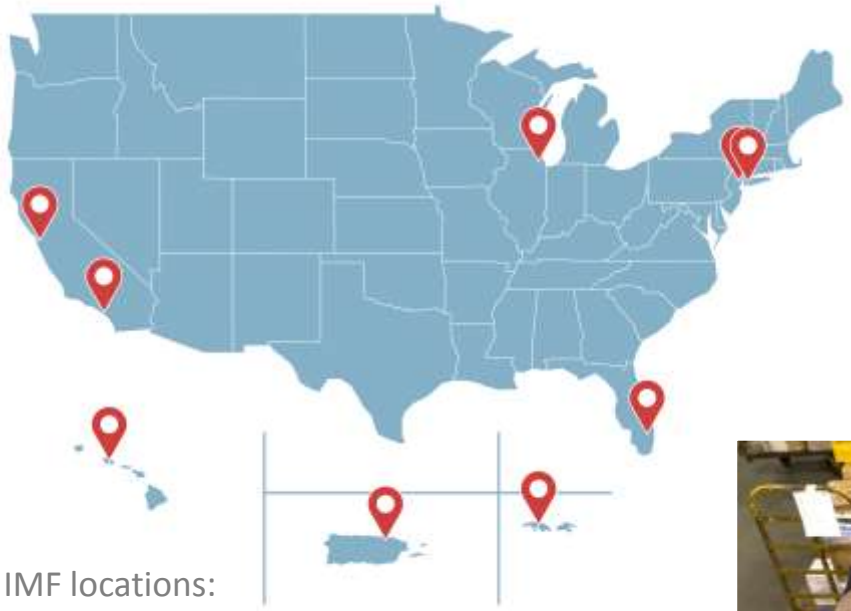
U.S. Food and Drug Administration and the International Mail Facilities

The fight to keep illegal, unapproved, counterfeit and potentially dangerous drugs from entering the United States

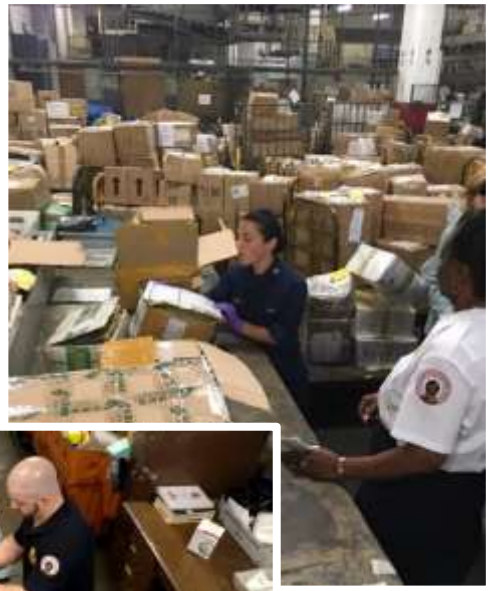
Updated April 2019

The FDA's presence at the International Mail Facilities (IMF) helps provide a front line defense against illegal, unapproved, counterfeit and potentially dangerous drugs from entering the United States. With staff assigned to all nine IMFs throughout the U.S., Puerto Rico and the U.S. Virgin Islands, FDA investigators are responsible for monitoring mail importations of FDA regulated products by conducting comprehensive examinations of packages suspected to contain drugs to determine if those drugs should be refused delivery to the U.S. consumer.



IMF locations:

- Los Angeles, CA
- San Francisco, CA
- Doral, FL
- Honolulu, HI
- Chicago, IL
- Jamaica, NY
- Jersey City, NJ
- Hato Rey, Puerto Rico
- St. Thomas, U.S. Virgin Islands



Packages for FDA review at JFK IMF

The IMFs receive international mail from more than 180 countries, which often lack advance information regarding the content of the packages that would aid in targeting shipments that are likely to contain illegal, unapproved, counterfeit and potentially dangerous drugs. How large is the scope of the problem? There's no way for the FDA or any federal agency to know. But 87% of the packages that the FDA has reviewed contain illegal, unapproved, counterfeit and potentially dangerous drugs.

