Tobacco and Nicotine Products: FDA Inspections and Enforcement

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FDLI, Introduction to Tobacco and Nicotine Law and Regulation
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Regulatory Overview

- The Family Smoking Prevention and Tobacco Control Act ("the Tobacco Control Act") granted FDA authority to regulate the manufacture, marketing, and distribution of tobacco products.
- FDA's Center for Tobacco Products ("CTP") is responsible for implementing FDA's authority under the Act, including:
  - Enforcement of tobacco laws and regulations *(e.g.*, through inspections);
  - Review of premarket applications for tobacco products;
  - Coordination of tobacco product research and testing; and
  - Establishment of warning labels for tobacco products.

FDA's "Three-Prong" Approach

- 1) Training and education
- 2) Monitoring of:
  - Retailers
  - Manufacturers
  - Importers
  - Distributors
- 3) Enforcement actions
  - Warning letters
  - Civil Money Penalties (CMP)
  - No-Tobacco-Sale Orders (NTSO)
  - Seizures, Injunctions, and Criminal Prosecution

Training and Education

- The “Compliance, Enforcement & Training” section of CTPs website offers a variety of materials intended to help tobacco retailers, manufacturers, importers, and distributors comply with FDA regulations, including:
  - Educational materials;
  - Regulations and guidance;
  - Webinars;
  - Trainings; and
  - Overviews of federal laws and regulations.

https://www.fda.gov/tobacco-products/compliance-enforcement-training

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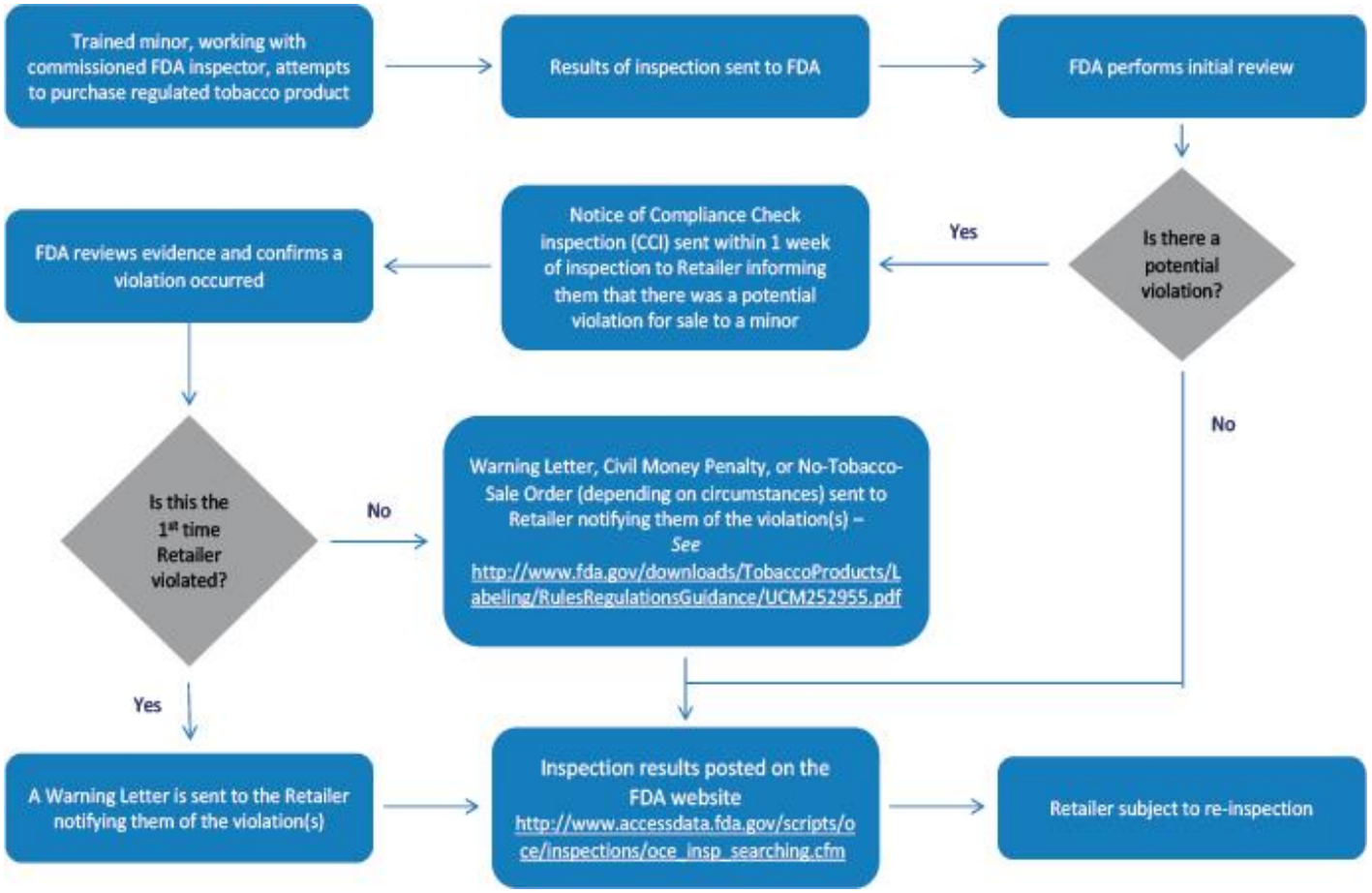
Retailer Inspections

