

NACS Tool-Kit:
A Step-by-Step Guide to Responding to
Complaints from the Center for Tobacco Products

Introduction

As you know, the Center For Tobacco Products (CTP) issues warning letters and complaints alleging violations of tobacco sales regulations. The statute and regulations set out a system where civil money penalties become more severe depending on how many prior violations a store has had in the past. These violations can result in warning letters, civil money penalties and, for numerous violations, a tobacco “no-sale order” for your store.

Recently, a NACS member successfully contested a civil money penalty. In that case, CTP sought to impose a \$500 fine against a retailer that failed two inspections (22 months apart) for selling cigarettes to a minor and failing to check ID. The CTP claimed that there were 3 violations within 24 months and the penalty was justified. The Administrative Law Judge reviewing the case disagreed, finding that each inspection was one violation, which means no civil money penalty (for 2 violations 22 months apart). **The bottom line is that the Judge ruled that retailers cannot be charged with two violations for a single inspection and that retailers are entitled to a hearing to challenge warning letters (or other penalties).** Although the CTP is appealing that case, this tool-kit allows you make similar arguments in response to Complaints and Warning Letters from CTP and fully protect your rights.

Enclosed is a step-by-step guide that lays out your options for responding to warning letters and complaints from the Center from Tobacco Products. Fill out Form A to challenge the Complaint against you.¹ **Remember you must act quickly to protect your rights under the regulations.** You have 30 days from receipt of a Complaint to provide an Answer or to request an extension. *See* Appendix X, Regulation on Civil Money Penalty Hearings, 21 C.F.R. § 17.9.

Instructions To Respond to A Complaint – USE FORM A

1. Carefully read the Complaint you received. Make notes of anything you disagree with or anything that is factually incorrect.
2. If you received a Complaint, note the date you received it. You must send in an Answer to the Compliant within 30 days of receipt or request an extension. *See* Regulation on Civil Money Penalty Hearings, 21 C.F.R. § 17.9. If the deadline falls on a Saturday, Sunday or Federal Holiday, your Answer can be filed the next business day. *See* Regulation on Civil Money Penalty Hearings, 21 C.F.R. § 17.30.

¹ This tool-kit provides the information that a retailer will typically need to respond to a warning letter or complaint from the Center for Tobacco Products. You can be represented by a lawyer in this process, but one is not required. This tool-kit does not provide individual legal advice or create an attorney-client relationship.

- a. It is best to file an Answer within 30 days. If that is not possible, you can request an extension for up to an additional 30 days. An extension requires “good cause” – a reason why you were not able to complete the Answer in 30 days. The extension request must be filed within the initial 30 days. *See* Regulation on Civil Money Penalty Hearings, 21 C.F.R. § 17.9.
 - b. If you do not file an answer (or request an extension) within 30 days, you waive the right to contest the amount penalties assessed against you. *See* Regulation on Civil Money Penalty Hearings, 21 C.F.R. § 17.12.
3. Answering a Complaint
- a. To Answer a Complaint, customize the fillable Form A attached or create your own response based on the attached suggestions. There are three separate sections of your Answer to customize based on this Complaint you receive: (1) factual errors, (2) legal errors – imposition of more than one “violation” per visit and (3) any claim that a fee is unreasonably high for your store.
 - i. If you have ever objected to a Warning Letter, you should attach your warning letter and objection to your Answer.
4. Submit Your Answer
- a. Two Options for submitting your response:
 - i. Create PDF and E-mail to: FDA-ALJ-Dockets@fda.hhs.gov
 - ii. Print and mail to:

Division of Dockets Management
Food and Drug Administration
Center for Tobacco Products
Attention: FDA ALJ Dockets
10903 New Hampshire Avenue
WO 1 – 1310
Silver Spring, MD 20993-0002
5. Watch for a Notice of Hearing
- a. If you file an Answer, you will receive Notice of a Hearing laying out the next steps. *See* Regulation on Civil Money Penalty Hearings, 21 C.F.R. § 17.13. Be sure to carefully review the Notice of Hearing and submit any required forms.
 - b. A hearing can be conducted via telephone.

**DEPARTMENT OF HEALTH AND HUMAN SERVICES
BEFORE THE ADMINISTRATIVE LAW JUDGE
U.S. FOOD AND DRUG ADMINISTRATION**

Name:

Date:

FDA Docket No.

ANSWER

Section 1: Admission or Denial of Factual Obligations and Defenses

In response to the factual allegations alleged in the Complaint, Respondent (check one):

Admits all of the factual allegations

Denies all or some of the allegations (if so, complete section 2)

In response to the charges alleged in the Complaint, Respondent raises the following defenses in addition to any denial of factual allegations above (check all that apply):

Rejects the calculation of the penalty (if so, complete section 3)

Contests the reasonableness of the penalty amount and requests a reduced penalty amount (if so, complete section 4)

Section 2: Denial of Factual Allegations

Complete this section only if you are denying some or all of the allegations in the Complaint. If you indicated above that you are admitting to all of the allegations, please skip this section.

Note: Allegations not specifically denied may be considered admitted.

Respondent denies the specific allegations listed in the Complaint for the following reasons:

Section 3: The CTP Seeks an Impermissible Civil Money Penalty

Complete this section if you are raising the defense that the CTP has impermissibly calculated the civil money penalty amount.

Respondent contests the civil money penalty sought by CTP for the following reasons:

Section 4: Support for Reduced Penalty Amount

Complete this section if you are raising the defense that the penalty sought by CTP is inappropriate.

Section 5: Request for Settlement Discussions

Would you like to request settlement discussions with CTP?

No.

Yes. If yes, ensure contact information is included in Section 6 or 7 below.

Section 6: Representation

Are you represented by counsel in this matter?

No. Respondent is proceeding without counsel OR

Yes. If Respondent is proceeding with counsel, please provide the following information:

Notice of Appearance of Attorney Representing Respondent

Name of Attorney:

Street Address:

City, State, Zip:

Business Phone/Cell Phone:

Email:

Section 7: Respondent's or Representative's Signature

Type or Print Name:

Signature of Respondent or Representative:

Title:

Date:

Street Address:

City, State, Zip:

Business Phone/Cell Phone:

Email: