April 7, 2025

The Honorable James R. Comer
Chairman
Committee on Oversight & Government Reform
2157 Rayburn House Office Building
Washington, DC 20515

The Honorable Gerald E. Connolly
Ranking Member
Committee on Oversight & Government Reform
2265 Rayburn House Office Building
Washington, DC 20515

RE: Hearing on "Restoring Trust in FDA: Rooting Out Illicit Products"

Dear Chairman Comer and Ranking Member Connolly:

Thank you for holding a hearing on "Restoring Trust in FDA: Rooting Out Illicit Products." Our industry has significant concerns about FDA's handling of the nation's tobacco and nicotine programs. A number of aspects concerning regulated tobacco and nicotine products are unclear and leave the regulated industry in a difficult position to try to ensure compliance with the law. The clearest example has resulted in a situation in which illegal e-cigarettes have flooded the U.S. market.

The current market for e-cigarettes is characterized by a large number of illicit products and a number of actors, from manufacturers to retailers, acting irresponsibly to make and sell products that should not be sold in the United States. In fact, many of these illicit products are coming in from China.

The market for e-cigarettes (also referred to as electronic nicotine delivery systems or "ENDS" products) needs to be cleaned up and needs more enforcement. We and many members of our industry have asked for exactly that. We would like to work with the Committee to achieve this goal.

An important aspect of the current situation is that there is widespread regulatory confusion in this market. Businesses have tremendous difficulty deciphering the regulatory status of ENDS products. The result is that even good actors who expend significant resources attempting to comply with the legal limits on sales of ENDS products may inadvertently sell products that should not be sold.

Many responsible retailers invest significant time and resources in training employees on policies and procedures on the sale of age-restricted programs. They try to fully comply with the law and follow, as best they can, all relevant regulations. But, getting clear information is challenging even for large companies with in-house legal departments, not to mention for the majority of the industry which consists of single-store operators. These businesses need regulators to provide complete information so that everyone knows how to comply.

Background on the Convenience and Fuel Retailing Industry

NACS is an international trade association representing the convenience store industry with more than 1,500 retail and 1,600 supplier companies as members, the majority of whom are based in the United States.[1]

[1] Data on the industry comes from the NACS, State of the Industry Annual Report of 2021 Data *available at* https://nacsannualreport.convenience.org.

The convenience and retail fuels industry employed approximately 2.74 million workers and generated more than $859.8 billion in total sales in 2023, representing 3.1 percent of U.S. gross domestic product. Of those sales, approximately $532.2 billion came from fuel sales alone.

The industry, however, is truly an industry of small business. More than 60 percent of convenience stores are single-store operators. Less than 0.2% of convenience stores that sell gas are owned by a major oil company and about 4% are owned by a refining company. More than 95% of the industry, then, are independent businesses.

Members of the industry process more than 165 million transactions every single day. That means about half the U.S. population visits one of the industry's locations on a daily basis. In fact, 93% percent of Americans live within 10 minutes of one of our industry's locations. These businesses are particularly important in urban and rural areas of the country that might not have as many large businesses. In these locations, the convenience store not only serves as the place to get fuel but is often the grocery store and center of a community.

History on ENDS Market Confusion

To understand the breadth and depth of the challenges presented by the current regulatory regime, it helps to recognize how we got here. Prior to 2016, ENDS products were not regulated by the U.S. Food and Drug Administration's (FDA's) Center for Tobacco Products (CTP). In May 2016, the CTP deemed ENDS products subject to its regulatory authority conferred by the Family Smoking Prevention and Tobacco Control Act.

Given that decision, the CTP could have ordered ENDS products to be swiftly removed from the market because they were not on the market as of February 15, 2007, (and therefore considered "pre-existing tobacco products") and had not received the premarket authorization required under the Federal Food, Drug, and Cosmetic Act before new tobacco products can be introduced to the U.S. market. But the CTP did not order all ENDS products off of the market. Instead, it decided that manufacturers of products on the market at the time the CTP began regulating ENDS products (i.e., August 8, 2016) should submit premarket tobacco product applications (PMTAs) by a certain date and that products for which such applications were timely submitted could continue to be sold while the CTP reviewed those applications.

The CTP, however, was flooded with applications, and the review process has taken much longer than anyone anticipated. In fact, that process continues today. Following multiple extensions of the application filing deadlines, a number of groups sued the FDA in an attempt to speed up the process. The result of the lawsuit was that applications would have to be submitted by May 2020 (later extended to September 2020 due to COVID)[2] and that products for which an application was submitted by the deadline could remain on the market for up to one year following the date of submission during the CTP's review. The idea was that those applications would be reviewed, and decisions would be made as to whether each of those products could continue to be sold within one year of submission of those applications. That is not what happened.