- FDA conducts inspections of tobacco product retailers and websites to determine a retailer's compliance with the Act, as well as with the Agency's rules and regulations.
- The Agency issues **Warning Letters** to domestic "brick and mortar" retailers, as well as online retailers, the first time a tobacco compliance check inspection reveals a violation of the federal tobacco laws and regulations that FDA enforces.
- Failure to promptly and adequately correct all violations and ensure compliance with all applicable laws and regulations may lead to enforcement actions, including **Civil Money Penalties** ("CMPs") or **No-Tobacco-Sale Orders** ("NTSOs").

Types of Inspections

- The first inspection of a retail establishment will be either an Undercover Buy (“UB”) or Advertising and Labeling (“A&L”) inspection.
- UB inspections are conducted without notice.
- A&L inspections are conducted without use of minors and generally with an FDA Notice of Inspection (Form FDA 482).
- Compliance follow-up assignments include both types of inspections, usually conducted on different days.

Undercover Buy Inspections



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Online Retailers

- CTP conducts routine surveillance of online retailer websites, social media accounts, and publications.
- When surveillance reveals violations of the FD&C Act, FDA will take appropriate actions (usually a warning letter).
- Common violations for online retailers:
  - Selling to underage consumers;
  - Offering products for sale without the required warning statements;
  - Offering products for sale without the required marketing authorization; and
  - Selling tobacco products as modified risk tobacco products without an FDA order in effect.
    - *E.g.* claiming "vaping is a safer and healthier alternative to smoking."

Warning Letters

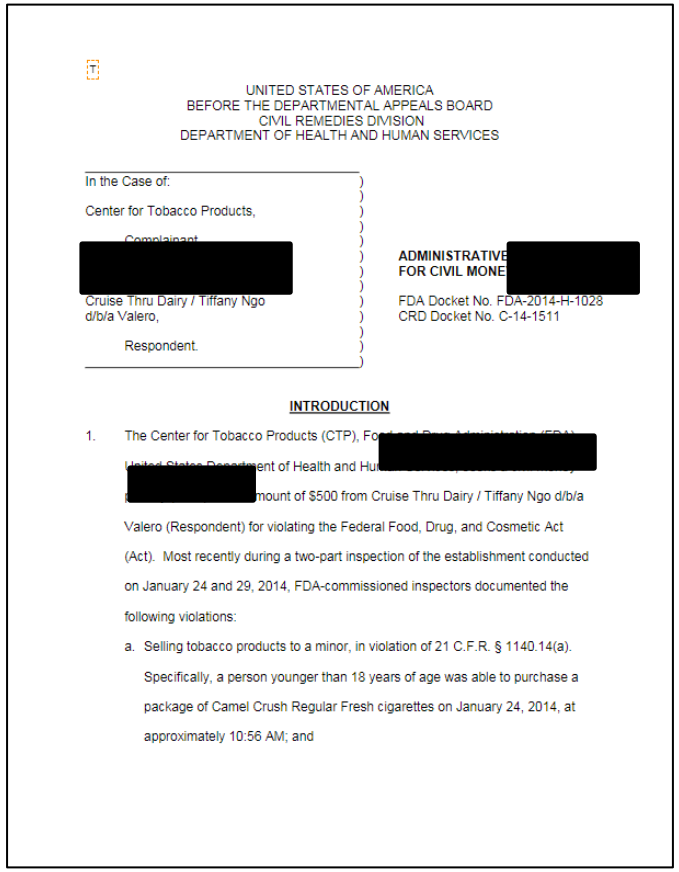
- Informs the recipient that:
  - They are in violation of federal tobacco laws and regulations; and
  - Failure to correct the violations may lead to FDA taking regulatory action without further notice, including, but are not limited to, CMP, NTSO, seizure, and/or injunction.
- Violations indicated in the letter may not be exhaustive.
- There are 15 working days to respond.
- The response should include:
  - Your current contact information (address, telephone number, email);
  - The reference number on the top of the warning letter; and
  - An explanation of the steps you will take to address any violations and prevent future violations.

