KEYNOTE SESSION:

The Essential Value of Good Suppliers

How to Identify and Select the Right Suppliers as a Part of your PMTA and What to Do if You Need to Change Suppliers Along the Way.

Mike Bond
Labstat

Bonnie Coffa, PhD, DABT
Chemular

JANUARY 30 | 11:00AM - 11:30AM

Labstat
A Certified Group Company

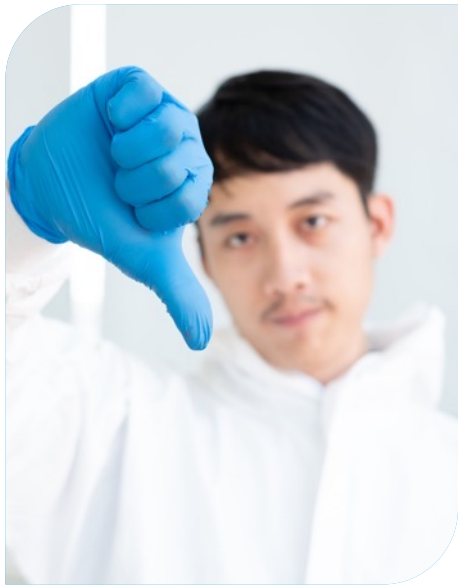
What can happen if you select the wrong testing lab (supplier)?

Spend more money

Testing takes longer

FDA issues deficiency letter because methods and validation reports not in a lab TPMF

Bad data



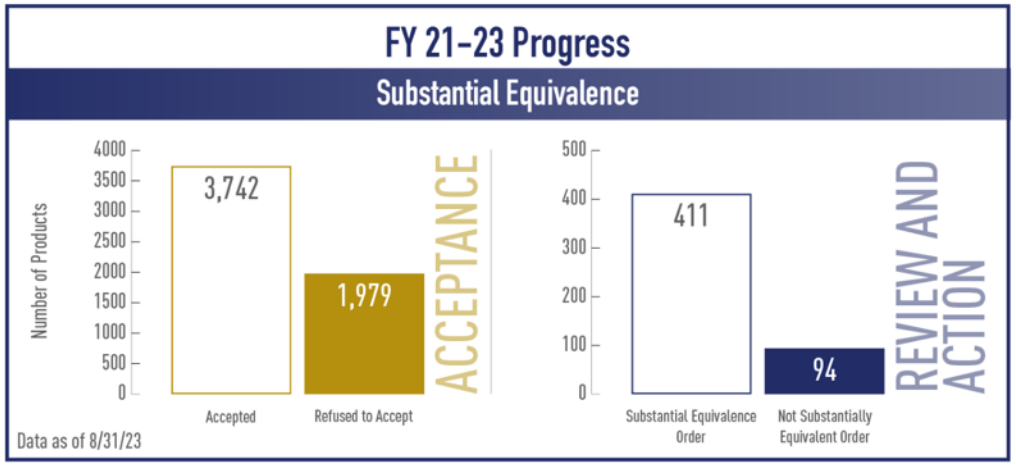
Start testing all over

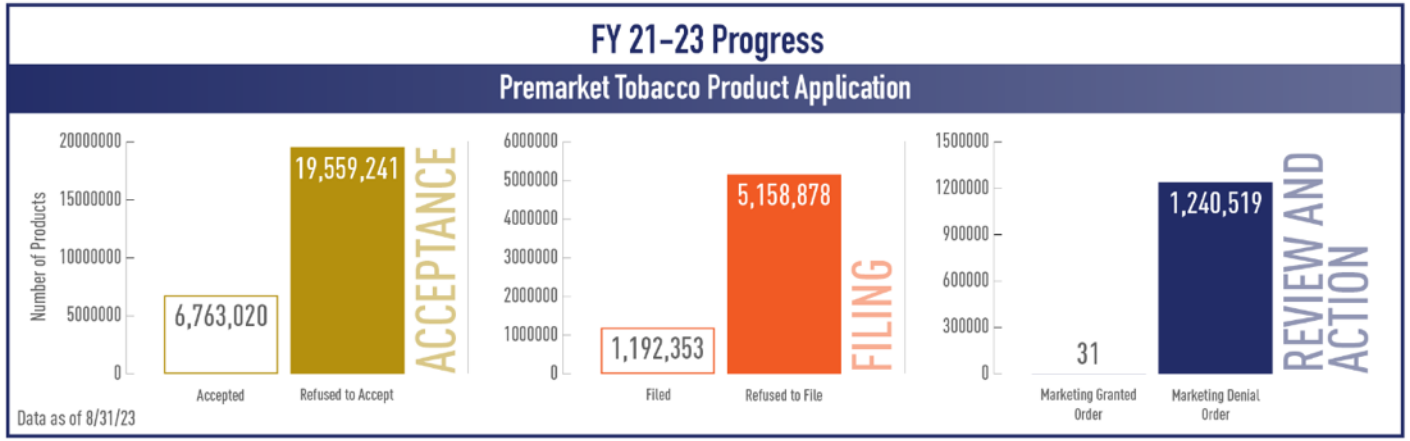
PMTA Landscape

- FDA's Application Review status FY 20-23
  - 26 million applications received, mostly e-cigs
  - 99% have been rejected in some way
  - 23 marketing authorizations for e-cigarettes (MGO)

FDA Rejections – They Didn't Have the Science

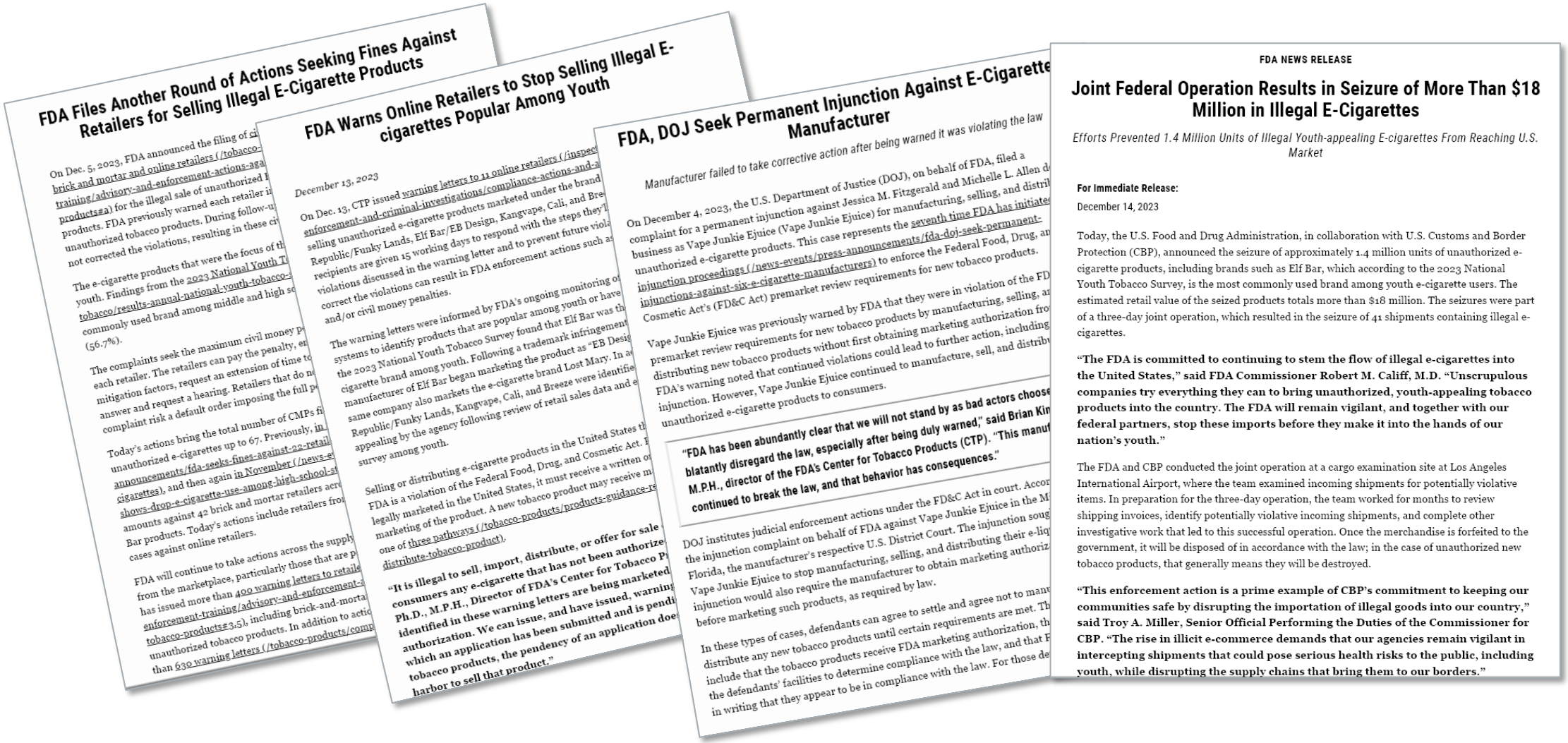
- **RTA** – Applications failed to meet the "minimum threshold for scientific review" (missing information)
- **MDO** – Missing or incomplete scientific details; failure to adequately address impact on public health (quality of the information)





