CLEARING THE MARKET OF ILLEGAL ENDS PRODUCTS BEGINS AT THE US PORTS

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Poster # 10

ABSTRACT

The Food and Drug Administration's (FDA) compliance and surveillance efforts are in place to ensure that regulated industry, specifically regulated tobacco products are compliant with the laws designed to protect the public's health and to prevent tobacco use by minors. However, millions of illegal Electronic Nicotine Delivery Systems (ENDS) products are on the U.S. market today and being sold at retail establishment to underage purchasers daily. According to 2022 National Youth Tobacco Survey (NYTS) in 2022, about 1 in 10 or more than 2.5 million U.S. middle and high school students currently used e-cigarettes. The most used devices among the current users (defined as use on ≥1 day during the past 30 days) are ENDS disposables (55.3%) and nearly 85% used flavored e-cigarettes. The agency has not authorized any flavored ENDS products to date. Most ENDS products are manufactured outside of the US and outside of the agency's inspection biennial surveillance activities. Importers are required to ensure the tobacco products imported or offered for import comply with all the applicable requirements under the FD&C Act. According to the U.S Department of Commerce's Census Bureau consumption imports of vapor product devices rose from 2016's $204.1 million to over $513.1 million in 2022 and the estimated forecast for 2023 is over $620 million. By strengthening the Customs and Border Protection Agency's (CBP) and FDA's surveillance efforts, which include physical inspections, mandating proof of the Tobacco Control Act compliance at entry points and amplifying random screenings at ports of entry and International Mail Facilities, can significantly impact the influx of illegal ENDS products which will aid in preventing these products from making it to store shelves, thereby safeguarding public health.

COLLABORATION BETWEEN THE FDA AND CBP

FDA and CBP share a vital, collaborative responsibility in safeguarding the health and safety of the American public. This partnership is centered on monitoring, regulating, and ensuring the safety and compliance of imported products that fall under the FDA's jurisdiction. All imported shipments of FDA-regulated products are reviewed by the FDA and must comply with the same standards as domestic products.

Table1: Collaborative Efforts at U.S. Ports

Regulatory Oversight	• Share regulatory responsibilities; Entries submitted to CBP then refers entries of FDA regulated products to FDA for review
Surveillance	• CBP detain shipments violating FDA regulations; Alerts FDA to conduct field exams or lab analysis of shipments to confirm compliance.
Information Sharing	• Both agencies maintain open channels of communication, sharing real-time data and intelligence regarding emerging threats, or global trends that may impact product safety.
Joint Operations	• Both agencies conduct joint surveillance at ports; sharing resources and expertise to detect and detain non-compliant products.
Enforcement Actions	• FDA, with CBP's logistical support, can initiate enforcement action such as refusals, seizures or initiating legal actions.

FDA'S IMPORT PROGRAM

The FDA's import operation programs are responsible for 353 ports of entry across the U.S. and its territories, in addition to multiple modes of transportation including truck, air, mail, and sea cargo ships, including mail entering the U.S. from abroad arrives at a U.S. Postal Service (USPS) sorting facility (International Mail Facility). There are currently nine IMF locations across the U.S., with one location in Florida, Hawaii, Illinois, New Jersey, New York, Puerto Rico, U.S. Virgin Islands respectively and two locations in California.

Figure 1: FDA Import Offices and Ports

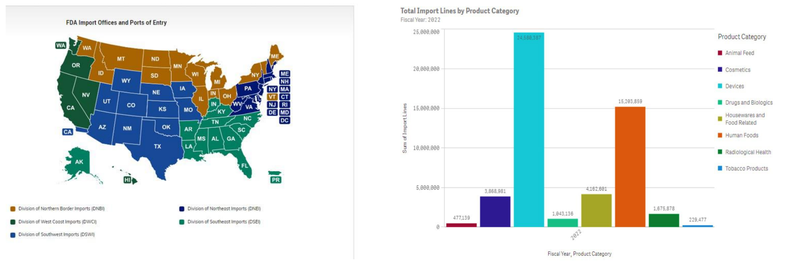
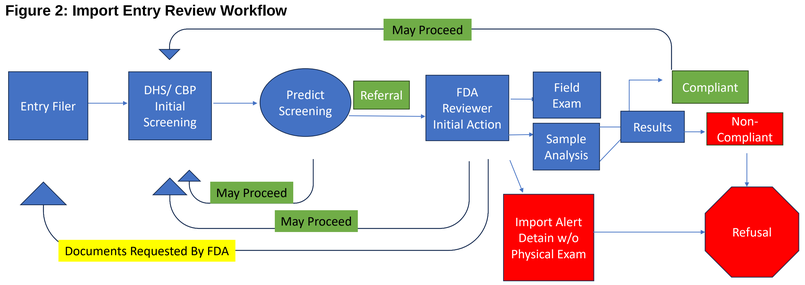