What Comes After A Warning Letter?

- FDA will conduct a follow up inspection;
- Inspections will be added to the Compliance Check Inspection database; and
- If violations are observed during a follow up, then FDA may take additional action (CMPs, NTSOs, etc.).
  - Additional actions begin with a complaint…

Complaints

- Retailers will receive complaints when FDA has information suggesting a violation of the Tobacco Control Act.
- Complaints are the legal document identifying the statutory or regulatory violations that are the basis for seeking a CMP or NTSO.
- It will identify the amount of a CMP or the duration of the NTSO being sought.
- The complaint initiates the CMP or NTSO action.
- Complaints are often served through the mail or courier.



UNITED STATES OF AMERICA
BEFORE THE DEPARTMENTAL APPEALS BOARD
CIVIL REMEDIES DIVISION
DEPARTMENT OF HEALTH AND HUMAN SERVICES

In the Case of:

Center for Tobacco Products,

Complainant

[redacted]

Cruise Thru Dairy / Tiffany Ngo
d/b/a Valero,

Respondent.

ADMINISTRATIVE [redacted]
FOR CIVIL MONE

FDA Docket No. FDA-2014-H-1028
CRD Docket No. C-14-1511

INTRODUCTION

1. The Center for Tobacco Products (CTP), Fo[redacted]ent of Health and Hu[redacted]mount of $500 from Cruise Thru Dairy / Tiffany Ngo d/b/a Valero (Respondent) for violating the Federal Food, Drug, and Cosmetic Act (Act). Most recently during a two-part inspection of the establishment conducted on January 24 and 29, 2014, FDA-commissioned inspectors documented the following violations:

   a. Selling tobacco products to a minor, in violation of 21 C.F.R. § 1140.14(a). Specifically, a person younger than 18 years of age was able to purchase a package of Camel Crush Regular Fresh cigarettes on January 24, 2014, at approximately 10:56 AM; and

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Responding to the Complaint

- You must respond within 30 days.
  - You can file an answer or request an extension.
- No response may result in a default judgment.
- You may obtain an attorney, but you do not have to.

Civil Money Penalties

- A CMP is a fine assessed for a violation of law.
- FDA is authorized to seek CMPs for violations of the Federal Food, Drug, and Cosmetic Act ("FD&C Act") relating to tobacco products under section 303(f)(9) of the FD&C Act (21 U.S.C. § 333(f)(9)).
- FDA's CMP regulations are set forth at 21 C.F.R. Part 17.

CMP Amounts

Number of Regulation Violations	CMP Amount
1*	$0 (CTP will send a Warning Letter)
2 within a 12-month period	$320
3 within a 24-month period	$638
4 within a 24-month period	$2,559
5 within a 36-month period**	$6,397
6 within a 48-month period	$12,794

https://www.fda.gov/tobacco-products/compliance-enforcement-training/ctp-compliance-enforcement

*FDA counts only one violation from first inspection
**Threshold for NTSO (discussed in a subsequent slide)

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CMP Administrative Process

- There is an opportunity for settlement based on defenses and mitigating factors.
- Potential for a hearing on the CMP before an Administrative Law Judge ("ALJ") for contested complaints.
- Right of appeal to the HHS Departmental Appeals Board and the appropriate U.S. Court of Appeal.

