

**NACS Tool-Kit:**  
**A Step-by-Step Guide to Responding to Warning Letters**  
**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. **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 a 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. If you have received a warning letter and did not receive the opportunity for a hearing (which we understand is the standard procedure today), we encourage you to file a letter objecting to the lack of process. *See* Form B attached.<sup>1</sup>

## **Instructions for Responding to a Warning Letter**

1. Carefully read the Warning Letter you received.
2. If the letter does not provide you with the opportunity for a hearing, customize and submit fillable Form B
3. Submit Your Answer or Letter – Two Options for submitting your letter:
  - i. Print and E-mail to: [FDA-ALJ-Dockets@fda.hhs.gov](mailto: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

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<sup>1</sup>This tool-kit provides the information that a retailer will typically need to respond to a warning letter 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.

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

**Re: Warning Letter to \_\_\_\_\_ received on**  
\_\_\_\_\_

To the Center For Tobacco Products:

On \_\_\_\_\_, \_\_\_\_\_ received a Warning Letter from the Center from Tobacco Products dated \_\_\_\_\_. \_\_\_\_\_ was not provided with a hearing before this Warning Letter was issued. \_\_\_\_\_ denies the allegations contained in this Warning Letter.

It is my understanding that the Center for Tobacco Products has previously taken the position that the inspection findings listed in this Warning Letter would count as a violation of the Federal Food, Drug, and Cosmetic Act. \_\_\_\_\_ objects to that position, as it is contrary to the regulations which provide for a hearing under the Administrative Procedure Act before a penalty may be imposed. *See* 21 USC § 333(f)(5); *CTP v. Orton Motor*, FDA-2015-H-3414 (Feb. 8, 2016).

\_\_\_\_\_ reserves all its legal rights, including, but not limited to the right to a hearing and the opportunity to contest the allegations contained in the Notice Letter.

Sincerely,

\_\_\_\_\_

\_\_\_\_\_  
Title