

Webinar for Retailers and Small Business:
Civil Money Penalty and No-Tobacco-Sale Order
Fall 2018

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Acknowledgment Form

If the Respondent (Retailer) pays the full amount of the Civil Money Penalty requested in the Complaint or agrees to a settled Civil Money Penalty amount, the Retailer signs an Acknowledgment form.

This form states that the Retailer is authorized to settle claims on behalf of the retail establishment, acknowledges that all of the violations described in the Complaint occurred, agrees to make a sufficient payment to settle the matter, and waives the establishment's ability to contest these violations in the future.

See Webinar 2, How to Pay Your Civil Money Penalty Using the Online Payment Portal

Acknowledgment and Pre-Hearing Order

The Acknowledgment and Pre-Hearing Order is a document issued by the Administrative Law Judge (ALJ) assigned to the case that sets forth important dates associated with the case and provides the names, addresses, and telephone numbers of the parties. The Acknowledgment and Pre-Hearing Order also advises both parties on the proper procedures for presenting evidence and arguments in the case.

See Webinar 5, The Hearing Process for a Civil Money Penalty or a No-Tobacco-Sale Order Complaint

Administrative Law Judge

(ALJ)

The Administrative Law Judge, or ALJ, is the presiding officer in an administrative hearing. The ALJ is impartial, independent, and qualified to conduct hearings on the record. An ALJ from the Civil Remedies Division (CRD) of the Departmental Appeals Board (DAB) is assigned to each Civil Money Penalty (CMP) or No-Tobacco-Sale Order (NTSO) Complaint filed by the Food and Drug Administration/Center for Tobacco Products (FDA/CTP). (See 21 CFR § 17.3).

See Webinar 5, The Hearing Process

Answer

An Answer is a legal document that contains the Respondent's (Retailer's) formal response to the Complaint. The Answer must admit or deny each of the allegations made in the Complaint and include any and all defenses to the action, as well as reasons or explanations why the amount of the CMP or the duration of the NTSO should be less than sought in the Complaint. An Answer also serves as a request for hearing unless the Respondent states otherwise. (See 21 CFR § 17.9(a)).

See Webinar 3, How to File an Answer and Consequences for Not Filing an Answer

Center for Tobacco Products

(CTP)

The FDA's Center for Tobacco Products, or CTP, is responsible for carrying out the Family Smoking Prevention and Tobacco Control Act, which Congress passed in 2009. This law, commonly called the Tobacco Control Act, gives CTP broad authority to regulate the manufacturing, distributing, and marketing of tobacco products. In a tobacco CMP or NTSO case, the FDA's CTP is the Complainant.

See Webinar 1, Introduction to Civil Money Penalty and No-Tobacco-Sale Order Complaints

Civil Money Penalty

(CMP)

A Civil Money Penalty, or a CMP, is a monetary penalty assessed for a violation of the law. The FDA is authorized to assess CMPs for violations of the Federal Food, Drug, and Cosmetic (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 regulations governing CMP procedures are established in 21 CFR part 17.

See Webinar 2, How to Pay Your Civil Money Penalty Using the Online Payment Portal

Civil Remedies Division

(CRD)

The Civil Remedies Division (CRD) is the division within the Departmental Appeals Board (DAB) whose Administrative Law Judges (ALJs) are assigned to preside over Complaints for CMPs and NTSOs filed by FDA/CTP.

See Webinar 3, How to File an Answer and Consequences for Not Filing an Answer

Complainant

The Complainant is the party that initiates a case against a Respondent. In a tobacco CMP or NTSO case, the Complainant is the Food and Drug Administration's Center for Tobacco Products (FDA/CTP).