RTA = Refuse to accept
MDO = Marketing Denial Order

FDA Action Ramped Up in 2023



FDA Files Another Round of Actions Seeking Fines Against Retailers for Selling Illegal E-Cigarette Products

On Dec. 5, 2023, FDA announced the filing of ci
brick and mortar and online retailers (/tobacco-
training/advisory-and-enforcement-actions-aga
products#a) for the illegal sale of unauthorized
products. FDA previously warned each retailer i
unauthorized tobacco products. During follow-u
not corrected the violations, resulting in these ci

The e-cigarette products that were the focus of th
youth. Findings from the 2023 National Youth To
tobacco/results-annual-national-youth-tobacco-
commonly used brand among middle and high sc
(56.7%).

The complaints seek the maximum civil money p
each retailer. The retailers can pay the penalty, er
mitigation factors, request an extension of time to
answer and request a hearing. Retailers that do n
complaint risk a default order imposing the full p

Today's actions bring the total number of CMPs fi
unauthorized e-cigarettes up to 67. Previously, in
announcements/fda-seeks-fines-against-22-retail
cigarettes), and then again in November (/news-e
shows-drop-e-cigarette-use-among-high-school-s
amounts against 42 brick and mortar retailers acr
Bar products. Today's actions include retailers fro
cases against online retailers.

FDA will continue to take actions across the supply
from the marketplace, particularly those that are p
has issued more than 400 warning letters to retail
enforcement-training/advisory-and-enforcement-a
tobacco-products#3,5), including brick-and-morta
unauthorized tobacco products. In addition to actio
than 630 warning letters (/tobacco-products/comp

FDA Warns Online Retailers to Stop Selling Illegal E-cigarettes Popular Among Youth

December 13, 2023

On Dec. 13, CTP issued warning letters to 11 online retailers (/inspect
enforcement-and-criminal-investigations/compliance-actions-and-a
selling unauthorized e-cigarette products marketed under the brand
Republic/Funky Lands, Elf Bar/EB Design, Kangvape, Cali, and Bre
recipients are given 15 working days to respond with the steps they
violations discussed in the warning letter and to prevent future viola
correct the violations can result in FDA enforcement actions such as
and/or civil money penalties.

