

# CIVIL MONEY PENALTY AND NO-TOBACCO-SALE ORDER COMPLAINTS: HOW TO FILE AN ANSWER AND CONSEQUENCES FOR NOT FILING AN ANSWER

*Presented by:*

*Office of Compliance and Enforcement*

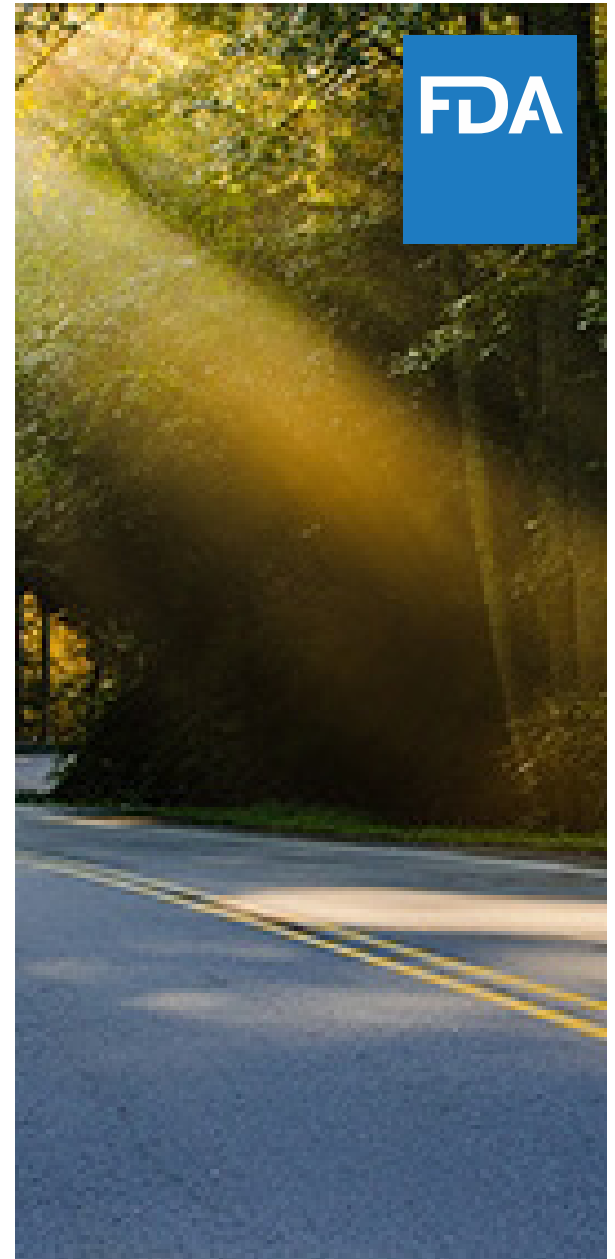
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**CENTER FOR TOBACCO PRODUCTS**

# AGENDA

- This is the 3rd in a series of 5 webinars for Retailers and Small Businesses.
- How to File an Answer and Consequences for Not Filing an Answer.

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# AGENDA

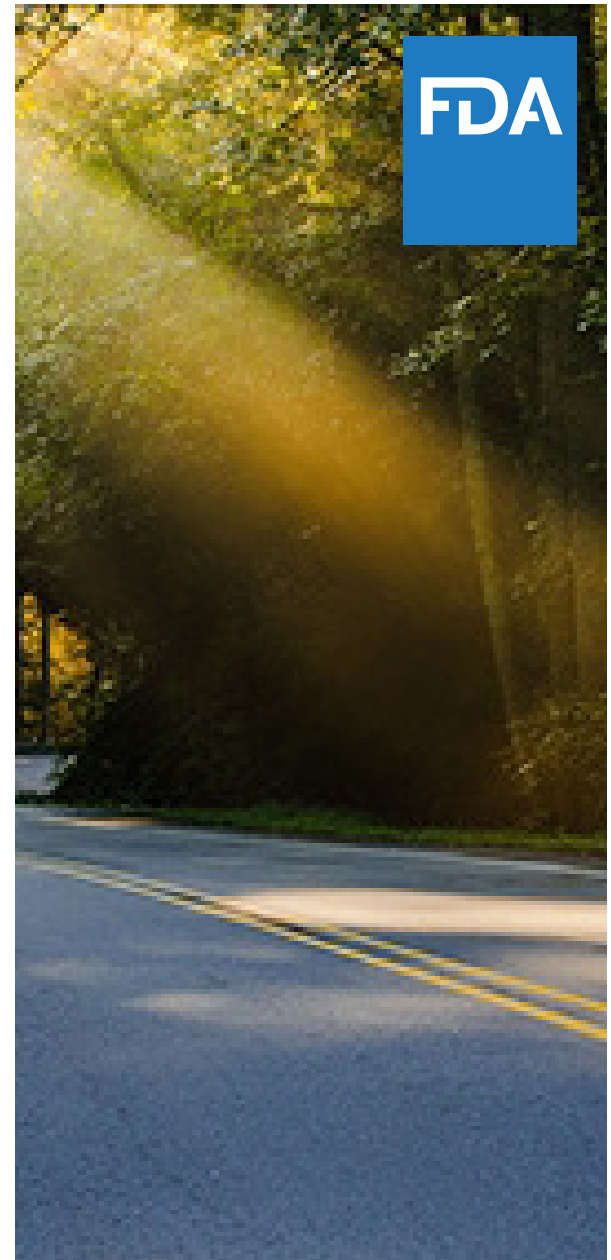
## Other webinar topics:

- Introduction to Civil Money Penalty (CMP) and No-Tobacco-Sale Order (NTSO) Complaints
- How to Pay a CMP Using the Online Payment Portal
- The Settlement Process
- 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](http://www.fda.gov), and follow the FDA Tobacco Compliance Webinars link in search results.
- Webinars are organized by year.