CMP Mitigating Factors

- Nature, circumstances, extent, and gravity of violation(s).
- Ability to pay and effect on ability to continue to do business.
- Any history of prior violations.
- Degree of culpability.
- Amount of any penalties paid by the retailer to the State for same violation(s).
- Retailer's implementation of employee training program
- Other relevant matters.

No-Tobacco Sale Orders

- NTSOs are orders prohibiting the sale of tobacco products at a retail establishment.
- NTSO complaints are used to initiate an administrative legal action against a retailer that can result in the prohibition of the sale of tobacco products at a retail outlet indefinitely or for a specified period of time.
- FDA issues NTSO complaints to tobacco retailers when five repeated violations have been observed during compliance check inspections over a 36-month period.

NTSOs- Applicability and Duration

- FDA's current policy is to consider *each* retail location to be a separate retail outlet when determining if there are repeated violations that provide grounds for FDA to seek an NTSO (*see* Guidance for Tobacco Retailers, Determination of the Period Covered by an NTSO and Compliance With an Order, Aug. 2015).
- In determining the period to be covered by an NTSO, FDA must take into account the nature, circumstances, extent, and gravity of the violations and, with respect to the violator, ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability, and "such other matters as justice may require."

NTSOs – Duration of the Order

Number of NTSOs Received by Retailer	Maximum Period of Time for NTSO
First NTSO	30 Calendar Days
Second NTSO	6 Months
Third (and subsequent) NTSO(s)	Permanent

NTSOs- Mitigating Factors

- In determining whether to impose the NTSO or reduce the period of time FDA seeks to impose in the NTSO, the Agency will generally consider whether a retailer has taken effective steps to prevent the sale of tobacco products in violation of the minimum age requirements, including:
  - adopting and enforcing a written policy against sales to minors;
  - informing its employees of all applicable laws;
  - establishing disciplinary sanctions for employee noncompliance; and
  - requiring its employees to verify age by way of photographic identification or electronic scanning device.

NTSOs- Additional Thoughts

- Similar penalties for tobacco sales violations are addressed at the State level (*e.g.*, many states may suspend or revoke a retailer's license after multiple violations).
- An NTSO that permanently prohibits an individual retail outlet from selling tobacco products *must* allow the retail outlet, after a specified period of time, to request that FDA compromise, modify, or terminate the order.
- As of October 7, 2022, FDA has issued a total of 220 NTSOs.

Retailer Inspection and Enforcement Statistics

- Between October 2021 and September 2022:
  - Inspectors have conducted 84,974 retailer inspections;
  - FDA has issued 15,190 Warning Letters to retailers following compliance check inspections and online retailers stemming from surveillance activities;
    - 6,385 for cigars
    - 4,592 for ENDS/E-Liquid
    - 3,889 for cigarettes
  - FDA has issued 1,119 CMPs to retailers; and
    - 461 for cigars
    - 350 for ENDS/E-liquids
    - 274 for cigarettes
  - No NTSOs.
- And, since 2010, FDA has awarded over $434,573,608 in inspection contracts to assist with compliance check inspections of retail establishments.

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Poll

- What do you think the most common violation was last year?
  - A) Selling a product without prior authorization;
  - B) Failure to verify a purchaser's age;
  - C) Selling tobacco products to someone under 21 years of age; or
  - D) Labeling violations?

Common Violations

- 3,406 sales to a person under 21 years of age - 21 U.S.C. § 387f
- 2,084 failures to verify age - 21 C.F.R. § 1140.14(a)(2)(i)
- 222 sales to a minor – 21 C.F.R. § 1140.14(a)(1)
- 10 sales of individual cigarettes - 21 C.F.R. § 1140.14(a)(4)
- 4 sales from a prohibited vending machine - 21 C.F.R. § 1140.14(a)(3)
- 4 products with ads or labels including the terms “light,” “mild,” etc. - 21 U.S.C. § 387c
- 2 sales from a prohibited self-service display - 21 C.F.R. § 1140.16(c)
- 1 sale of a tobacco product lacking prior authorization - 21 U.S.C. § 387b(6)

Tobacco Product Manufacturer Responsibilities: What is a Manufacturer?