The warning letters were informed by FDA's ongoing monitoring of
systems to identify products that are popular among youth or have
the 2023 National Youth Tobacco Survey found that Elf Bar was th
cigarette brand among youth. Following a trademark infringement
manufacturer of Elf Bar began marketing the product as "EB Desig
same company also markets the e-cigarette brand Lost Mary. In a
Republic/Funky Lands, Kangvape, Cali, and Breeze were identifie
appealing by the agency following review of retail sales data and e
survey among youth.

Selling or distributing e-cigarette products in the United States th
FDA is a violation of the Federal Food, Drug, and Cosmetic Act. F
legally marketed in the United States, it must receive a written or
marketing of the product. A new tobacco product may receive m
one of three pathways (/tobacco-products/products-guidance-re
distribute-tobacco-product).

"It is illegal to sell, import, distribute, or offer for sale
consumers any e-cigarette that has not been authorize
Ph.D., M.P.H., Director of FDA's Center for Tobacco P
identified in these warning letters are being marketed
authorization. We can issue, and have issued, warning
which an application has been submitted and is pendi
tobacco products, the pendency of an application doe
harbor to sell that product."

FDA, DOJ Seek Permanent Injunction Against E-Cigarette Manufacturer

Manufacturer failed to take corrective action after being warned it was violating the law

On December 4, 2023, the U.S. Department of Justice (DOJ), on behalf of FDA, filed a
complaint for a permanent injunction against Jessica M. Fitzgerald and Michelle L. Allen d
business as Vape Junkie Ejuice (Vape Junkie Ejuice) for manufacturing, selling, and distrib
unauthorized e-cigarette products. This case represents the seventh time FDA has initiate
injunction proceedings (/news-events/press-announcements/fda-doj-seek-permanent-
injunctions-against-six-e-cigarette-manufacturers) to enforce the Federal Food, Drug, an
Cosmetic Act's (FD&C Act) premarket review requirements for new tobacco products.

Vape Junkie Ejuice was previously warned by FDA that they were in violation of the FD
premarket review requirements for new tobacco products by manufacturing, selling, a
distributing new tobacco products without first obtaining marketing authorization fro
FDA's warning noted that continued violations could lead to further action, including
injunction. However, Vape Junkie Ejuice continued to manufacture, sell, and distrib
unauthorized e-cigarette products to consumers.

"FDA has been abundantly clear that we will not stand by as bad actors choose
blatantly disregard the law, especially after being duly warned," said Brian Kin
M.P.H., director of the FDA's Center for Tobacco Products (CTP). "This manuf
continued to break the law, and that behavior has consequences."

DOJ institutes judicial enforcement actions under the FD&C Act in court. Accor
the injunction complaint on behalf of FDA against Vape Junkie Ejuice in the M
Florida, the manufacturer's respective U.S. District Court. The injunction soug
Vape Junkie Ejuice to stop manufacturing, selling, and distributing their e-liq
injunction would also require the manufacturer to obtain marketing authoriz
before marketing such products, as required by law.

In these types of cases, defendants can agree to settle and agree not to manu
distribute any new tobacco products until certain requirements are met. Th
include that the tobacco products receive FDA marketing authorization, th
the defendants' facilities to determine compliance with the law, and that F
in writing that they appear to be in compliance with the law. For those de

FDA NEWS RELEASE

Joint Federal Operation Results in Seizure of More Than $18 Million in Illegal E-Cigarettes

Efforts Prevented 1.4 Million Units of Illegal Youth-appealing E-cigarettes From Reaching U.S. Market

For Immediate Release:
December 14, 2023

Today, the U.S. Food and Drug Administration, in collaboration with U.S. Customs and Border Protection (CBP), announced the seizure of approximately 1.4 million units of unauthorized e-cigarette products, including brands such as Elf Bar, which according to the 2023 National Youth Tobacco Survey, is the most commonly used brand among youth e-cigarette users. The estimated retail value of the seized products totals more than $18 million. The seizures were part of a three-day joint operation, which resulted in the seizure of 41 shipments containing illegal e-cigarettes.