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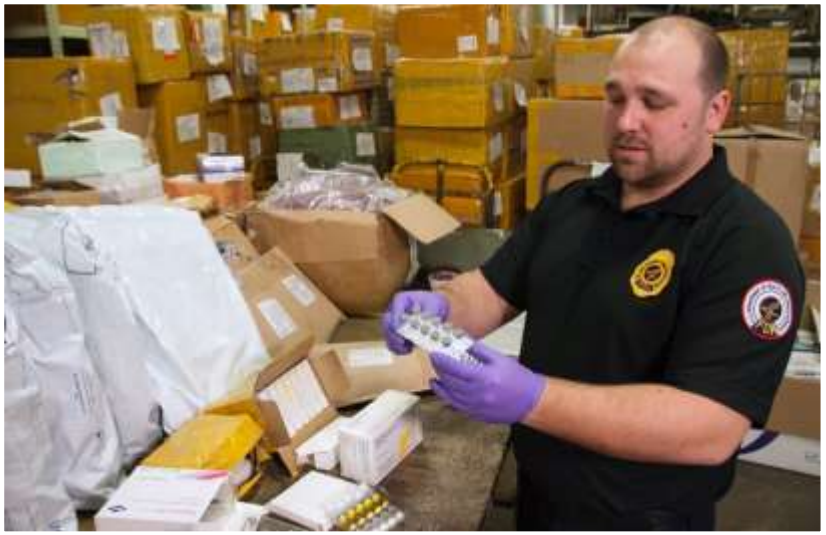
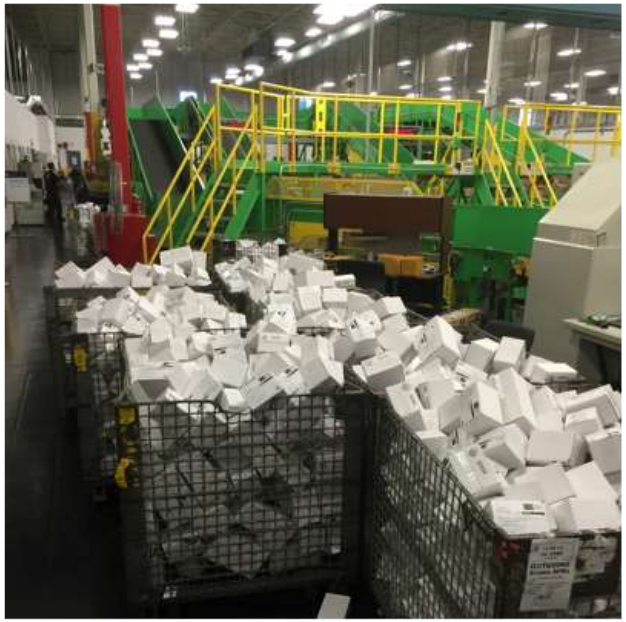


Hormones found at JFK IMF

Packages that are sent through private carriers require the submission of electronic data that helps Customs and Border Protection (CBP) target specific dangerous shipments, helping to intercept illicit and illegal drugs. However, most foreign postal services do not currently provide advance electronic information (AEI) on international mail shipments, a vulnerability that is increasingly exploited by bad actors. The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment for Patients and Communities Act (SUPPORT Act), signed into law on October 24, 2018, requires that, by December 31, 2020, AEI be submitted for all international mail shipments.