Prior to that application deadline, the CTP published a guidance document in April 2020.[3] That

[2] It is worth noting that final rules specifying the content, format, and review of PMTAs were finalized in October of 2021. See 86 Fed.Reg. 55,300 (October 5, 2021), available at Federal Register :: Premarket Tobacco Product Applications and Recordkeeping Requirements.

[3] Food and Drug Administration Center for Tobacco Products, "Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised)*" April 2020

guidance document made a number of difficult to follow statements. First and foremost, it laid out what the CTP considered as its "enforcement priorities" for ENDS products. The term itself was difficult to understand. The CTP had for years said that ENDS products could stay on the market based on CTP's exercise of its "enforcement discretion" with respect to ENDS products that were on the market on August 8, 2016. Were "enforcement priorities" the same thing as "enforcement discretion?" The answer appeared to be no, but that was less than fully clear – particularly to regulated businesses, many of them small businesses. If the terms were not the same, how exactly did they differ? That too was less than fully clear.

The April 2020 guidance also provided one year of "enforcement discretion" for the ENDS products for which applications had been filed by the September 2020 deadline and for which the CTP had not reached a decision. Other things were not so clear. For example, the guidance stated that priorities for enforcement would include pod-based ENDS products with flavors other than tobacco and menthol as well as any products for which premarket approval applications were not filed by the deadline. That gave a clear indication of products that should not be sold because they were "enforcement priorities" for the CTP. But it left things somewhat murky regarding the status of products that did not fall within the CTP's "enforcement priorities." Could those continue to be sold? For how long? The basic question of what could and could not be sold was not clearly answered.

The lack of clarity was recognized at the time as a problem. Senator Patty Murray took the lead on a letter from ten senators (including some from this committee) to the FDA in May 2020 seeking more information so that policymakers and the public had the information they needed regarding the status of these products.[4] Specifically, the letter sought development of a comprehensive list of the products for which applications were submitted by the September 2020 deadline so that everyone would know what products the CTP was allowing to remain on the market. Thanks to these efforts, there are now public lists of products for which applications have been filed, but those lists remain unclear in several respects.[5]

Current Guidance Remains Unclear

The lists of products for which timely applications have been filed are headed by a category that reads "Lists of products for which continued marketing until September 9, 2021 may fall outside of CTP's stated enforcement priorities."[6] The reference to a date three years ago raises confusing questions including what the status of those products is after September 9, 2021. Is CTP exercising enforcement discretion with respect to those products? Why haven't they clearly stated on the website what the status of those products is today?

This uncertainty is compounded by other information on CTP's website regarding these products. For example, CTP includes in its description of the category of "Tobacco products that cannot be legally marketed and risk enforcement by FDA" the following:

(available at Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization (Revised): Guidance for Industry (fda.gov)).

[4] Letter from Ten Senators to FDA Commissioner Stephen Hahn, May 28, 2020 (available at Letter on Public List of Tobacco Products For Which Applications Submitted_05-20_20_final.pdf (senate.gov)).

[5] See "Deemed New Tobacco Product Applications Lists" (last accessed March 28, 2024; "content current as of 08/09/2021") (available at Deemed New Tobacco Product Applications Lists | FDA).

[6] See *Id*.

- "In general, a product that is on the market and not the subject of a pending, timely-filed premarket application (excluding pre-existing and previously authorized tobacco products)."[7]

That description seems to imply that a product that is the subject of a timely-filed premarket application is not a product that "cannot be legally marketed" or risks enforcement. Anyone participating in the market would likely conclude from that description that products with timely-filed applications still under review can be sold. Nothing in the descriptions of the categories of e-cigarette products on the website clearly contradicts that common-sense conclusion.

The category also includes the following reference:

- "Products as described in the guidance on Enforcement Priorities for Electronic Nicotine Delivery Systems (ENDS) and Other Deemed Products on the Market Without Premarket Authorization."

That guidance would appear to allow products with timely-filed applications to be sold as they were not enforcement priorities.

CTP's website also includes a category of ENDS products described as "Tobacco products that cannot be legally marketed but, consistent with a court order, generally might remain on the market pending FDA premarket review while FDA continues to defer enforcement." The products in this category, however, are uncertain as the information on these from CTP's marketing denial order list generally identifies the manufacturer that submitted the application but not the actual products that are the subject of the court order. A list of applications on CTP's marketing denial order list that have exceptions allowing the products to be sold during the pendency of court or administrative reviews is attached to this testimony. It shows more than twenty different exceptions, but it is unclear how many products can still be sold due to these exceptions because in most instances the specific products covered are not identified by CTP, only the manufacturers are listed without any clarity as to the number of products effected.

