

THE SETTLEMENT PROCESS FOR A CIVIL MONEY PENALTY OR A NO-TOBACCO-SALE ORDER COMPLAINT

Presented by:

Office of Compliance and Enforcement

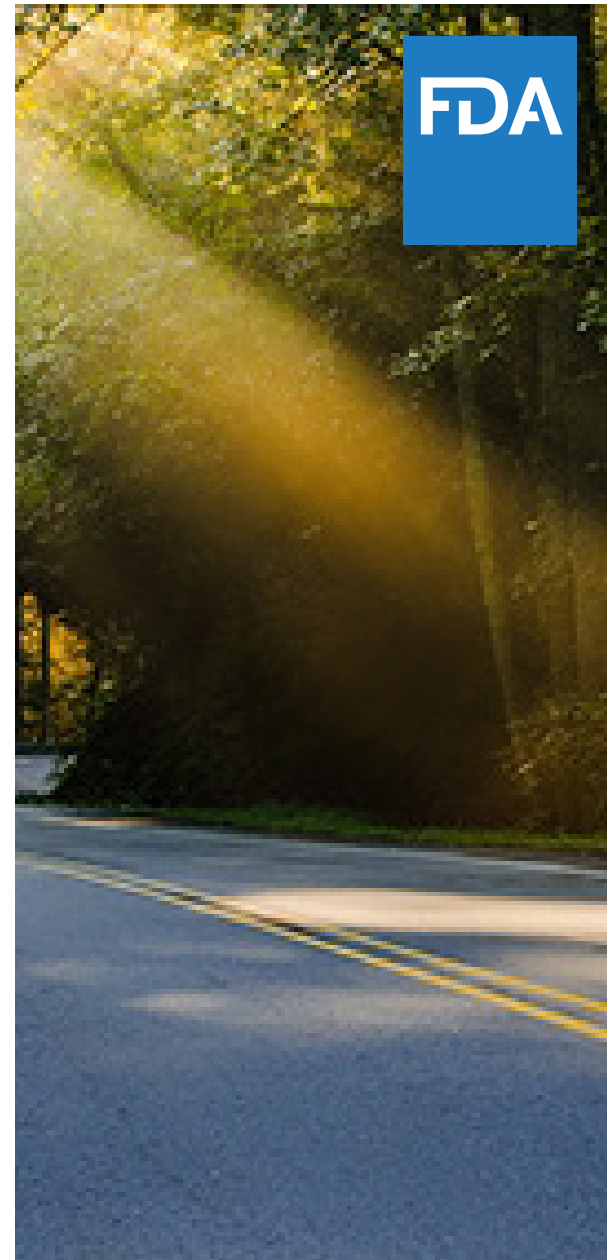
2018

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CENTER FOR TOBACCO PRODUCTS

AGENDA

- This is the 4th in a series of 5 webinars for Retailers and Small Businesses.
- The Settlement Process.