Numerous individual packages from single supplier



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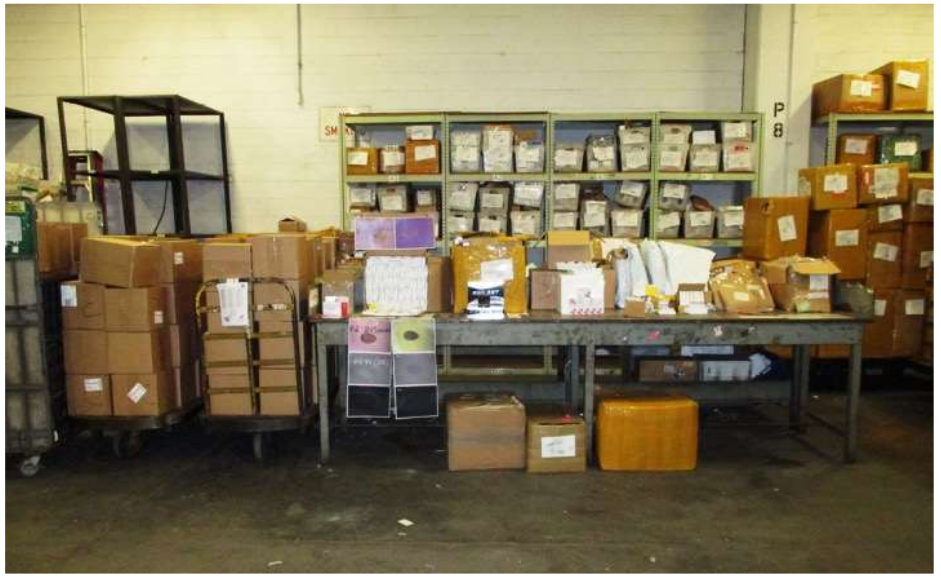
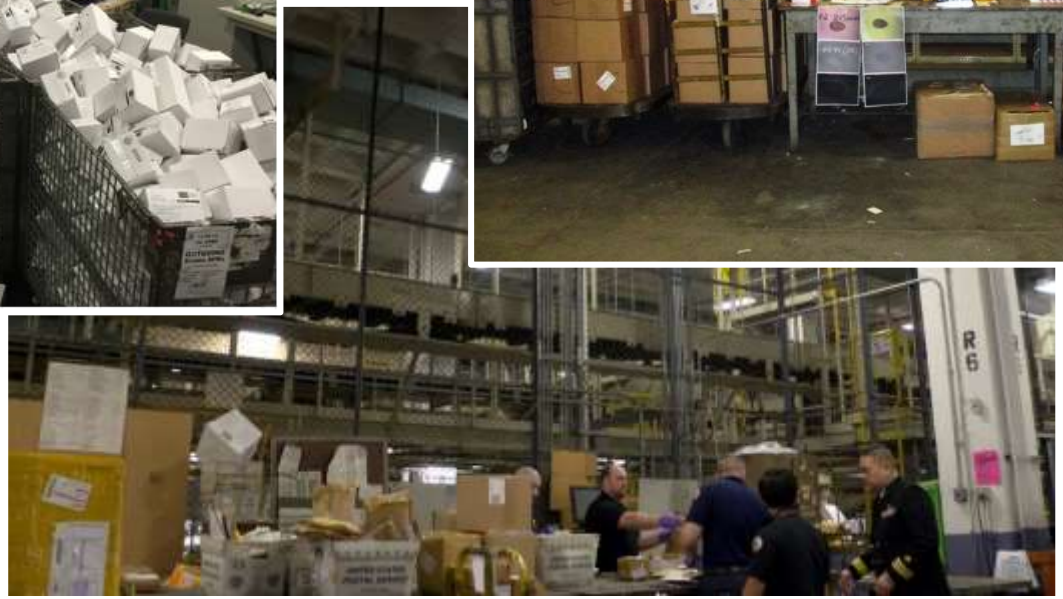
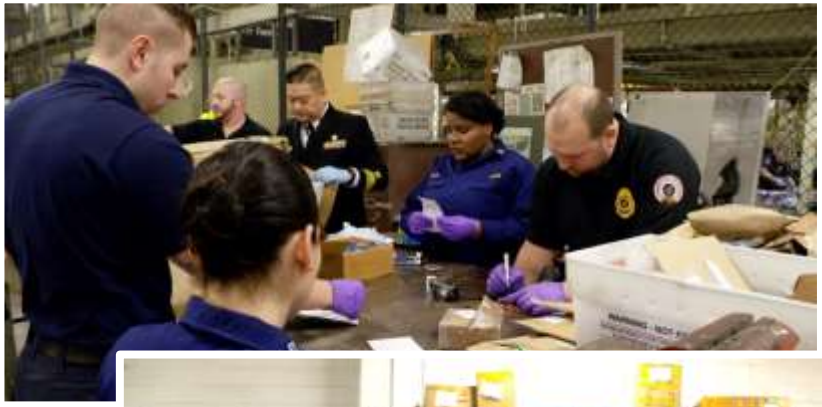