- If you make, modify, mix, manufacture, fabricate, assemble, process, label, repack, relabel, or import any "tobacco product," then FDA considers you a tobacco product "manufacturer."
- Importers of finished tobacco products may be distributors, tobacco product manufacturers, or both.
- Importers who do not own or operate a domestic establishment engaged in the manufacture, preparation, compounding or processing of a tobacco product are not required to register their establishment or provide product listing. However, they must comply with all other applicable tobacco product manufacturer requirements.

Manufacturer Compliance

- Tobacco product manufacturers must:
  - Report user fee information;
    - Only domestic manufacturers and importers of cigarettes, snuff, chewing tobacco, roll-your-own tobacco, cigars, and pipe tobacco. Manufacturers of electronic nicotine delivery systems (such as vaporizers or e-cigarettes), dissolvables, hookah/waterpipe, or nicotine gels are not required to report or pay user fees.
  - Pay user fees (*same as above*);
  - Register their establishment and submit a list of products, including labeling and advertisements.
  - Submit tobacco health documents;
  - Submit ingredient listing;
  - Apply to market any "new" tobacco product via one of three pathways (detailed in subsequent slide).
  - Include required warning statements on packages and advertisements; and
  - Submit quantities of Harmful and Potentially Harmful Constituents ("HPHCs").

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Registration and Listing

- Every person who owns or operates any domestic establishment engaged in manufacturing regulated tobacco products must register with FDA, and every registrant must file a list of its regulated tobacco products with the Agency.
- Under FDA's current compliance policy, the Agency will only enforce these registration and listing requirements with respect to finished tobacco products.
- The following must be included in the product listing submission:
  - A reference to the authority for the marketing of the tobacco product;
  - A copy of all labeling for the product;
  - A representative sampling of advertisements for the product; and
  - Product identification numbers (e.g., SKU, catalog number, UPC) as needed to uniquely identify the product.
- Such registrations will trigger FDA inspections of manufacturing facilities.

Health Documents Submission

- Documents developed after June 22, 2009, that relate to:
  - Health;
  - Toxicological;
  - Behavioral; or
  - Physiologic effects of:
    - Current or future tobacco products;
    - Their constituents (including smoke constituents);
    - Ingredients;
    - Components; and
    - Additives.
- FDA interprets "health, toxicological, behavioral, or physiologic" broadly to include, for example, cell-based, tissue-based, animal, or human studies, computational toxicology models, information on addiction, intentions to use, cognition, emotion, motivation, and other behavioral effects at both the population-level (epidemiology) as well as the individual level (such as abuse liability).
- *See* http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm208913.htm.

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Ingredient Submission

- The ingredient submission requirements under section 904(a)(1) of the Act apply to each "tobacco product manufacturer or importer."
- Ingredient lists must be submitted for each tobacco product by brand and by quantity in each brand and subbrand.
- A submission requires a listing of all ingredients, including tobacco, substances, compounds, and additives that are added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product as of the date of submission.
- In November 2018, FDA updated its Guidance for Industry, "Listing of Ingredients in Tobacco Products", *available at* https://www.fda.gov/regulatory-information/search-fda-guidance-documents/listing-ingredients-tobacco-products. This Guidance covers cigarettes, cigarette tobacco, roll your own tobacco, smokeless tobacco, and those tobacco products subject to FDA's Deeming Rule (*e.g.*, ENDS, waterpipe tobacco, etc.).

The “Deeming Rule” and New Tobacco Products

- Effective August 8, 2016, FDA finalized a rule extending FDA’s regulatory authority to cover all products that meet the definition of a tobacco product under section 201(rr) of the FD&C Act.
- Every domestic manufacturer and importer with a tobacco product not commercially marketed in the United States as of Feb. 15, 2007 must submit and obtain FDA authorization before marketing a new tobacco product.
- Examples of tobacco products previously regulated include:
  - Cigarettes;
  - Cigarette tobacco;
  - Roll-your-own tobacco; and
  - Smokeless tobacco.
- Examples of newly regulated tobacco products include:
  - Electronic nicotine delivery systems (ENDS);
  - Pipe tobacco;
  - Cigars;
  - Hookah/waterpipe tobacco; and
  - E-liquid.