CTP also provides the following disclaimer on its website: "It is important to keep in mind that the lists are only one source of information. For example, retailers should discuss with their suppliers about the current status of any particular tobacco product's application or any product's marketing authorization." For retailers, however, that disclaimer is not adequate. How are retailers to know which suppliers will provide fully accurate information and which will not do so? Obviously, some suppliers are manufacturers or financially tied to manufacturers who have a vested interest in moving one particular brand or product. It is the responsibility of CTP, as the regulatory agency, to provide this information to retailers. Are retailers supposed to rely on any information they receive from suppliers given the lack of clarity from CTP?

Given the problems getting accurate information from suppliers, retailers need complete and clear information from CTP. We do not have that today.

The ENDS Market Today

In the shadow of this lack of regulatory clarity, bad actors have taken advantage of the situation and flooded the market with new ENDS products. Many of these are single-use products that were not

[7] *Id*.

described as enforcement priorities in the April 2020 guidance.[8] And many of these clearly illegal products are being made and shipped to the U.S. from China. It is estimated that these clearly illegal products may make up as much as half of the U.S. market for ENDS products today.[9]

While regulated businesses are informed when the CTP announces enforcement actions regarding a particular product and there is a list of the 34 marketing granted orders that the CTP has issued for ENDS products, there are thousands of products with timely-filed applications for which clarity remains lacking.

One thing that the CTP has written, in spite of some statements suggesting the contrary, is that *there are ENDS products that have not received marketing granted orders that can be sold*. We have pressed for, but have not been provided, a listing of the specific products that can be sold. In a letter responding to our requests last year, for example, the CTP wrote:

> There are a few products that have received a marketing denial order (MDO) that are under further agency review and for which FDA has stated the Agency does not intend to pursue enforcement action during the pendency of the re-review. In addition, in a very limited number of instances, some courts have granted stays of MDOs pending judicial review in order to maintain the status quo, or FDA has administratively stayed MDOs. In those particular instances, FDA does not intend to take enforcement action.

The CTP did not provide any additional information regarding the products that fell into these categories. The marketing denial order list on the CTP's website, for example, does not list the products that are the subject of denial orders. It lists only the companies that submitted the applications that were denied. At least some of the denials cannot cover all of a company's products because many companies are listed more than once on the list. There are notations on the list for at least 19 companies indicating that some or all of the products that are the subject of the denial order might still be able to be sold because part or all of the denial order was rescinded or because it is the subject of further agency review or court challenges. The result is that the status of the ENDS products from those 19 companies cannot be known with any certainty.

The CTP also has not provided clarity regarding the status of ENDS products that were on the market in 2016 and are covered by timely filed PMTAs that remain under review. The one-year timeframe for enforcement discretion following the filing of those applications has ended, but it is not entirely clear what the CTP wants to happen with those products today as they are not part of its "enforcement priorities."[10] Importantly, following the close of the one-year period, CTP leadership never expressly or impliedly communicated an expectation that applicants remove their ENDS products from the market during the pendency of the CTP's evaluation of them.

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[8] "Once a niche market, cheaper disposables made up 40% of the roughly $7 billion retail market for e-cigarettes last year, according to data from analytics firm IRI obtained by the AP." Matthew Perrone, "Thousands of unauthorized vapes are pouring into the US despite the FDA crackdown on fruity flavors," APNEWS.COM (June 26, 2023) (available at https://apnews.com/article/fda-vapes-vaping-elf-bar-juul-80b2680a874d89b8d651c5e909e39e8f); "The market share of disposable e-cigarettes increased from 24.7 % to 51.8% during the study period, with disposable brands Elf Bar and Breeze Smoke among the top-selling e-cigarette brands alongside Vuse, JUUL, and NJOY." Truth Initiative, "E-cigarette market surges amid urgent need for comprehensive regulation and enforcement," TRUTHINITIATIVE.ORG (July 12, 2023) (available at https://truthinitiative.org/research-resources/emerging-tobacco-products/e-cigarette-market-surges-amid-urgent-need).

[9] See *Id*.

[10] Does the CTP, for example, think it makes sense for products that it has denied authorization but which are undergoing additional review to be sold on the market, while products for which CTP has never issued a denial order because it still has not completed its review many years after filing should be removed from the market?