Compounding the problem is the hazardous nature of various types of synthetic drugs that are being sent through the IMFs. Processing inbound international mail is primarily a manual process and requires CBP officers to sort through large bags and bins by hand. At the IMFs, FDA investigators open and examine packages flagged for screening by CBP. Given the sheer volume of mail—and the amount of time it takes to inspect just one package—this is a challenging task.



Packages for FDA review at JFK IMF

At the IMFs, the FDA is asked to examine the packages pulled by CBP and believed to contain FDA-regulated products. In fiscal year 2017, the IMFs received an estimated 275 million packages. Of these, the FDA estimates that approximately 9% of them contained drugs of some kind. In FY19, the FDA plans to screen approximately 45,000 packages after recently increasing staffing to full capacity at the IMFs. Previously, the FDA was inspecting between 10,000-20,000 packages annually. With additional resources, we hope to increase that number to 100,000 packages per year.

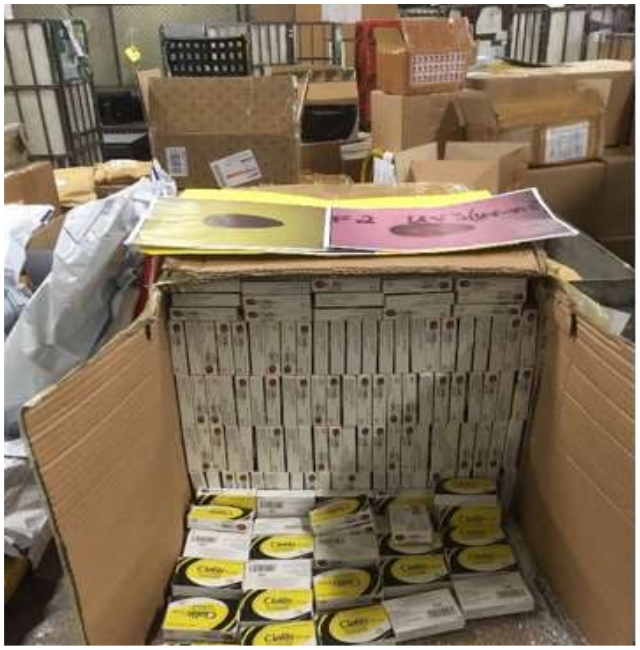
Various loose blister packs

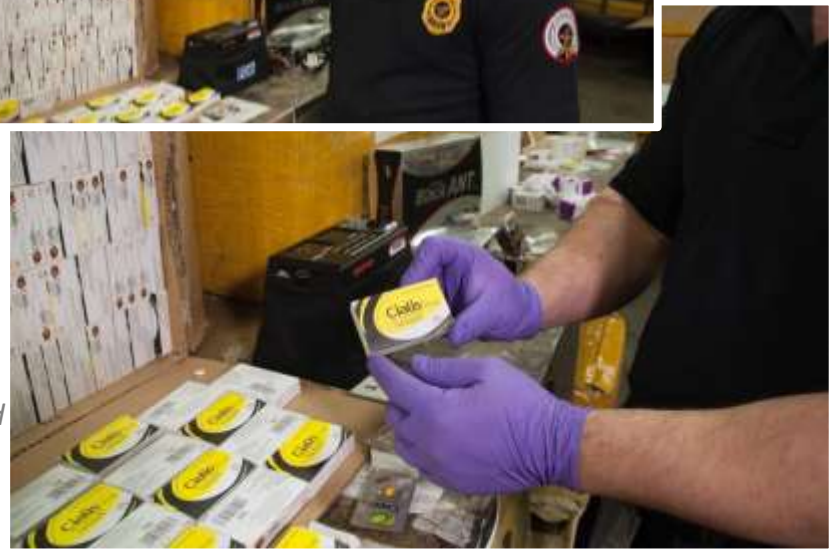
Unmarked, unlabeled capsules at JFK

It’s estimated that the FDA is able to inspect less than 0.18% of the packages assumed to contain drug products that are shipped through the international mail facilities.