Figure 2: Import Entry Review Workflow



IMPORT TRENDS FOR ENDS: FISCAL YEAR 2020-

Between 2020 and August 2023, ENDS import trends experienced fluctuations, largely influenced by the evolving FDA enforcement priorities and supply chain issues due to COVID -19 pandemic. Beginning in **January 2020** when the FDA released guidance which prioritized enforcement against certain ENDS, notably those flavored cartridge-based systems. By **March 2020**, the Agency initiated compliance actions against ENDS firms for products that were prioritized per the guidance. A significant impact was the placement of these firms on the import alert "red list", effectively meaning that products imported by these entities faced detainment, and if determined to be in violation of the FD&C Act, were subsequently refused entry. In **August 2021**, FDA issued numerous marketing denial orders, instructing firms to withdraw their products from the US market due to their lack of premarket authorization. In **May 2023**, the FDA added several importers of popular disposable vape brands, to the "red list", facilitating the detainment of their products without the need for physical examinations the import alert was no marketing authorization .

Figure 3: ENDS Imports to the US by Country of Origin

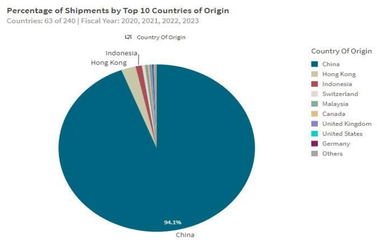
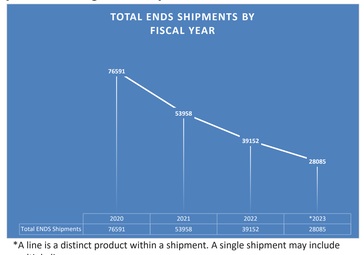


Figure 4: Total ENDS Shipments to the US (FY 2020-August 2023)



*A line is a distinct product within a shipment. A single shipment may include multiple lines.

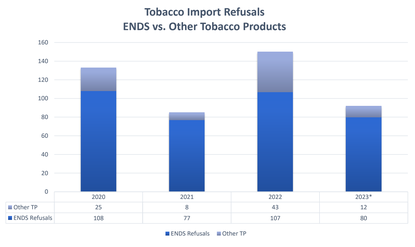
Based on FDA's Import Entry Dashboard from October 2019- August 2023, it shows the largest percentage of ENDS (includes E-cigarette and ENDS product codes) were imported from China (94%) and the remaining 6% from other countries. According to FDA's Import data, the total ENDS shipments referred by CBP decreased over the last 4 years. The data indicates a decline in ENDS shipments; however, it's important to recognize that this decrease may not be attributed solely to surveillance and enforcement actions. Other external factors could also play a role in this observed trend.

TOOLS TO COMBAT THE FLOW OF ILLEGAL ENDS AT PORTS

The FDA has several robust sets of import compliance and enforcement tools at their disposal to combat the influx of illegal ENDS, it begins with the **Predictive Risk-based Evaluation for Dynamic Import Compliance Targeting** aka PREDICT. The electronic system harnesses advanced analytics to prioritize inspections based on potential risks, zeroing in on suspicious shipments.

Figure 4: Import Surveillance and Enforcement Tools

Table 2: Tobacco Import Refusals FY2020-August 2023



	2020	2021	2022	2023*
Other TP	25	8	43	12
ENDS Refusals	108	77	107	80

Over the past four years, the FDA and CBP have employed a range of import tools to combat the surge of illegal ENDS products into the U.S. market. This included adding over 20 firms to Import Alerts (red list for marketing without authorization), detaining shipments leading to their refusal, and in certain instances, seizing illegal ENDS products. Such initiatives underscore the effective utilization of these tools, resulting in successful outcomes. However, more needs to be done to ensure a comprehensive solution.

CASE STUDIES 2020-2021: IMPORT ENFORCEMENT ACTIONS

CBP and FDA have a collaborative partnership aimed at bolstering surveillance and enforcement measures to combat the entry of counterfeit and illegal ENDS into the U.S. These joint efforts often result in enforcement actions such as seizures, particularly aimed at intercepting counterfeit and unauthorized ENDS products.