# AGENDA

- What is an Answer and what should it include?
- Deadline to file an Answer.
- DAB Electronic Filing System (DAB E-File).
- Initial Order Establishing Procedures (IOEP) and Guidance Establishing Procedures (GEP).
- Requesting an extension to file an Answer.
- Consequences for failing to file an Answer.



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# WHAT IS AN ANSWER

# WHAT IS AN ANSWER?

- Formal response to the CMP or NTSO Complaint.
- It is a document the retailer files with the Departmental Appeals Board (DAB) that either admits or denies the allegations contained in the Complaint.

# WHAT SHOULD AN ANSWER INCLUDE?



- Should include written responses admitting or denying the allegations in the “Current Allegations” section of the Complaint.
- No express denial is considered to be an admission.



# WHAT SHOULD AN ANSWER INCLUDE?



- Can contest some or all of the allegations in the Complaint.
- Can disagree with the penalty sought.
- Answer should include any reasons why the amount of the CMP, or the duration of the NTSO, should be less than what is sought in the Complaint.

# ANSWERS, CONTINUED



- An Answer is considered a request for a hearing, unless you waive the right to a hearing.
- An Answer must be filed within 30 days after receiving the Complaint.

# DEPARTMENTAL APPEALS BOARD (DAB) FILING REQUIREMENTS

# ELECTRONIC FILING



- DAB asks the retailer to file the Answer using its electronic filing system.
- The system is called the DAB E-File.

- Register and request access to DAB E-File by creating an account at the DAB E-File website, <http://dab.efile.hhs.gov>.
- Instructions can be found on the DAB E-File welcome page.
- Will need:
  - Email address
  - Business address
  - Phone number
- For technical assistance, email: [OSDABImmediateOffice@hhs.gov](mailto:OSDABImmediateOffice@hhs.gov).

# REQUESTING A WAIVER FROM THE REQUIREMENT TO E-FILE



If unable to file an Answer electronically, the retailer may request a waiver from the requirement to e-file:

- Request must be submitted by mail.
- Request must explain why the retailer is unable to file electronically.
- The address to send the waiver request is provided in documents that accompany the Complaint, as well as documents sent to the retailer by the ALJ.

# DOCUMENTS SENT BY THE DAB



The DAB will assign an ALJ to the case and that judge will send both the retailer and the FDA/CTP:

- Initial Order Establishing Procedures (IOEP)

Or

- Guidance Establishing Procedures (GEP)

- Notifies the retailer of the date by which they must file an Answer.
- Will usually include a form to help the retailer submit the Answer.
- The retailer is not required to use the provided form.



# REQUESTING AN EXTENSION OF TIME TO FILE AN ANSWER

# REQUEST FOR EXTENSION



- In the request, the retailer must explain why they need the additional time to file an Answer.
- The ALJ may, for good cause shown, grant up to 30 additional days within which to file an Answer.

# REQUEST FOR EXTENSION, CONTINUED



- A request for an extension of time to file an Answer must be filed within 30 days of receiving the Complaint.
- A request for an extension is not automatically granted.
- Unless the ALJ grants your request for an extension of time, you must submit your Answer by the original due date.

# CONSEQUENCES FOR NOT FILING AN ANSWER

# DEFAULT JUDGMENTS



- Decision issued by the ALJ.
- Finds the allegations listed in the Complaint to be true.
- Imposes the full penalty requested in the Complaint.

# HOW TO AVOID A DEFAULT JUDGMENT



- File an Answer by the due date;
- Successfully request an extension of time to file the Answer, AND meet any new deadlines that the ALJ establishes;
- Acknowledging and paying the full CMP amount or agree to an NTSO duration before the deadline to file an Answer; or
- Settling your case with the FDA/CTP before the deadline to file an Answer.

# FINALIZED DEFAULT JUDGMENTS



- A default will become final and binding after 30 days, unless the retailer files a timely appeal to the DAB or a Motion to Reopen the case with the ALJ.
- Once a default becomes final and binding, the retailer will be responsible for paying the CMP amount in the final decision or complying with the NTSO.
- For an NTSO, a letter from FDA/CTP will specify the exact dates of the NTSO period.

- What is an Answer and what should it contain?
- Due dates for filing an Answer.
- DAB E-File and requesting a waiver from electronic filing requirements.
- IOEP and GEP.
- Requesting an extension of time to file an Answer.
- Consequences for failing to file an Answer.



# WHAT'S NEXT?

## Additional webinars:

- Introduction to CMP and NTSO Complaints
- How to Pay Your CMP Using the Online Payment Portal
- The Settlement Process
- Hearing Process

# HOW TO FIND THE WEBINARS



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