The situation with JUUL provides one case study of the regulatory confusion. Last year, CTP announced that it was denying applications for all JUUL ENDS products and that those products would need to be removed from the market. While this was momentous, it was at least clear that it applied to all JUUL products. Announcements relating to some other manufacturers were not clear regarding the specific products covered.

Following FDA's denial order, JUUL sued the FDA. Rather than defend its decision in court, however, FDA quickly asked for a stay of the litigation while it reconsidered its decision.[11] That meant the denial order was stayed and JUUL products could continue to be sold. That remained the situation for JUUL products until last summer – when FDA announced it was rescinding its denial order for JUUL products entirely. Now, the applications for JUUL products are in the category of the many such applications that were timely filed and remain under review.

Some have advocated that products with pending applications under review should not be able to be sold. But it is very difficult to see that result as coherent. That would mean that JUUL and many other categories of products could be sold while they had denial orders from the CTP which were being reviewed but that if CTP decided it was in error in denying those products and rescinded those orders, then the products actually could not be sold. That does not seem to be a reasonable or coherent result.

Clarity and Enforcement

Without regulatory clarity and increased enforcement, we are likely to see bad actors continue to exploit the current state of confusion to grow sales of illicit products. The best way to get that clarity is for CTP to finish reviewing the applications it has and issue decisions. As with JUUL, it may face challenges for products it denies, but it is better to start that process sooner rather than later so that we can all know what can and cannot be sold. The more time that elapses with products in the indeterminate state of being considered by CTP – particularly with the lack of clarity about what can or cannot be done with those products in the meantime – the worse the current situation with large numbers of illegal products on the market will become.

We also need additional enforcement efforts to stop imports of illegal products coming in from China. Of course, that job is more difficult for Customs and Border Protection officials if they do not have a clear picture of which products are and are not legal. The FDA has sent some warning letters and brought some enforcement actions against some of the worst offenders in this market. That is a helpful start, but more of that enforcement activity is needed.

[11] See Matthew Perrone, "FDA weighs oversight changes after formula, JUUL troubles," APNEWS.COM (July 19, 2022) (available at https://apnews.com/article/science-health-tobacco-industry-regulation-robert-califf-bbf49dd28719a34872771d82cd60cf02).

CTP, as the agency with regulatory authority over these products, has the responsibility to provide the clarity that stakeholders and enforcement officials need regarding which products can and cannot be on the market. If the CTP would provide an up-to-date and accurate list of the status of ENDS products (not just manufacturers or applications covering multiple products), the many different aspects of enforcement become much easier to achieve – and voluntary compliance with the law becomes possible. With widespread voluntary compliance, CTP will be able to focus its enforcement efforts on bad actors and can become much more effective clearing the market of illegal products.

Sincerely,

Doug Kantor
NACS General Counsel

MDO List Exceptions

The list of marketing denial orders (MDOs) issued by the Center for Tobacco Products (CTP) can be found here: Tobacco Products Marketing Orders | FDA. The list generally includes manufacturer names but not product names. As a result, regulated entities cannot know which specific products have been reviewed and cannot be sold. It cannot be assumed that all of a manufacturer's products have received an MDO because many manufacturers are listed more than once.

In addition, the MDO list includes many notations seemingly indicating that those manufacturers' products may be sold either because of ongoing court proceedings or further agency proceedings. Each of those notations are copied below and in total there are such notations for more than 24 manufacturers. It is not clear how many products those manufacturers have that are subject to the noted exceptions. Only a couple of those entities note the specific products involved.

- **SWT Global Supply:** "On July 31, 2024, the United States Court of Appeals for the Fifth Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA." (MDO Issuance Date: 8/31/21)
- **Diamond Vapor:** "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA." (MDO Issuance Date: 9/1/21)
- **Johnny Copper:** "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA." (MDO Issuance Date: 9/7/21)
- **SWT Global Supply:** "On July 31, 2024, the United States Court of Appeals for the Fifth Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA." (MDO Issuance Date: 9/7/21)
- **Bidi Vapor:** "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA." (MDO Issuance Date: 9/7/21)
- **My Vape Order Inc.:** "On October 18, 2021, the Agency issued a stay for this MDO pending its review. On January 19, 2022, FDA partially rescinded this denial with respect to certain products." (MDO Issuance Date: 9/8/21)
- **Vaporized Inc.:** "On July 31, 2024, the United States Court of Appeals for the Fifth Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA." (MDO Issuance Date: 9/8/21)
- **Fumizer LLC:** "On October 22, 2021, FDA partially rescinded this denial with respect to certain products." (MDO Issuance Date: 9/9/21)
- **Paradigm Distribution:** "On July 31, 2024, the United States Court of Appeals for the Fifth Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA." (MDO Issuance Date: 9/10/21)
- **ECS Global:** "On October 26, 2021, FDA partially rescinded this denial with respect to certain products." (MDO Issuance Date: 9/10/21)
- **Central Vapors:** "On February 4, 2025, FDA partially rescinded this denial with respect to certain products." (MDO Issuance Date: 9/10/21)
- **SV Packaging LLC:** "On July 31, 2024, the United States Court of Appeals for the Fifth Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA." (MDO Issuance Date: 9/10/21)