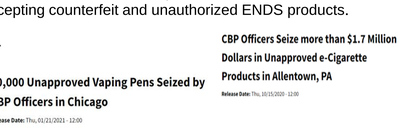

FDA NEWS RELEASE

CBP, FDA Seize Counterfeit, Unauthorized E-Cigarettes

Flavored Pods Resembling Puff Bar Products Valued at Over $719K

50,000 Unapproved Vaping Pens Seized by CBP Officers in Chicago

Release Date: Thu, 01/21/2021 - 12:00


CBP Officers Seize more than $1.7 Million Dollars in Unapproved e-Cigarette Products in Allentown, PA

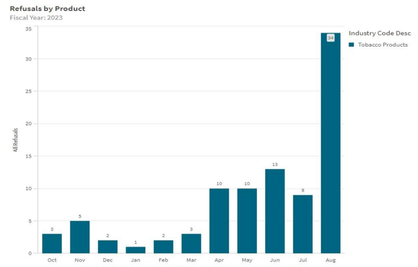
Release Date: Thu, 10/15/2020 - 12:00

- **October 2020-** CBP Officers seize more than $1.7 Million Dollars in unauthorized e-Cigarette in Allentown, PA
- **December 2020-** CBP Officers seize a shipment from China intercepted at Dallas International Airport- over 33,000 unit of counterfeit and unauthorized ENDS
- **January 2021-** CBP Officers seize 50,000 vape pens in Chicago; products were mis-manifested as lithium-ion batteries.
- **March 2021-** CBP officers at Chicago O'Hare's International Mail Branch seized more than 77,000 Rick and Morty Vape Pens.
- **June 2021-** CBP officers at the Port of Atlanta seized 66 boxes of counterfeit vape pens originated from China.

APPROACH TO INCREASE IMPORT SURVEILLANCE

As the challenge of illegal ENDS continues to evolve, it is imperative to not only fully utilize existing import tools but also to innovate new regulatory mechanisms that can more effectively stem the tide. Current tools like the PREDICT system, Import Alerts, and Field Exams provide a solid foundation for import surveillance. This year witnessed a notable surge in the refusals of ENDS since May, significantly driven by the addition of firms to the Import Alert "red list". However, more needs to be done to ensure a comprehensive solution.

Figure 5: Import Refusals October 2022- August 2023



Recommendations to Enhance Import Surveillance of ENDS:

- **Joint CBP and FDA Port Blitz:** Increase frequency of random joint blitz operations in ports with higher detainments of ENDS, including International Mail Facilities (IMFs).
- **Field Exams:** Raise the number of field examinations conducted per month for imported tobacco products to verify the accuracy of declared shipments, especially in high import regions for ENDs finished products, component and parts.
- **Update ACE Rule:** Prioritize the revision of the Automated Commercial Environment (ACE) rule to mandate entry filers to provide documentation of marketing status including STN numbers, ensuring compliance with regulatory requirements.
- **Explore Legal Reinforcement for Disguised Noncompliance:** identify the appropriate legal framework aimed at flagging noncompliant importers who attempt to evade surveillance by operating under new business names or entities.
- **Engaging and Educating Custom Brokers**: Prioritize regular communication sessions, workshops, and information dissemination to ensure they are updated and fully aware of the current import alerts and the "red list" specific to illegal ENDS.
- **Establish a Joint Enforcement Forum with Industry**: Create an open dialogue and collaboration with responsible tobacco manufacturers, stakeholders within the tobacco industry, and major regulatory bodies such as CBP, FDA and state tobacco enforcement agencies fostering a sense of shared responsibility to addressing the Illegal ENDS on the market.

CONCLUSIONS

Clearing the marketplace of illegal ENDS begins with intensifying surveillance and enforcement mechanisms at U.S. ports—where most of these products often make their unobstructed entry. In reflecting on the past four years, while the FDA has observed a decline in ENDS shipments, the sheer volume of ENDS products infiltrating the marketplace remains considerable. According to the U.S. Department of Commerce's Census Bureau, electronic cigarette imports amounted to 221.8 million pieces, valued at $224.3 million, from June 2022 to June 2023. This signifies an increase of over 21.9 million pieces, a near 11.0% growth in volume. The data emphasizes the necessity for continuous and adaptive regulatory oversight in the face of evolving market dynamics.

Over the last year, the increased number of refusals bears testimony to the intensified efforts and the efficacy of the measures in place. While it's an ongoing process that won't yield immediate, sweeping results, the key lies in maintaining relentless vigilance and harnessing tools proven effective in other surveillance realms is pivotal in enhancing oversight and capabilities.

Addressing the challenge of illegal ENDS in the marketplace requires more than just a single solution or single agency response—it demands a concerted, multi-agency and multi-pronged approach. By fostering inter-agency collaborations, harmonizing strategies, and deploying diverse tools, a comprehensive defense against these illegal ENDS products can be mounted.

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