275,000,000	•In 2017, USPS's inbound international mail topped 275 million pieces, an increase of 232% between 2013 and 2017.
43,000,000	•Across all modes of entry and all FDA-regulated products, the FDA receives over 43 million import lines per year. FDA has seen a 10% increase in imports every year for more than a decade.
20,117	•In FY18, across all 9 IMF locations, FDA reviewed 10,231 mail entries (parcels), which contained 14,995 lines of product.
87	•In FY17, 86% of the packages FDA screened contained drugs. In FY18, this number has grown slightly to appx. 87% of packages to-date.
22	•FDA has 22 Import Investigators to cover the 9 IMF locations.
12	•FDA has 12 Office of Criminal Investigations Port of Entry Special Agents to cover the 9 IMFs and other Ports of Entry.

The investigation process takes time. An experienced FDA investigator can process a package containing a single product in about 20 minutes. This time can increase if a package contains multiple products, if the product is unlabeled or if the product is labeled in a language other than English. This estimate only includes work conducted by the FDA investigator in the IMF and does not include the amount of time required to detain the suspect package and work through the detention and hearing process leading to a final admissibility determination. To lessen the time spent by FDA investigators on multiple shipments of illegal drugs by the same person, the SUPPORT Act gave FDA authority to treat any shipments of drugs from a person as illegal after FDA has determined that such person is engaging in a pattern of illegally importing adulterated or misbranded drugs from the same manufacturer, distributor, or importer.





Single mail parcel containing appx. 3,200-4,000 tablets of suspected counterfeit Cialis after being screened using the CD3 Counterfeit Detector.

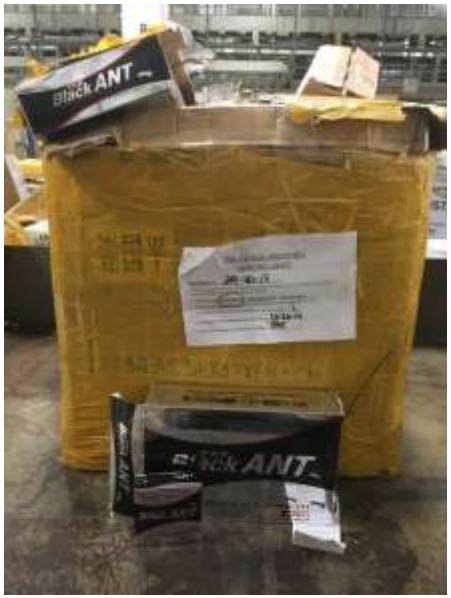
When a product lacks proper labeling, the FDA needs to act quickly to determine if a product should be detained, so a creative approach is needed. To enable faster decisions, the agency employs a variety of tools, including one that can determine if a drug is a counterfeit, one that can determine if a product contains undeclared drugs and another that uses the same technology as airport security to swipe your luggage for explosives. The FDA is actively working on developing an opioid screening method and intends to initiate a pilot study using this method at the IMFs soon. Additionally, the SUPPORT Act gave FDA authority to treat an article as a drug if it includes an active ingredient in an FDA-approved drug or licensed biologic, or an analogue of that active ingredient, and the ingredient presents a significant public health concern. This new authority will help FDA refuse and destroy illegal and potentially dangerous drugs that are unlabeled or mislabeled.