See Webinar 5, The Hearing Process

Complaint

A Complaint is a legal document that identifies the statutory and/or regulatory violations that the FDA/CTP is alleging as the basis for a Civil Money Penalty (CMP), No-Tobacco-Sale Order (NTSO), or both. The Complaint also identifies the amount of the CMP and/or duration of the NTSO that FDA/CTP is seeking. FDA/CTP's filing of a Complaint for CMP and/or NTSO, officially opens an administrative enforcement action. Once the Complaint is filed, it is assigned to an

Administrative Law Judge (ALJ) who will preside over the case. FDA/CTP serves a copy of the Complaint on the Retailer at the establishment where the violation occurred.

See Webinar 1, Introduction to Civil Money Penalty and No-Tobacco-Sale Order Complaints

Discovery

Discovery is the process through which a party (Retailer or FDA/CTP) makes a request to the other party for production of documents that are relevant to the case. Documents must be provided no later than 30 days after the request has been received by a party.

See Webinar 5, The Hearing Process

Default Judgment

If the Respondent (Retailer) does not file an Answer within the time prescribed in 21 CFR § 17.9 and if service has been effected as provided in 21 CFR § 17.7, the presiding officer shall assume the facts alleged in the Complaint to be true; if such facts establish liability, the presiding officer shall issue an initial decision within 30 days after the time the Answer was due, imposing: (1) The maximum amount of penalties provided for by law for the violations alleged; or (2) The amount asked for in the Complaint, whichever amount is smaller. (See 21 CFR § 17.11).

See Webinar 3, How to File an Answer and Consequences for Not Filing an Answer

Departmental Appeals Board

(DAB)

The Department of Health and Human Services, Departmental Appeals Board (DAB), provides its Civil Remedies Division (CRD) Administrative Law Judges (ALJs) to conduct impartial, independent hearings to adjudicate tobacco CMP and NTSO Complaints. The DAB Appellate Division provides review of decisions appealed by Respondents (Retailers) in administrative tobacco cases.

See Webinar 3, How to File an Answer and Consequences for Not Filing an Answer

Extension of Time

If the Respondent (Retailer) is unable to file an Answer within the time allowed, the Respondent must request an extension of time not later than 30 days after receiving the Complaint. The request must explain why the Respondent is unable to file its Answer in the time allowed and why an extension should be granted. If the Respondent shows good cause for an extension, the Administrative Law Judge may grant up to 30 additional days to file an Answer (see 21 CFR § 17.9(c)). Note that a request for extension is *not* automatically granted and is *only* granted for good cause shown.

See Webinar 3, How to File an Answer and Consequences for Not Filing an Answer

Family Smoking Prevention and Tobacco Control Act

(Tobacco Control Act / TCA)

FDA ensures compliance with the Family Smoking Prevention and Tobacco Control Act. To protect the public and create a healthier future for all Americans, the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act), signed into law on June 22, 2009, gives FDA authority to regulate the manufacture, distribution, and marketing of tobacco products.

See Webinar 1, Introduction to Civil Money Penalty and No-Tobacco-Sale Order Complaints

FDA Docket Number

An FDA Docket Number is assigned to each Civil Money Penalty (CMP) or No-Tobacco-Sale Order (NTSO) Complaint and is one of two reference numbers assigned to the administrative action. The FDA docket number is located on the first page of the Complaint. The FDA docket number can be used to find Complaints on www.regulations.gov. You will need this number when calling the FDA/CTP regarding settlement, and/or you would like to pay the penalty.

See Webinar 2, How to Pay Your Civil Money Penalty Using the Online Payment Portal

Federal Food, Drug, and Cosmetic Act

(FD&C Act)

The Federal Food, Drug, and Cosmetic Act was passed in 1938. The FDA Center for Tobacco Products (CTP) was established by the Family Smoking Prevention and Tobacco Control Act (the Tobacco Control Act), which was signed into law on June 22, 2009. The Tobacco Control Act amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by, among other things, granting the FDA authority to regulate the manufacturing, marketing, and distribution of tobacco products to protect the public health and to reduce tobacco use by minors.

See Webinar 1, Introduction to Civil Money Penalty and No-Tobacco-Sale Order Complaints

Hearing

The ALJ conducts a hearing with all parties, via telephone and on the record, to determine whether the Respondent is liable for a Civil Money Penalty or a No-Tobacco-Sale Order, and the appropriate penalty.