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AGENDA

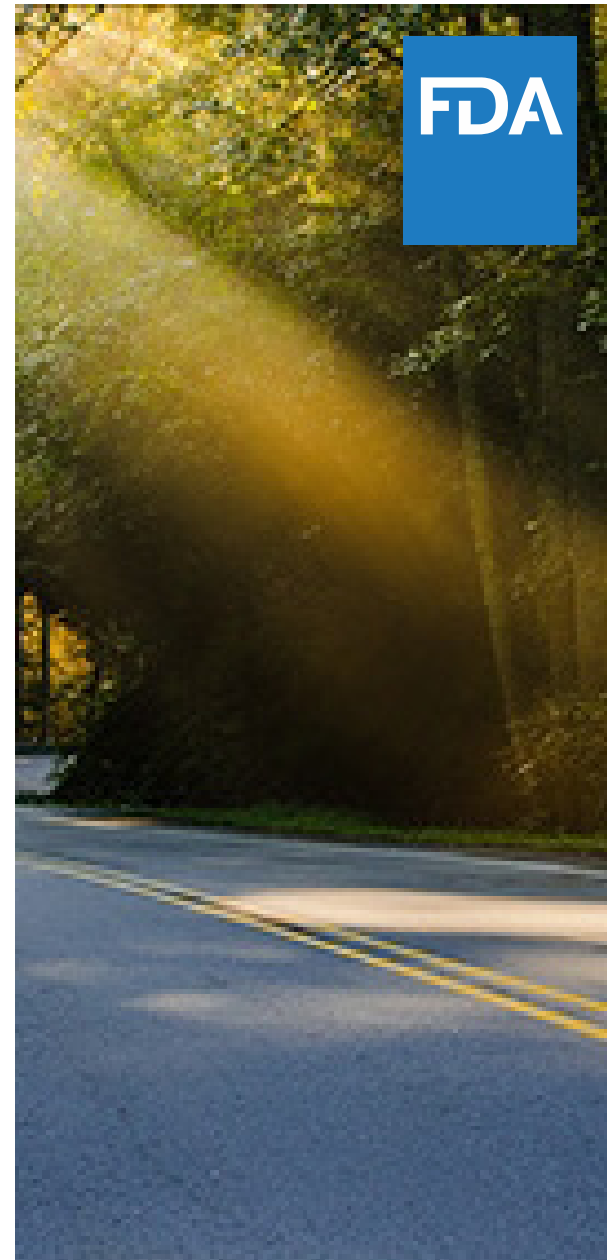
Other webinar topics:

- Introduction to Civil Money Penalty (CMP) and No-Tobacco-Sale Order (NTSO) Complaints
- How to Pay a CMP Using the Online Payment Portal
- How to File an Answer and Consequences for Not Filing an Answer
- The Hearing Process

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OVERVIEW

- All 5 webinars available on the FDA Tobacco Compliance Webinars webpage.
- Enter key words “Tobacco Compliance Webinars” in the search bar on the main FDA homepage, www.fda.gov, and follow the FDA Tobacco Compliance Webinars link in search results.
- Webinars are organized by year.

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AGENDA

- What is Settlement?
- What is a Settlement Conference?
- What will be discussed during the Settlement Conference?
- What is the Settlement Agreement?



FDA

WHAT IS SETTLEMENT?

SETTLEMENT, GENERALLY

- Agreement with the FDA/CTP to pay a reduced penalty amount or serve a shorter NTSO period.
- Can occur any time after receiving the Complaint, and before a final decision has been reached in your case.
- If settlement cannot be reached, the case will still proceed through the hearing process.

WHAT IS A SETTLEMENT CONFERENCE?

SETTLEMENT CONFERENCE



- Informal discussion of appropriateness of the penalty sought.
- If the retailer is represented by an attorney, FDA/CTP will communicate with the retailer through the attorney.

CONTACT FDA/CTP TO SET UP A SETTLEMENT CONFERENCE



- By phone or email
- **Phone:** (877) 287-1373, extension 6
- **Email for CMP:** CTP-CMP@fda.hhs.gov
- **Email for NTSO:** CTP-NTSO@fda.hhs.gov
- Provide name, contact information, and the FDA docket number when you contact FDA/CTP.

COVER LETTER: DOCKET NUMBERS



- Docket Numbers

CENTER FOR TOBACCO PRODUCTS



VIA UPS

XYZ LLC
d/b/a ABC Tobacco Store
Attn: Site Manager
123 Main Street
Silver Spring, MD 20993

Re: Civil Money Penalty (CMP) Complaint
ABC Tobacco Store, 123 Main Street, Silver Spring, MD
FDA Docket No. FDA-2017-H-1002
CRD Docket No. T-17-0000
Retailer Case No. 3009739700

Dear Retailer:

This letter and the enclosed Complaint notify you that the U.S. Food and Drug Administration's (FDA) Center for Tobacco Products (CTP) has filed an administrative action against you. FDA seeks a **\$559** civil money penalty for three violations of the Federal Food, Drug, and Cosmetic Act (Act) and implementing regulations within a twenty-four-month period.

