



Tobacco and Nicotine Products: FDA Inspections and Enforcement

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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, including through inspections;
 - Review of premarket applications for tobacco products;
 - Coordination of tobacco product research and testing; and
 - Establishment of warning labels for tobacco products.

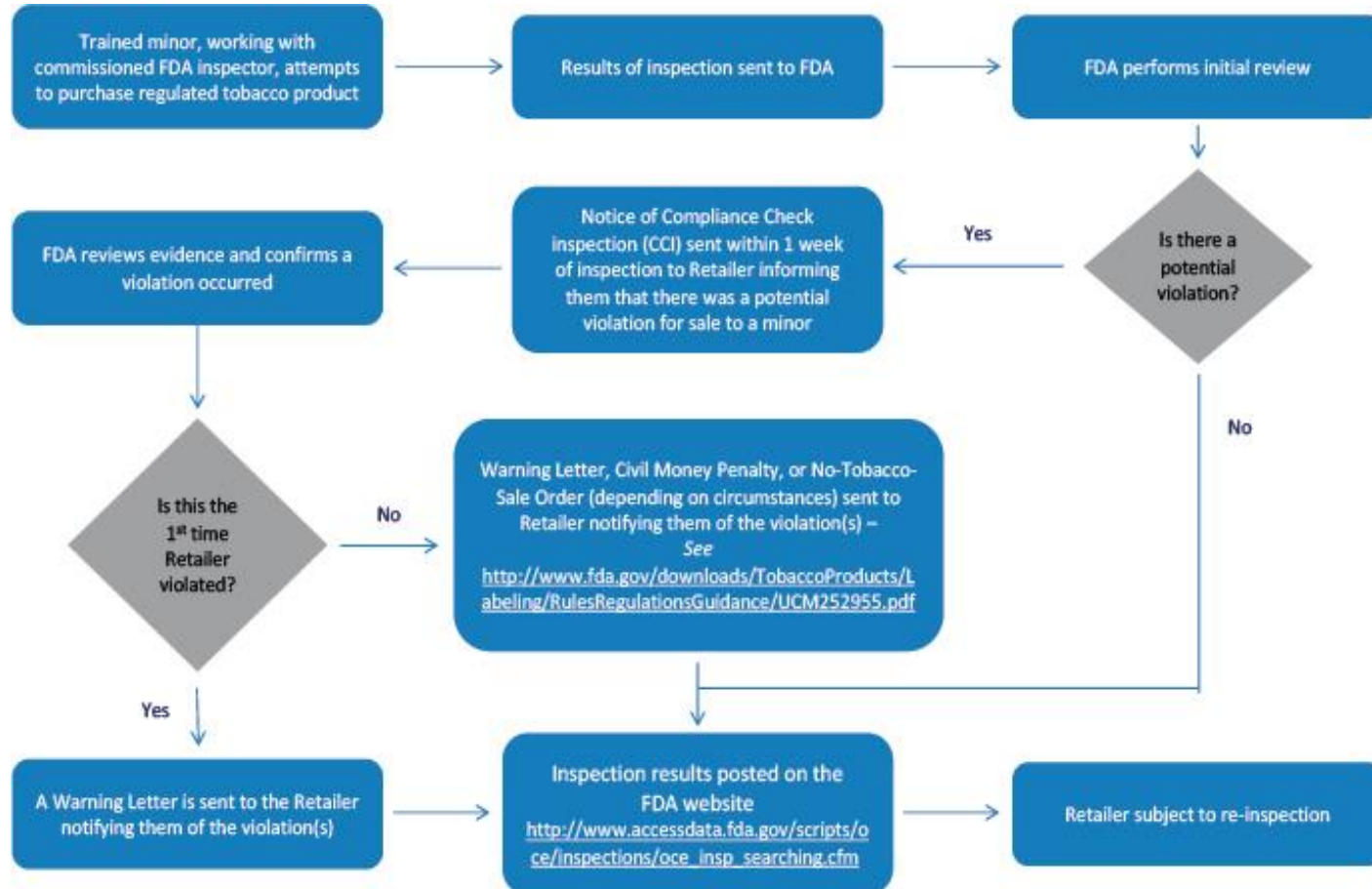
Retailer Inspections

- FDA conducts inspections of tobacco product retailers 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 and manufacturers, 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



Common Violations

- Sale to minor/failure to check identification for customer under 27 (21 C.F.R. § 1140.14(a), (b))
- Unlawful sampling (21 C.F.R. § 1140.16(d))
- Use of prohibited self-service display or vending machine (21 C.F.R. § 1140.16(c))
- Sale of product in quantity smaller than smallest manufacturer-distributed package (21 C.F.R. § 1140.16(b))
- Sale of cigarettes/components with prohibited characterizing flavors (21 U.S.C. § 387g(a)(1)(A))
- Modified Risk Tobacco Product (MRTP) violations (21 U.S.C. § 387k)

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.
- 15 working days to respond
- Violations indicated in the letter may not be exhaustive

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	\$297
3 within a 24-month period	\$594
4 within a 24-month period	\$2,381
5 within a 36-month period**	\$5,952
6 within a 48-month period	\$11,904

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

*FDA counts only one violation from first inspection

**Threshold for NTSO (discussed below)

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

- 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.
 - Each of the five violations will represent the second or subsequent violation of a particular requirement of the FDC&C Act, as amended by the Tobacco Control Act.

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 June 2021, FDA has issued a total of 221 NTSOs.

Retailer Inspection and Enforcement Statistics

- Between October 2020 and September 2021:
 - Inspectors have conducted 8,934 retailer inspections;
 - Down from over 33,000 the year before. Covid?
 - FDA has issued 95 Warning Letters to retailers following compliance check inspections and online retailers stemming from surveillance activities;
 - FDA has issued 8 CMPs to retailers; and
 - FDA has issued 1 complaint for an NTSO.
- And, since 2010, FDA has awarded over \$350,800,961 in inspection contracts to assist with compliance check inspections of retail establishments.

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 warning plans for smokeless tobacco and warning plans for cigars.
 - Submit quantities of Harmful and Potentially Harmful Constituents (“HPHCs”).

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
 - Smokeless tobacco
- Examples of newly regulated tobacco products include:
 - Electronic nicotine delivery systems (ENDS)
 - Pipe tobacco
 - Cigars
 - Hookah/waterpipe tobacco
 - 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
- The deadline for applications to market deemed regulated **combustible** products, such as cigars, pipe tobacco, and hookah was **August 8, 2021**.
- Pre March 2019 FDA guidance, applications to market deemed regulated **non-combustible** products, such as ENDS or e-cigarettes, were to be submitted by August 8, 2022. However, In July 2019, a U.S. District Court in Maryland ordered that applications for deemed tobacco products such as e-cigarettes, cigars, pipe tobacco, and hookah tobacco that were on the market as of August 8, 2016, must be submitted to FDA no later than May 12, 2020. This deadline was extended once more to **September 9, 2020**, because of the COVID-19 pandemic. Although this deadline has passed, 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.
 - Flavored vaping products to be “banned” unless and until PMTAs approved.
 - Important resource: <https://www.fda.gov/tobacco-products/compliance-enforcement-training/effective-and-compliance-dates-applicable-retailers-manufacturers-importers-and-distributors-deemed>.

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 (other than a tobacco- or menthol-flavored 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).

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.
 - 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.

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* <http://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM192053.pdf>. 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.).

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>.

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.

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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