"The FDA is committed to continuing to stem the flow of illegal e-cigarettes into the United States," said FDA Commissioner Robert M. Califf, M.D. "Unscrupulous companies try everything they can to bring unauthorized, youth-appealing tobacco products into the country. The FDA will remain vigilant, and together with our federal partners, stop these imports before they make it into the hands of our nation's youth."

The FDA and CBP conducted the joint operation at a cargo examination site at Los Angeles International Airport, where the team examined incoming shipments for potentially violative items. In preparation for the three-day operation, the team worked for months to review shipping invoices, identify potentially violative incoming shipments, and complete other investigative work that led to this successful operation. Once the merchandise is forfeited to the government, it will be disposed of in accordance with the law; in the case of unauthorized new tobacco products, that generally means they will be destroyed.

"This enforcement action is a prime example of CBP's commitment to keeping our communities safe by disrupting the importation of illegal goods into our country," said Troy A. Miller, Senior Official Performing the Duties of the Commissioner for CBP. "The rise in illicit e-commerce demands that our agencies remain vigilant in intercepting shipments that could pose serious health risks to the public, including youth, while disrupting the supply chains that bring them to our borders."

Major Manufacturers are Pressing for Action

Press Release

Home > Investors > Press Releases > Press Release Details

NJOY Brings Sweeping Litigation Against Illicit Disposable Vapor Manufacturers

RICHMOND, Va.--(BUSINESS WIRE)-- Altria Group, Inc. (Altria) announces today its operating company NJOY, LLC (NJOY) has filed sweeping litigation against 34 foreign and domestic manufacturers, distributors and online retailers of illicit disposable e-vapor products that are unlawfully marketed and sold in the State of California and elsewhere. The suit alleges that these companies manufacture, distribute, market and sell products that violate California's flavor ban law, are unlawful under federal law and subject to FDA action, and illegally compete against companies that comply with state and federal laws.

The suit seeks a nation-wide injunction against the import, marketing and sale of these illicit products and significant compensatory and punitive damages.

"These companies knowingly violate federal and state laws and need to be held accountable," said Murray Garnick, Altria's Executive Vice President and General Counsel. "Today there are two markets – one for those who play by the rules and one for those who flagrantly ignore them. We are taking this action because the current state of the illicit e-vapor market is intolerable, and we must see more action from FDA and others."

The litigation, filed in the United States District Court for the Central District of California, is brought under four claims: unfair competition, false advertising, false advertising in violation of the Lanham Act and violation of the Prevent All Cigarette Trafficking Act of 2009.

Named Defendants in the suit manufacture and distribute illicit disposable e-vapor products which include, but are not limited to, brands such as: *Breeze*, *Elf Bar*, *EB*, *EB Create*, *Esco Bar*, *Flum*, *Juice Box*, *Lava Plus*, *Loon*, *Lost Mary*, *Mr. Fog* and *Puff Bar*. Domestic Defendants include companies doing business in Arizona, California, Delaware, Florida, Michigan, Minnesota, New Jersey, New York and Texas. Foreign Defendants are all based in China.

None of the Defendants has received premarket authorization from the FDA. In many instances, Defendants also have not filed the required application for premarket approval. Several of these Defendants have already received warning letters from the FDA stating that their products are adulterated and misbranded and cannot be sold without a marketing authorization. Additionally, some of these Defendants are subject to an FDA-ordered import alert authorizing U.S. Customs and Border agents to seize their products.

NJOY may add additional manufacturers, distributors and retailers to this complaint and will consider further litigation activity.

Despite a ban on the sale of flavored tobacco products that went into effect in December 2022, flavored vapor products make up more than 97 percent of the California market according to a recent study commissioned by Altria and available on altria.com. Conducted by an independent research firm WSPM Group, the study collected 15,000 empty discarded cigarette packs and 4,529 e-vapor product packages from May 1st through June 28th in 10 California cities.