- **TPB International LLC:** "This order was rescinded on October 7, 2021." (MDO Issuance Date: 9/14/21)
- **Wages & White Lion Investments dba Triton Distribution:** "On January 3, 2024, the United States Court of Appeals for the Fifth Circuit issued an order setting aside the MDO and remanding to FDA." (MDO Issuance Date: 9/14/21)
- **Humble Juice Co., LLC:** "This order was rescinded on November 2, 2021." (MDO Issuance Date: 9/15/21)
- **Union Street Brand:** "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA." (MDO Issuance Date: 9/15/21)
- **Paradigm Distribution:** "On July 31, 2024, the United States Court of Appeals for the Fifth Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA." (MDO Issuance Date: 9/15/21)
- **Vapetasia LLC:** "On January 3, 2024, the United States Court of Appeals for the Fifth Circuit issued an order setting aside the MDO and remanding to FDA." (MDO Issuance Date: 9/16/21)
- **Pop Vapor Co, LLC:** "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA." (MDO Issuance Date: 9/16/21)
- **Vapornine LLC dba New Leaf Vapor Company:** "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA." (MDO Issuance Date: 9/16/21)
- **Cloud House:** "On July 31, 2024, the United States Court of Appeals for the Fifth Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA." (MDO Issuance Date: 9/8/21)
- **Vapor Unlimited:** "On August 23, 2022, the United States Court of Appeals for the Eleventh Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA." (MDO Issuance Date: 9/10/21)
- **Al Khalifa Group LLC:** "This order was rescinded on March 1, 2022." (MDO Issuance Date: 10/6/21)
- **Fontem US LLC:** "On Aug. 29, 2023, the United States Court of Appeals for the District of Columbia Circuit issued its opinion in Fontem US, LLC v. FDA, which affirmed in part and vacated and remanded in part MDOs issued on April 8, 2022, for certain myblu products. Specifically, the court's opinion affirmed the MDOs for new products, including myblu Intense Tobacco Chill 2.5% and myblu Intense Tobacco Chill 4.0%. The court's order granted Fontem's petition for review with respect to the myblu Device Kit, myblu Intense Tobacco 2.4%, myblu Intense Tobacco 3.6%, myblu Gold Leaf 1.2%, and myblu Gold Leaf 2.4%, setting aside the MDOs for those products, and remanding those matters to FDA." (MDO Issuance Date: 4/8/22)
- **JUUL Labs, Inc.:** "On Jun. 6, 2024, FDA rescinded these denials." (MDO Issuance Date: 6/23/22)
- **R.J. Reynolds Vapor Company:** "On March 23, 2023, the United States Court of Appeals for the Fifth Circuit granted a stay of the MDO issued to R.J. Reynolds Vapor Company's Vuse Vibe menthol e-cigarette products pending review." (MDO Issuance Date: 1/24/23)
- **R.J. Reynolds Vapor Company:** "On March 29, 2023, the United States Court of Appeals for the Fifth Circuit granted stay of the MDOs issued to R.J. Reynolds Vapor Company's Vuse Solo menthol e-cigarette products pending review." (MDO Issuance Date: 3/17/23)

- **SWT Global:** "On July 31, 2024, the United States Court of Appeals for the Fifth Circuit granted the petitions for review, set aside the MDOs, and remanded the matters to FDA." (MDO Issuance Date: 5/12/23)
- **Fontem US, LLC:** "On Oct. 13, 2023, FDA rescinded this denial." (MDO Issuance Date: 7/10/23)
- **R.J. Reynolds Vapor Company:** "On February 2, 2024, the United States Court of Appeals for the Fifth Circuit granted a stay of the MDOs issued to R.J. Reynolds Vapor Company's Vuse Alto menthol e-cigarette products pending review." (MDO Issuance Date: 10/12/23)