Preparing test sample for ion mobility spectrometer analysis

CD-3, counterfeit detection device

Testing a dietary supplement using a benchtop ion mobility spectrometer

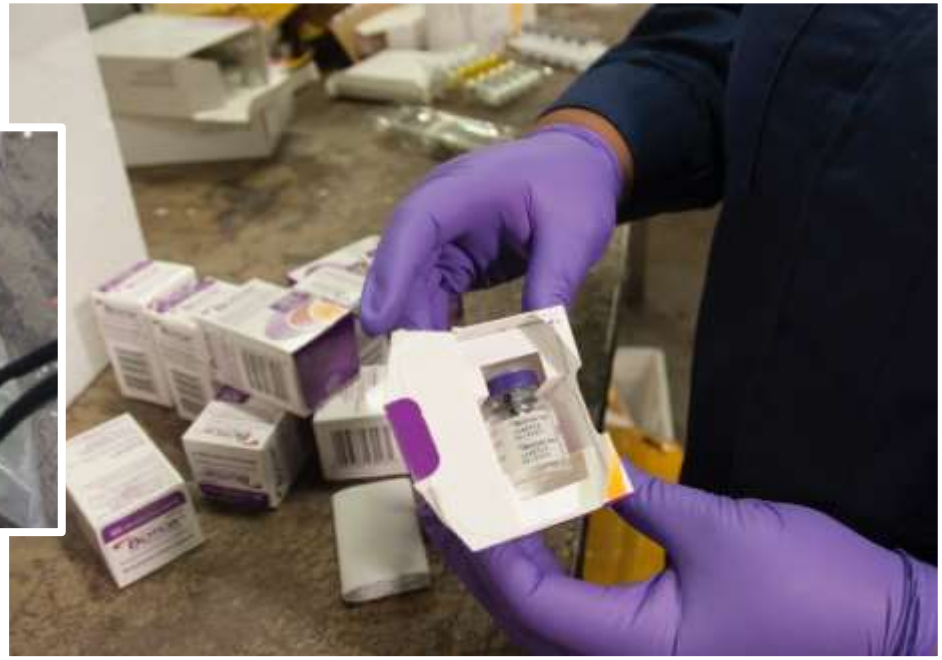
Thousands of the packages entering through the IMFs contain what appear to be FDA-regulated products. These packages include unapproved products; counterfeit or substandard drugs; purported dietary supplements being sold for weight loss, sexual enhancement, bodybuilding or pain relief that contain potentially dangerous undeclared drug ingredients; and, increasingly, products laced with the highly-potent opioid fentanyl. The risks related to illicitly-made fentanyl are just one example of how quickly new threats can emerge, the tough challenges we must confront and the dangers Americans face from these emerging risks. The SUPPORT Act provided FDA with a new tool for deterring illegal imports of drugs by expanding the Agency's debarment authority to include illegal importation of drugs or controlled substances. Once debarred, that person is prohibited from being involved in any future drug importation for a period of up to 5 years and violation of a debarment order is a criminal offense.



Sexual enhancement product with undeclared drug ingredient

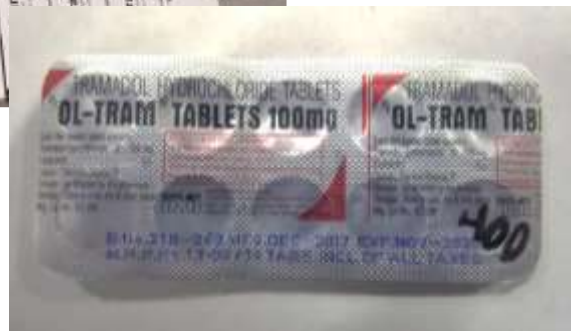
Unlabeled, unmarked pills

Foreign, unapproved Botox



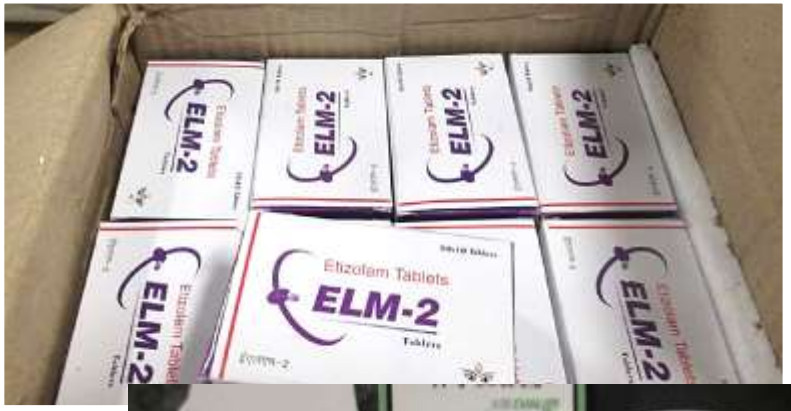
While CBP handles the majority of opioid interdictions within the IMFs, the FDA also encounters these products. When the FDA does find illegal opioids, it means that the agency is the final stop from preventing them from reaching consumers. Examples of opioids the FDA has found include tramadol, codeine and morphine.