You must respond to the attached Complaint. If you do not take action within 30 days after receipt of this Complaint, you will be in default and the Administrative Law Judge may issue an initial decision ordering you to pay the penalty under 21 C.F.R. § 17.11. Instructions for requesting a hearing are enclosed as well as additional options for responding. Please note that this is a federal administrative enforcement action governed by 21 C.F.R. Part 17, and according to those regulations, you may choose, but are not required, to retain counsel at any time.

To contact CTP, please call (877) 287-1373, extension 6, or email CTP-CMP@fda.hhs.gov.

WHO PARTICIPATES IN A SETTLEMENT CONFERENCE?



- The retailer
- An attorney, if the retailer has one
- FDA/CTP representatives

WHAT IS DISCUSSED DURING THE SETTLEMENT CONFERENCE?

The retailer should be prepared to discuss specific facts or circumstances that may reduce the CMP amount or the time that the NTSO is in effect.

Can include:

- Ability to pay;
- Effect on ability to continue to do business;
- History of prior violations;
- Degree of culpability;
- Amount of any penalties paid to a State for the same violation; and
- Any other matters as justice may require.

FDA will also will consider whether the retailer has taken steps to prevent future violations, including:

- Disciplinary sanctions for employee noncompliance with tobacco sales regulations;
- Additional employee training;
- Installation of point of sale electronic scanning system for age verification; and
- Voluntary compliance check programs.

EXAMPLES: DOCUMENTATION FOR SETTLEMENT DISCUSSIONS



- Financial documents related to revenue from tobacco sales.
- Documents showing financial hardship.
- Documentation of actions taken to come into compliance after receiving a Warning Letter, CMP, or NTSO Complaint in the past.

SETTLEMENT AGREEMENT

CMP: SETTLEMENT AGREEMENT



- If reaching a settlement for a CMP, the retailer will receive a follow-up letter.
- The letter will include:
 - Agreed upon reduced penalty amount
 - Date payment is due
 - Instructions on how to acknowledge the violations in the CMP Complaint and pay the penalty amount.

CMP: NOTICE OF SETTLEMENT AGREEMENT



CMP Notice of Settlement Agreement (NSA):

- Informs the Administrative Law Judge (ALJ) that the case was resolved through settlement agreement between the retailer and FDA/CTP;
- Confirms that the retailer made sufficient payment;
- Confirms that the retailer acknowledged the violations occurred;
- Makes request to ALJ to close the case.

NTSO: SETTLEMENT AGREEMENT



- The retailer will receive a Settlement Agreement.
- It will require acknowledgment of the violations alleged in the Complaint.
- It will contain all terms, including:
 - NTSO duration,
 - Start and end dates for the NTSO, and
 - Penalty for failing to meet the terms of the agreement.
- Settlement Agreement must be signed and returned to FDA/CTP by the requested due date.

MEETING DEADLINES



- Case will move forward based on dates set out by the Administrative Law Judge (ALJ) until the Notice of Settlement Agreement (NSA) is filed and the ALJ closes the case.
- Must file an Answer within 30 days after receiving the CMP or NTSO Complaint unless the case is closed before this date.
- If an Answer is filed before the deadline and no settlement is reached, the case will proceed through the hearing process.

SUMMARY

- Settlement, generally;
- Settlement Conference and how to request one;
- Mitigating Factors;
- Notice of Settlement Agreement.

WHAT'S NEXT?

Additional webinars:

- Introduction to CMP and NTSO Complaints
- How to Pay a CMP Using the Online Payment Portal
- How to File an Answer and Consequences for Not Filing An Answer
- The Hearing Process

HOW TO FIND THE WEBINARS



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