New Tobacco Product Pathways and Compliance Deadlines

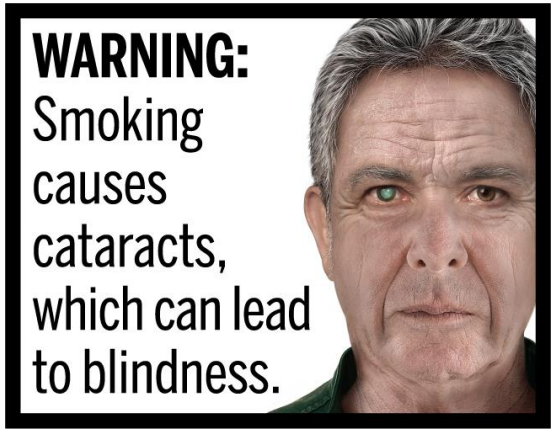
- There are three pathways available, based on date introduced into interstate commerce:
  - 180 days prior to introduction into interstate commerce: “New tobacco products” submitted as a Premarket Tobacco Application (PMTA)
  - 90 days prior to introduction into interstate commerce: “New tobacco product” submitted for substantial equivalence (SE) review via an SE Report
  - 60 days prior to introduction into interstate commerce: “New tobacco product” submitted with a request for exemption from substantial equivalence
- Any company who wishes to introduce a new tobacco product onto the market must submit a premarket application and receive authorization from FDA before doing so.

Required Warning Statements

- Currently, covered tobacco products (e.g., cigarettes, liquid nicotine, and roll-your-own tobacco) must feature this statement:

  WARNING: This product contains nicotine. Nicotine is an addictive chemical.

- Effective October 6, 2023 a new warning scheme requiring one of several graphic warnings goes into effect, such as:



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HPHC Submission

- Under section 904(a)(3) of the FD&C Act, “each tobacco product manufacturer or importer, or agents thereof” must report quantities of HPHCs for tobacco products by brand and subbrand.
- Per FDA, HPHC includes any chemical or chemical compound in a tobacco product or in tobacco smoke that:
  - is, or potentially is, inhaled, ingested, or absorbed into the body, including as an aerosol (vapor) or any other emission; and
  - that causes or has the potential to cause direct or indirect harm to users or non-users of tobacco products.

What Are HPHCs?

- Examples of constituents that have the "potential to cause direct harm" to users or non-users of tobacco products include constituents that are toxicants, carcinogens, and addictive chemicals and chemical compounds.
- Examples of constituents that have the "potential to cause indirect harm" to users or non-users of tobacco products include constituents that may increase the exposure to the harmful effects of a tobacco product constituent by:
  - potentially facilitating initiation of the use of tobacco products;
  - potentially impeding cessation of the use of tobacco products; or
  - potentially increasing the intensity of tobacco product use (*e.g.*, frequency of use, amount consumed, depth of inhalation).
- Another example of a constituent that has the "potential to cause indirect harm" is a constituent that may enhance the harmful effects of a tobacco product constituent.

Abbreviated Lists of HPHCs

- For current lists of HPHCs, consult:
  - FDA's Draft Guidance for Industry, "Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under Section 904(a)(3) of the Federal Food, Drug, and Cosmetic Act", Mar. 2012, *available at* http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm297828.pdf (for cigarettes, smokeless tobacco, roll-your-own tobacco, and cigarette filler).
  - FDA's Draft Guidance for Industry, "Premarket Tobacco Product Applications for Electronic Nicotine Delivery Systems", Updated June 2019, *available at* https://www.fda.gov/media/127853/download (for ENDS products).
  - FDA Proposed Rule, "Premarket Tobacco Product Applications and Recordkeeping Requirements", 84 Fed. Reg. 50,566 (Sept. 25, 2019), https://www.federalregister.gov/documents/2019/09/25/2019-20315/premarket-tobacco-product-applications-and-recordkeeping-requirements. Comments to this proposed rule were reopened in March 2020 and due April 9, 2020.

