

INTRODUCTION TO CIVIL MONEY PENALTY AND NO-TOBACCO-SALE ORDER COMPLAINTS

Presented by:

Office of Compliance and Enforcement

2018

CENTER FOR TOBACCO PRODUCTS

Disclaimer: This is not a formal dissemination of information by FDA and does not represent Agency position or policy.

OVERVIEW

- Series of 5 webinars for Retailers and Small Businesses
- What a retailer can do once they receive a Complaint seeking a Civil Money Penalty (CMP) or a No-Tobacco-Sale Order (NTSO)

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5 WEBINAR TOPICS

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

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OVERVIEW

- All 5 webinars are available on the FDA Tobacco Compliance Webinars webpage.
- Enter keywords “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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CMP AND NTSO COMPLAINTS AGENDA

- What is a CMP?
- What is a NTSO?
- What is a Complaint?
 - What's in a Complaint?
 - What other documents are included with the Complaint?
 - What happens after the Retailer receives a Complaint?



FDA

CMP: CIVIL MONEY PENALTY



- Monetary sum assessed for a violation of the law.
- Federal Food, Drug, and Cosmetic Act (FD&C Act) gives FDA/CTP authority to assess a CMP for violations of certain requirements of the Act.
- Based on a published penalty schedule.
 - Each additional violation could change the CMP amount.
 - Each inspection can result in more than one violation.

NTSO: NO-TOBACCO-SALE ORDER



- Order prohibiting sale of tobacco products at a retail establishment.
- Issued for repeated violations of certain restrictions of the FD&C Act.
 - “Repeated violations” means at least 5 violations over a 36-month period that constitute a repeated violation.
- NTSO duration sought: 30 days (1st NTSO), 6 months (2nd NTSO), indefinite period of time (3rd or subsequent NTSO).

CMP AND NTSO: GLOSSARY OF COMMON TERMS



- List of common terms the retailer will encounter when dealing with CMPs and NTSOs.
- Glossary of terms attached to the end of this presentation.
- This presentation can be downloaded from the Tobacco Compliance Webinars page.

CIVIL MONEY PENALTY (CMP) AND NO-TOBACCO-SALE ORDER (NTSO) COMPLAINTS

WHY DID THE RETAILER RECEIVE A COMPLAINT?



- FDA/CTP has information to indicate that the establishment violated the Tobacco Control Act.
- FDA/CTP initiates a CMP or NTSO action by serving the retailer with a document called the Complaint.
- “Serving” the Complaint means that the Complaint has been delivered to the retailer.

WHAT IS A COMPLAINT?

- Legal document
- Alleges the violations that form the basis for seeking a CMP or NTSO
- Identifies amount of the CMP or the duration of the NTSO

COMPLAINT SECTIONS: INTRODUCTION AND LEGAL AUTHORITY



- Introduction
 - Lists the parties to the Complaint, FDA/CTP and the retailer
 - Amount of the CMP or duration of the NTSO sought
- Legal Authority
 - Lists laws that grant FDA/CTP authority to bring the Complaint

COMPLAINT - SECTIONS

Sample First Page:

- Heading, or the Caption
- Docket Numbers
- Introduction
- Legal Authority



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,

v.

XYZ LLC
d/b/a ABC Tobacco Store,
Respondent.

**ADMINISTRATIVE COMPLAINT
FOR CIVIL MONEY PENALTY**

FDA Docket No. FDA-2017-H-1002
CRD Docket No. T-17-0000

INTRODUCTION


1. The Center for Tobacco Products (CTP), Food and Drug Administration (FDA), United States Department of Health and Human Services, seeks a civil money penalty (CMP) in the amount of **\$559** from XYZ LLC, d/b/a ABC Tobacco Store (Respondent) for violating FDA's tobacco regulations promulgated under Section 906(d) of the Federal Food, Drug, and Cosmetic Act (Act) (21 U.S.C. § 387f(d)) at least three times within a twenty-four month period.

LEGAL AUTHORITY

2. FDA has the authority to seek a civil money penalty from any person who violates a requirement of the Act related to tobacco products. 21 U.S.C. § 333(f)(9).

- Current Allegations = Most recent facts and circumstances

CURRENT ALLEGATIONS

- 
7. Respondent owns an establishment that does business under the name ABC Tobacco Store and is located at 123 Main Street, Silver Spring, MD 20993.
 8. Respondent's establishment receives tobacco products in interstate commerce, including Global cigarettes, and holds them for sale after shipment in interstate commerce.
 9. On July 1, 2017, an FDA-commissioned inspector conducted an inspection of ABC Tobacco Store. During this inspection, Respondent committed a violation for selling cigarettes or smokeless tobacco to a minor, in violation of 21 C.F.R. § 1140.14(a)(1). Specifically, a person younger than 18 years of age was able to purchase a package of Global cigarettes on March 1, 2018, at approximately 10:00 AM.
 10. Respondent committed a violation for selling cigarettes or smokeless tobacco to a minor, in violation of 21 C.F.R. § 1140.14(a)(1). Specifically, a person younger than 18 years of age was able to purchase a package of Global cigarettes on March 1, 2018, at approximately 10:00 AM.

- Previous Case History = Previous CMP or NTSO

PREVIOUS CASE HISTORY

14. Previously, on January 1, 2017, CTP initiated a CMP action alleging that Respondent committed violations for sale to a minor (21 C.F.R. §1140.14(a)(1)) on November 1, 2016 and February 1, 2016.

See Compl., FDA-2016-H-0000, T-16-0000 (First CMP Action).
15. The First CMP Action was closed after XYZ LLC d/b/a ABC Tobacco Store admitted all of the allegations in the Complaint and paid the agreed upon penalty. In acknowledging that the alleged violations occurred, Respondent expressly waived its right to contest such violations in subsequent actions. See Notice of Settlement Agreement FDA Docket FDA-2016-H-0000, CRD Docket T-16-0000 (First CMP Acknowledgment Form documenting admission of liability attached to the Notice).

RESPONDING TO COMPLAINT

18. Respondent must respond to this Complaint. The cover letter provides information on options for responding. Respondent has the right to request a hearing by filing an Answer within 30 days after service of the Complaint. 21 C.F.R. § 17.9. The Answer will be deemed to be a request for a hearing, unless the Answer states otherwise. Failure to file an Answer within 30 days after service of the Complaint may result in a default order imposing the proposed civil money penalty. 21 C.F.R. § 17.11. The Answer must be filed with the Departmental Appeals Board, Civil Remedies Division, 330 Independence Ave., S.W., Cohen Building, Room G-644 (MS 6132), ATTN: FDA CMP, Washington, D.C. 20201. The Answer must include both the FDA Docket Number and CRD Docket Number which are found at the top of this document.
19. Respondent has the right, but is not required to retain counsel for representation.

- If a retailer chooses to contest the matter, the retailer must take action within 30 days to avoid default judgment
 - Filing an Answer
 - Successfully requesting an extension
- Taking no action could result in a default judgment.
- A retailer has the right, but is not required, to obtain an attorney.

COVER LETTER



Sample CMP Cover Letter Page 1

- Case Name
- Docket Numbers
- Retailer Case Number
- CMP Amount
- Duration of the NTSO sought
- FDA/CTP Contact Information

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 complaint 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.

Sample CMP Cover Letter, Page 3

- Options for responding to the Complaint

Page 3 – CMP Cover Letter – XYZ LLC d/b/a ABC Tobacco Store

OPTIONS FOR RESPONDING TO THE COMPLAINT

Option A: Acknowledge that the violations occurred and pay the full penalty amount of \$559.

Go to: <https://userfees.fda.gov/ctpcmp>

You will be asked to enter the following:

FDA Docket Number: FDA-2017-H-1002

Retailer Case Number: 3009739700

1. To pay the penalty in full you must first submit the online Acknowledgment Form. By signing the form you are acknowledging that:
 - you are the owner of the establishment and/or are authorized to settle all claims for this matter; and, if represented by counsel, you have conferred with the attorney of record prior to signing this form;
 - all of the violations including, but not limited to, the violations cited in any Warning Letter(s) described in the Complaint occurred;
 - you agree to make sufficient payment to settle the matter;

Sample CMP Cover Letter, Page 5

- How to submit documents

Page 5 – CMP Cover Letter – XYZ LLC d/b/a ABC Tobacco Store

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Prepare and submit your Answer (discussed in Options B and C).

1. To prepare your Answer you must:

- include both the FDA Docket Number and CRD Docket Number, which are found at the top of the cover letter and the Complaint;
- admit or deny each allegation made in the Complaint;
- state all the reasons why you believe you are not responsible or liable for the allegations in the Complaint;
- state all the reasons why you believe the penalty should be less than the requested amount; and
- if you are retaining counsel, state his/her name, address, telephone number, and email, if available.

Note: The Civil Remedies Division of the Departmental Appeals Board may provide a form Answer, which you may use instead of drafting your own Answer.

2. **Submit your Answer so that it is received by the Civil Remedies Division of the Departmental Appeals Board within 30 days after the delivery of the Complaint.** This can be done electronically or by mail.

File your Answer Electronically (DAB E-file):

If you have an existing account you may use that account to access the system for

WHAT DOCUMENTS COME WITH THE COMPLAINT?



- Cover Letter
- Inspection Documents
- Photos Taken During the Inspection

WHAT HAPPENS AFTER THE RETAILER RECEIVES THE COMPLAINT?



- FDA/CTP files the Complaint with the U.S. Department of Health and Human Services (HHS), Departmental Appeals Board (DAB), Civil Remedies Division (CRD).
- Filing of a Complaint for CMP or NTSO officially opens an administrative enforcement action.

DEPARTMENTAL APPEALS BOARD (DAB)



- DAB Administrative Law Judges (ALJs) from its Civil Remedies Division (CRD), conduct hearings regarding CMPs and NTSOs.
- Impartial, independent review.
- Decides outcome of CMP and NTSO Complaints.
- For more information, please visit:
<https://www.hhs.gov/about/agencies/dab/index.html>



DEPARTMENTAL APPEALS BOARD (DAB)



- A CRD ALJ is assigned to each Complaint filed with the DAB.
- The ALJ decides the procedures and outcomes of the Complaint based on submissions from both sides.
- Once the ALJ has a copy of the Complaint, the ALJ will start communicating with the retailer and FDA/CTP regarding resolution of the Complaint.

SUMMARY



- CMPs
- NTSOs
- Complaint
- Cover letter
- Departmental Appeals Board (DAB)
- Glossary of Terms

WHAT'S NEXT?

Additional webinars:

- [How to Pay a CMP Using the Online Payment Portal](#)
- [How to File an Answer and Consequences for Not Filing an Answer](#)
- [The Settlement Process](#)
- [The Hearing Process](#)

- For more background information on CMPs or NTSOs, please visit our [FDA Tobacco Compliance Webinars](#) page.
- Helpful Webinars:
 - *Retail Compliance Check Inspections: An Overview for Tobacco Retailers (2016)*
 - *Guidance for Industry: Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order (2015)*

HOW TO FIND THE WEBINARS



- 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.