See Webinar 5: Hearing Process

Mitigating Factors

A Respondent (Retailer) or its representatives may engage in settlement discussions with FDA/CTP regarding the Civil Money Penalty or the No-Tobacco-Sale Order. Respondents may present relevant mitigating factors or arguments for FDA/CTP to consider reducing the penalty

amount or duration of the No-Tobacco-Sale Order. If there is a hearing, the ALJ will also consider any mitigating factors.

Mitigating factors may include the following:

- nature, circumstances, extent, and gravity of the violation(s),
- ability to pay,
- 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 a State for the same violation,
- retailer's implementation of an employee training program, and
- other relevant matters.

See Webinar 4, The Settlement Process

No-Tobacco-Sale Order

(NTSO)

The term No-Tobacco-Sale Order refers to an order under section 303(f)(8) of the FD&C Act prohibiting the sale of tobacco products at a retail outlet indefinitely or for a specified duration.

Under the law, the FDA/CTP may pursue a No-Tobacco-Sale Order (NTSO) against retailers that have a total of five or more repeated violations of certain restrictions within 36 months at a particular retail outlet. Retailers are prohibited from selling tobacco products at the specified location during the period of the NTSO.

See Webinar 1, Introduction to Civil Money Penalty and No-Tobacco-Sale Order Complaints

Payment Portal

A retailer may pay a Civil Money Penalty online, through the payment portal. Retailers may access the portal at <https://userfees.fda.gov/ctpcmp>. The payment portal accepts electronic checks and credit cards. Retailers must enter the FDA Docket Number and the Retailer Case Number to make payment. Both the FDA Docket Number and the Retailer Case Number can be found on the cover letter that accompanies the Complaint sent to the retailer.

See Webinar 2, How to Pay Your Civil Money Penalty Using the Online Payment Portal

Respondent

The Respondent (Retailer) is the party against whom a Complaint for Civil Money Penalty (CMP) and/or No-Tobacco-Sale Order (NTSO) is filed. In the Complaint, CTP alleges that the Respondent violated tobacco-related provisions in the Federal Food, Drug, and Cosmetic Act (FD&C Act). The Respondent will be identified in the heading of the Complaint and in certain accompanying documents. (See e.g., 21 CFR § 12.3(b)).

See Webinar 3, How to File an Answer and Consequences for Not Filing an Answer

Retailer

Retailer means any person or entity that sells tobacco products to individuals for personal consumption, or who operates a facility where vending machines or self-service displays are permitted under 21 CFR part 1140. The retailer is the Respondent in a CMP or NTSO Complaint, and can be either a person or a business entity. (See 21 CFR § 17.3(b)).

See Webinar 1, Introduction to Civil Money Penalty and No-Tobacco-Sale Order Complaints

Service

The Respondent will be notified of a CMP and/or NTSO Complaint when FDA/CTP properly serves the Complaint upon the retailer. Proper service is the delivery of any document in the case, including the Complaint, by an authorized method. (See 21 CFR § 17.7).

See Webinar 5, The Hearing Process

Settlement

The Respondent may request a settlement conference at any time.

Settlement discussions are often an efficient method of resolving a case. The Respondent may present information and documents to support mitigating factors that might reduce the CMP amount or the NTSO duration.

See Webinar 4, The Settlement Process

Settlement Agreement

A Respondent (Retailer) can resolve the case through a settlement agreement where Respondent agrees to pay a reduced penalty amount or serve a shorter No-Tobacco-Sale Order (NTSO) period than requested by the FDA/CTP, based on mitigating factors. If the Respondent and FDA/CTP arrive at an agreed upon settlement of a Complaint seeking a No-Tobacco-Sale Order, the Respondent will sign a settlement agreement agreeing to the terms of the NTSO and will be expected to comply with its terms unless or until it is terminated.

See Webinar 4, The Settlement Process