Altria's Profile

We have a leading portfolio of tobacco products for U.S. tobacco consumers age 21+. Our Vision is to responsibly lead the transition of adult smokers to a smoke-free future (Vision). We are *Moving Beyond Smoking*™, leading the way in moving adult smokers away from cigarettes by taking action to transition millions to potentially less harmful choices - believing it is a substantial opportunity for adult tobacco consumers, our businesses and society.

Our wholly owned subsidiaries include leading manufacturers of both combustible and smoke-free products. In combustibles, we own Philip Morris USA Inc. (PM USA), the most profitable U.S. cigarette manufacturer, and John Middleton Co. (Middleton), a leading U.S. cigar manufacturer. Our smoke-free portfolio includes ownership of U.S. Smokeless Tobacco Company LLC (USSTC), the leading global moist smokeless tobacco (MST) manufacturer, Helix Innovations LLC (Helix), a leading manufacturer of oral nicotine pouches, and NJOY, LLC (NJOY), currently the only e-vapor manufacturer to receive market authorizations from the U.S. Food and Drug Administration (FDA) for a pod-based e-vapor product.

Additionally, we have a majority-owned joint venture, Horizon Innovations LLC (Horizon), for the U.S. marketing and commercialization of heated tobacco stick products and, through a separate agreement, we have the exclusive U.S.

December 19, 2023

RJR Complaint Could Wreck Vaping Industry

FEATURED < HTTPS://TOBACCOREPORTER.COM/CATEGORY/FEATURED/> NEWS THIS WEEK < HTTPS://TOBACCOREPORTER.COM/CATEGORY/BREAKING-NEWS/> REGULATION < HTTPS://TOBACCOREPORTER.COM/CATEGORY/REGULATION/>

October 18, 2023 0 5 minutes read

The implications could be far-reaching. Reynolds American Inc. (RAI) has filed a U.S. International Trade Commission (ITC) complaint charging multiple manufacturers, distributors and retailers of several popular disposable vaping devices with unfair importation. It is one of several recent actions < https://vaporvoice.net/2023/05/03/reynolds-pens-letters-in-effort-to-end-flavored-vape-sales/> Reynolds has made to remove its competitor's vaping products from store shelves.

Reynolds is asking the ITC to investigate and issue an exclusion order preventing further U.S. imports of disposable vaping products. Several legal scholars have told *Tobacco Reporter* that if the ITC agrees with Reynolds, all flavored disposable vaping devices without marketing authorization could be stopped at the border and prevented from entering the U.S. market.

Reynolds wants the ITC to issue a permanent "cease and desist order" prohibiting *any* businesses from selling illegal vaping products. The move would push nearly the entire vaping industry underground, with the exception of products owned by major tobacco companies such as Reynolds that have received marketing orders from the FDA.

Several businesses were named specifically as "peddlers of illegal disposable vapes" in the Reynolds complaint, including the "manufacturers, importers, distributors and retailers" of Breeze, Elf Bar, Esco Bar, Hyde, Puff Bar, and R&M disposable vapes.

How to Identify & Select The Right Supplier

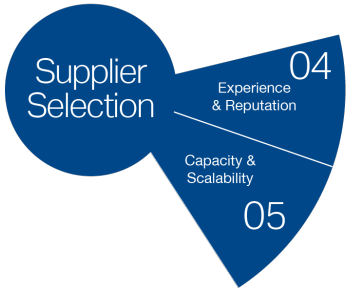
Supplier selection ensures quality and consistency of materials (essential for meeting regulatory standards). A reliable supplier helps maintain product integrity, reduces contamination risk, and improves cost-effectiveness.