Foreign, unapproved version of tramadol



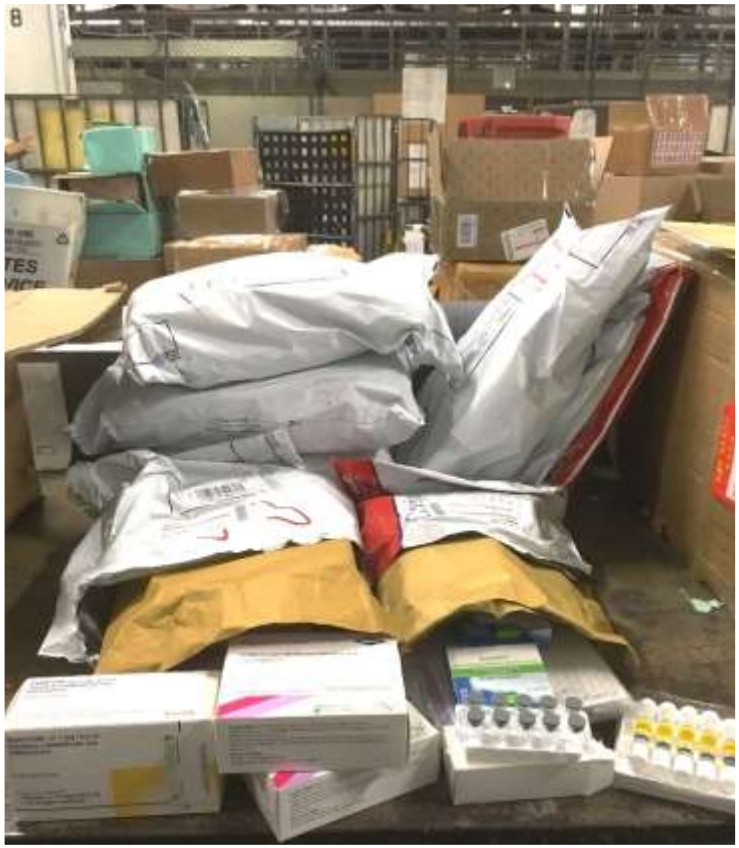
Foreign, unapproved version of tramadol

Foreign, unapproved anti-anxiety drug



Foreign, unapproved, controlled substance

The FDA has seen an increase of opioids illegally entering the country and is strengthening collaborative efforts with USPS, CBP and DEA to detect these opioids coming in through the mail. The FDA is also looking for ways in which information related to opioid interdictions can be used to better combat the smuggling of opioids.

