

May 14, 2018

Tammy L. Whitcomb
Acting Inspector General
United States Postal Service
1735 North Lynn Street
Arlington, VA 22209

Dear Ms. Whitcomb,

We are writing to provide an update on issues you raised in your recent report “Prohibited Inbound International Mailings,” and affirm our commitment to increasing our presence and activity at United States international mail facilities (IMFs) aimed at the interdiction of drugs illegally brought into the United States, including narcotics. We are very pleased that the United States Food and Drug Administration (FDA) was recently granted additional funding as part of the Omnibus, which will significantly aid in these efforts, as would the new and enhanced authorities that Congress is considering.

As you are aware, Americans are exposed to an overwhelming number of dangerous products, including drugs that may be counterfeit, contaminated, expired, or otherwise unsafe, that enter the United States through international mail packages. We are dealing with sophisticated bad actors who are deliberately exploiting potential gaps and weaknesses in our authorities.

As you noted in your report, addressing the large volumes of items received through the international mail presents significant challenges, including the fact that shippers often purposely avoid labeling in an attempt to defeat FDA jurisdiction. Currently, under the Federal Food, Drug, and Cosmetic Act, FDA is required, for every parcel, to determine its intended use as a drug and that it is, or appears to be, unapproved, adulterated, or misbranded. When there is no labeling, determining intended use can take a great deal of labor and resources and sometimes is not possible as a practical matter.

You specifically called attention to a particularly large volume of packages currently stored by the United States Postal Service (USPS) at the IMF in Miami pending identification of a permanent resolution. This matter has posed a significant logistical challenge for FDA and our federal partners given both the volume involved and the limitations in the existing law that hinder our ability to handle such packages in an expeditious and efficient way. However, I can now report that after careful consideration of all possible options that comply with current law, we have a plan as to the disposition of these packages. FDA plans to take possession of the 6,000 packages and process them for refusal and destruction.

As you noted in the report, at FDA's request, the USPS has possession of approximately 25 bulk mail containers, containing approximately 6,000 parcels from a single shipper – Global Drug Supply (GDS) which are declared as “prescription medications for personal use” and addressed to individual United States consumers. These packages were received at the IMF in Miami on or about July 2016.

Additionally, on or about June 2016, Customs and Border Protection (CBP) notified FDA they had received approximately 3,962 packages, via international mail, from GDS which also are declared as “prescription medications for personal use” and addressed to individual United States consumers. In July of 2016, FDA took custody of these GDS parcels, moved them to FDA's local resident post and subsequently processed them for admissibility. All but one of these 3,962 parcels were ultimately refused admission by FDA because they appeared to be unapproved and misbranded drugs.

Operation Safeguard was a foreign parcel interdiction operation led by CBP at IMFs and Express Courier Hubs during which a series of “blitz” operations were executed where up to 100 parcels were examined each day for three days. Under Operation Safeguard in 2016, 82 of the parcels that CBP randomly selected for examination were shipped by GDS. These articles were referred to FDA staff for physical examination and admissibility review.

Based on reviews of shipping labels, prescription order forms, product labeling and the content of the packages, FDA determined all 82 packages contained misbranded and unapproved new drugs from foreign or unknown sources. The outside of each of these 82 packages contained information that was identical to that of the approximately 10,000 GDS packages being held by FDA and USPS. All 10,000 packages have identical shipping labels on the outside of the package (customs declaration) stating: (1) the contents of the parcel are “Prescription Medications for Personal Use”; (2) a specific value under \$2,500; (3) a 7-digit reference number in the same format; namely Ref: XXXXXXXX; (4) the parcel was shipped by GDS from Barbados; and (5) if undeliverable, the parcel should be returned to a certain address.

Given the significant resources required to process these 10,000 packages due to factors such as the number of packages, the inherent challenges in determining intended drug use, the fact that the packages were being shipped to different parties, and the fact that many different products were involved, FDA spent considerable time determining how best to proceed. As stated above, FDA plans to take possession of the 6,000 packages USPS has been holding at our request, and work with the USPS to either process the packages at the USPS location or move them to another location for processing. We plan to send notifications of destruction to the individual addressees for the 3,962 packages FDA is holding, and dual notifications of refusal and destruction to the individual addressees for the 6,000 packages USPS is holding. Our intent is to seek destruction of all 10,000 parcels.

While we have reached a solution for handling the 10,000 GDS packages, ensuring this process is more efficient and effective going forward is of critical concern to the agency, and we are pursuing several actions to enhance our ability to proactively manage the risks posed to American consumers from drugs brought into the United States through the IMFs.

First, we are increasing FDA's presence and activity at the IMFs. Last year, FDA increased the number of import investigators in the IMFs from eight to twenty-two full-time employees which is staffing to our full capacity based on available space. This will allow us to nearly triple the number of suspicious packages that we can open and inspect, going to approximately 40,000 packages per year. With the additional funding granted to us, we will make another substantial increase in our import staff working in the IMFs. This will allow us to further increase the number of packages that we can open and inspect, to approximately 100,000 packages per year. To do so, we will be working closely with CBP and USPS to address the logistical challenges related to this expansion of our staff. We are confident that we can work together to inspect a far greater volume of suspicious packages that arrive at the IMFs and thereby reduce the risks these dangerous packages pose to American consumers.

We are increasing our intelligence gathering by our own experts and working with CBP to increase information sharing as well. We are also working to expand the use of enhanced technology and hand-held tools in the IMFs, and are making commensurate investments in our laboratories to ensure we have the regulatory science to support the actions. Lastly, we are increasing our already substantial collaborative efforts with CBP and USPS to find additional areas where we might better leverage our collective resources and expertise.

These are just some of the tools we are pursuing to enhance our mission and help ensure that we do not need to store large volumes of illegal drugs, including narcotics at the IMFs in the future.

I appreciate your interest in this effort and look forward to keeping you updated on our progress.

Sincerely,



Melinda K. Plaisier
Associate Commissioner for Regulatory Affairs