Regulatory Compliance & Quality Assurance

- The Act[1] stipulates use of and documented proof that your testing lab is accredited.
  - ISO 17025, GLP[2], OECD
- Key QMS Attributes:
  - Robust policies and procedures for confidentiality
  - ICH-compliant validations
  - Participation in proficiency testing programs
  - Sample isolation to avoid cross-contamination
  - Checks and balances for data review accuracy

1. § 1114.7(i)(4)(i)), 2. 21CFR Part 58

Expertise specific to the Tobacco/Nicotine Space

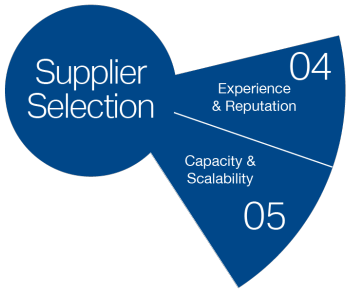


- Validations specific to tobacco/nicotine products
- Has an FDA Tobacco Product Master File (TPMF)
- Active in organizations that drive good science in the industry
  - CORESTA, ISO, ASTM
- Depth of experience with a wide range of regulatory submission types
- Experience with multiple stakeholders for reputation and broad perspective
  - Projects with Manufacturers, government organizations, academia, non-profit associations
- Formal presentations and peer-reviewed publications

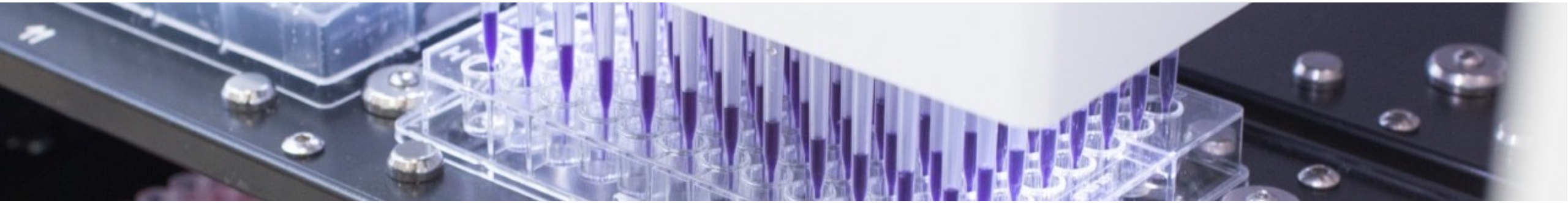
Experience & Offerings

- PMTA requires assessment and insights from the manufacturer
  - In addition to specific analytes, FDA requires: *“Other constituents, as appropriate for your particular product.”*

- Does your vendor offer…
  - Insight into other constituents?
  - Custom methods development?
  - Complex/custom statistical evaluation?
  - Customized/automated data handling?



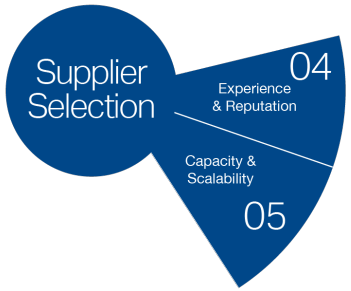
Capacity & Scalability



- Chemistry
- Microbial and Toxicology
- Environmental
- Varied puffing regimes for some products

- Clinical and bio-analytical
- Shelf-life studies
- Capacity & agility to prioritize deficiency letters