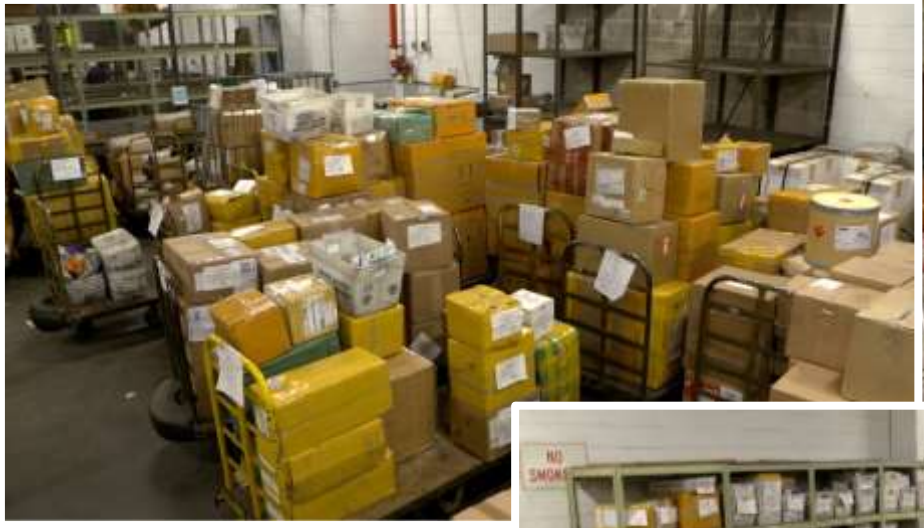


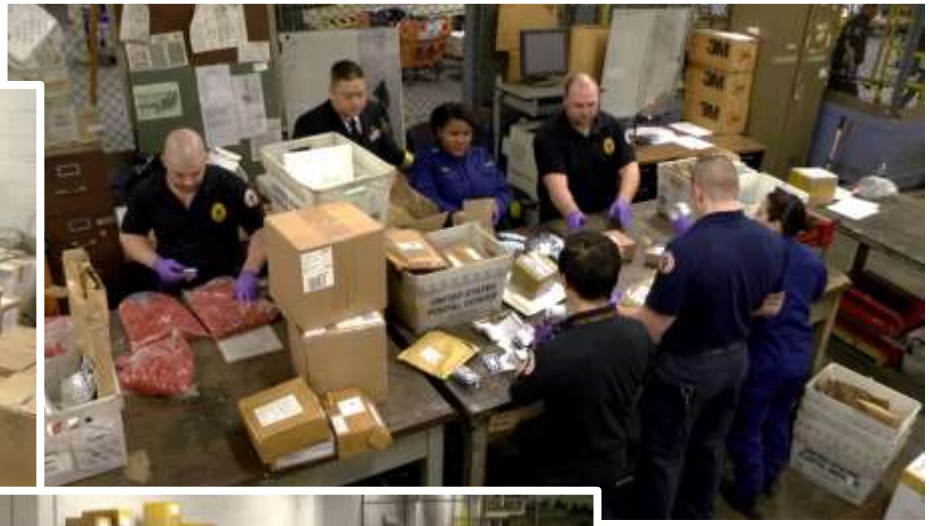
Hormones found at JFK IMF

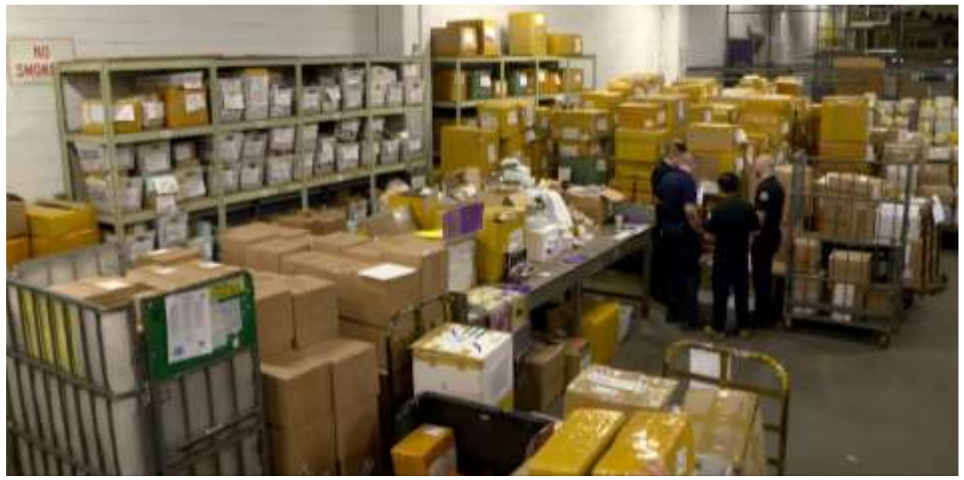
Repetitive bulk shipment from single supplier

600,000+ pills found with no markings

The FDA is on the front lines of the consumer protection mission and a robust import program is critical to this mission. To protect the public health from these illegal and potentially dangerous products, the FDA will continue to identify ways to both maximize and extend existing resources and authorities.







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