Enforcement Priorities for ENDS and Other Deemed Products on the Market without Premarket Authorization

- In January 2020, FDA issued its enforcement priorities guidance for ENDS and other deemed products without premarket authorization (*see* https://www.fda.gov/media/133880/download; amended in April 2020).
- For ENDS products marketed without FDA authorization, FDA intends to prioritize enforcement against:
  - Any flavored, cartridge-based ENDS product;
  - All other ENDS products for which the manufacturer has failed to take (or is failing to take) adequate measures to prevent minors' access; and
  - Any ENDS product that is targeted to minors or whose marketing is likely to promote use of ENDS by minors (this follows December 2019 legislation that increased the minimum tobacco purchase age from 18 to 21 nationwide)
- FDA also intends to prioritize enforcement of any ENDS product that is offered for sale after September 9, 2020, and for which the manufacturer has not submitted a premarket application (or after a negative action by FDA on a timely submitted application).

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Non-Tobacco Nicotine (NTN)

- Describes nicotine that did not come from tobacco plants ("synthetic nicotine").
- The Family Smoking Prevention and Tobacco Control Act, as amended in 2016, provided FDA the authority to regulate products containing nicotine from tobacco, leaving a grey area in the marketplace.
- The Consolidated Appropriations Act of 2022 expanded FDA's authority to regulate nicotine from any source. This went into effect in April 2022.
- Therefore, NTN products now require premarket authorization.
- As of September 16, 2022, no NTN products have received marketing authorizations.

Enforcement Against NTN Products

- In August FDA issued a first-of-its-kind warning letter against flavored nicotine gummies.
  - The Agency noted concern as this appears to be a kid-friendly product.
  - Product advertised as “tobacco free nicotine.”
- FDA has had the authority to regulate since April 14, 2022. As of September 6, 2022, FDA has issued:
  - 44 warning letters to manufacturers
  - 300 warning letters to retailers

Manufacturer Inspections

- At least once every two years, FDA investigators from the Agency's Office of Regulatory Affairs inspect tobacco establishments to ensure that they are in compliance with provisions of the FD&C Act, including:
  - That products are not adulterated or misbranded;
  - Registration and product listings;
  - Ingredient listings;
  - Requirements for packaging, labeling, and advertising; and
  - Marketing authorization for certain tobacco products.
- During these inspections, FDA reviews:
  - Processes and procedures;
  - Observes and evaluates manufacturing operations;
  - Documents and collects information;
  - Identifies violations;
- Procedures for investigations can be found in the Investigations Operations Manual (IOM): https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/inspection-references/investigations-operations-manual

After a Manufacturer Inspection

- Potential violations and objectionable conditions will be communicated to the establishment's management; and
- Any proposed corrective action plans will be documented.
- FDA issues one of three classifications based on its findings:
  - **No Action Indicated**, when the inspectors find no objectionable conditions or practices;
  - **Voluntary Action Indicated**, when findings are serious enough to record but do not require regulatory action; or
  - **Official Action Indicated**, when inspectors find significant, objectionable conditions or practices and regulatory action is warranted.
- During the next routine inspection, FDA follows up on the outcome of the actions it recommended.
  - If FDA finds that the establishment did not address its recommendations, it may Issue a warning letter, or it may take an enforcement action, such as a CMP, making a seizure, issuing an injunction, or launching criminal prosecution.

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Importing Tobacco Products into the U.S.

- All FDA-regulated products, including tobacco products, imported into the United States are required to meet the same laws and regulations as domestic goods.
- FDA-regulated products are subject to inspection when offered for import into the U.S. Products may be refused entry if they appear, from examination or otherwise, to violate FDA requirements.
- As discussed above, importers of finished tobacco products may be distributors, tobacco product manufacturers , or both. Importers who do not own or operate a domestic establishment engaged in the manufacture, preparation, compounding or processing of a tobacco product are not required to register their establishment or provide product listings. However, they must comply with all other applicable tobacco product manufacturer requirements.

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Questions?

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