  sometimes with only a few weeks or months to respond



Business Continuity

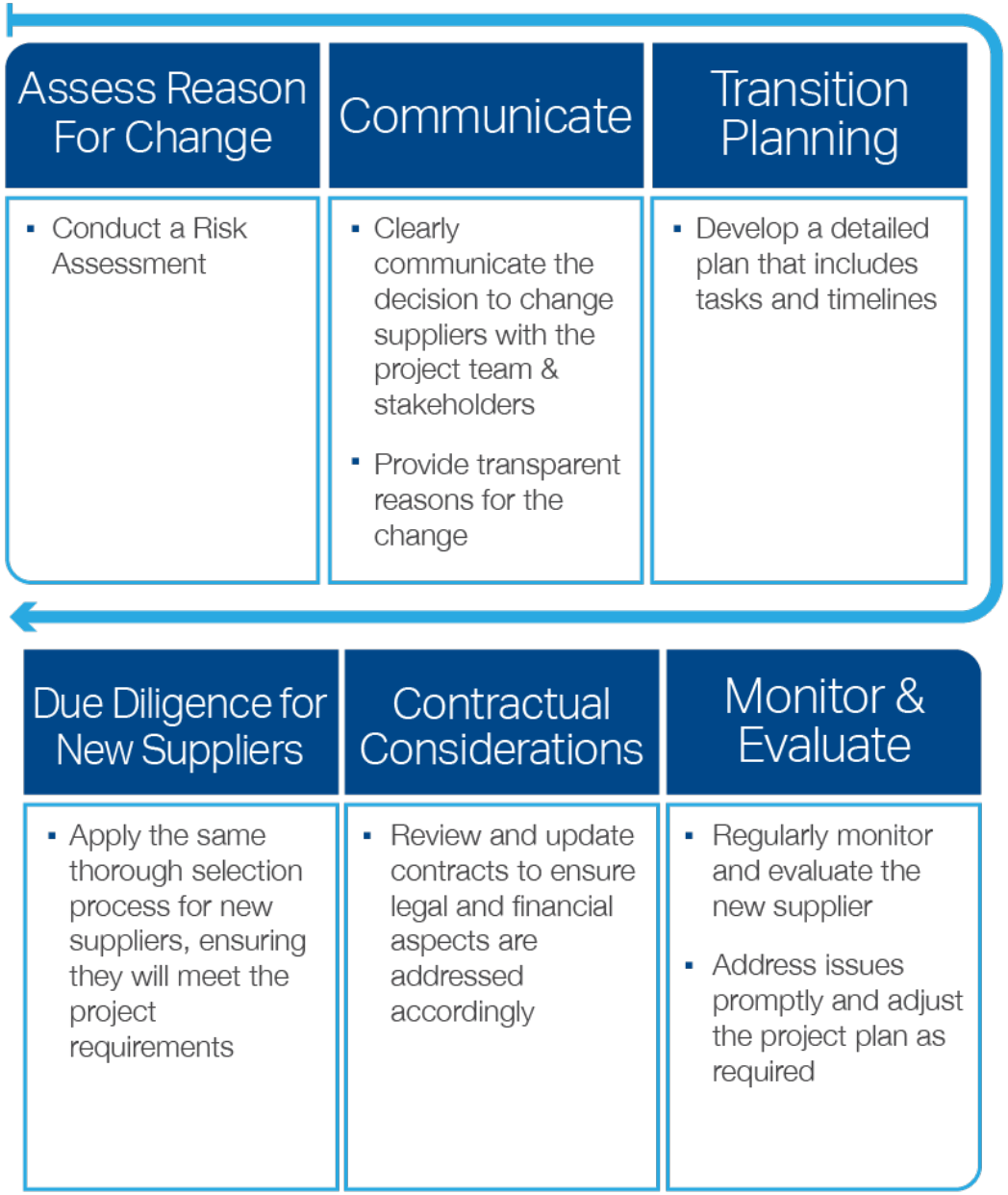
- Redundancy equipment
- Back-up power for stability storage
- Multiple sites, networked laboratories
- Full redundancy for microbiological work

Strategic with Testing Plan

- Strategic testing (pilot, prototype, bridging)
- Budget can influence testing cadence (file amendments)
- Develop testing plan to prioritize data generation and study plans for future testing
- “Basically, show FDA you are doing the right thing”

Changing Suppliers Along the Way

What if you need to change suppliers? Approach the process strategically and focus on minimizing risks and maintaining project continuity.



Visit the Labstat Website

How can we help you?

Request a meeting at TPE in your message

Labstat

A Certified Group Company

THANK YOU