

THE HEARING PROCESS FOR A CIVIL MONEY PENALTY OR A NO-TOBACCO-SALE ORDER COMPLAINT

Presented by:

Office of Compliance and Enforcement

2018

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

CENTER FOR TOBACCO PRODUCTS

AGENDA

- This is the last in a series of 5 webinars for Retailers and Small Businesses.
- The Hearing Process.

The FDA logo is a blue square with the letters "FDA" in white, positioned in the upper right corner of the slide.

AGENDA

Other webinar topics:

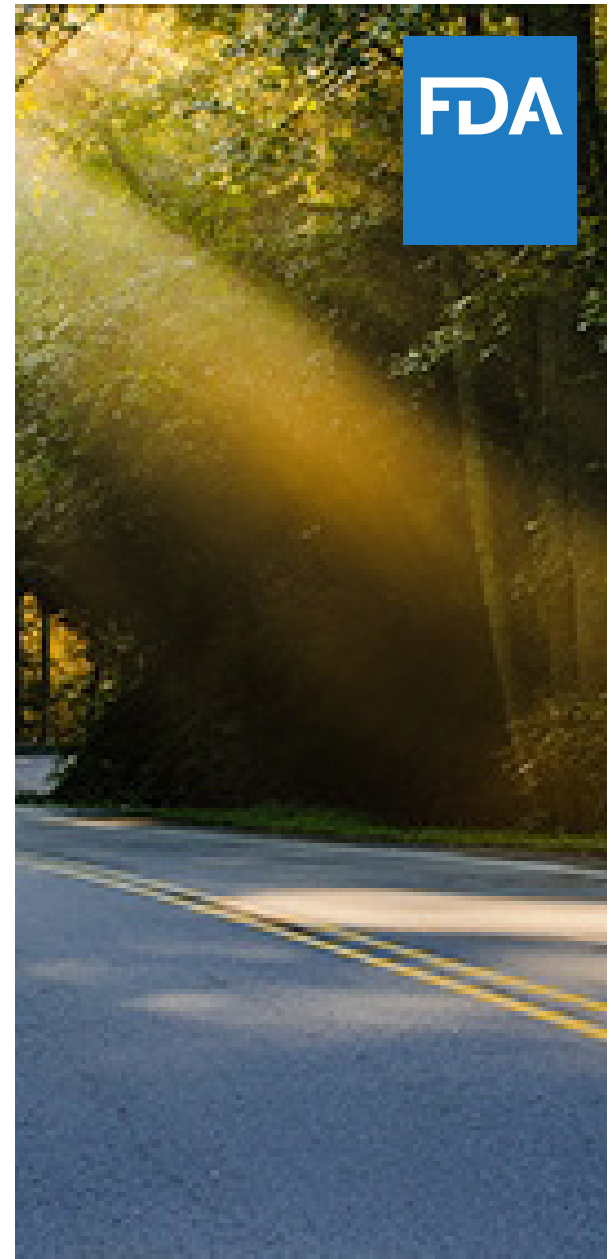
- Introduction to Civil Money Penalty (CMP) and No-Tobacco-Sale Order (NTSO) Complaints
- How to Pay a CMP Using the Online Payment Portal
- How to File an Answer and Consequences for Not Filing an Answer
- The Settlement Process



FDA

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, and follow the FDA Tobacco Compliance Webinars link in search results.
- Webinars are organized by year.



AGENDA

- What is a hearing;
- How to request a hearing;
- Who conducts the hearing;
- What happens once a hearing is requested;
- What happens at the hearing; and
- What happens after the hearing.



FDA

THE RETAILER'S RIGHT TO A HEARING



- The retailer has the right to a fair and impartial hearing.
- The retailer can, but is not required to, have an attorney during the hearing process.

INITIATING THE HEARING PROCESS



- Initiated when the retailer submits an Answer.
- Answer deemed a request for a hearing, unless the retailer waives the right to a hearing.
- If the retailer waives the right to a hearing, Administrative Law Judge (ALJ) will decide the outcome based on documents and arguments submitted.

- Hearings conducted in accordance with rules set forth in Part 17 of Title 21 of the Code of Federal Regulations.
- Part 17 can be found at:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=17>
- Or use “Code of Federal Regulations Title 21, Part 17” in your internet browser search bar.

DEPARTMENTAL APPEALS BOARD (DAB)



- Hearings conducted by the Departmental Appeals Board, Civil Remedies Division (CRD).
- CRD employs Administrative Law Judges (ALJs) who conduct hearings regarding CMPs and NTSOs.



ADMINISTRATIVE LAW JUDGE (ALJ)



- Presiding officer in an administrative hearing.
- Impartial and independent.
- Qualified to conduct hearings on the record.

ADMINISTRATIVE LAW JUDGE (ALJ) RESPONSIBILITIES



- Sets date and time of the hearing.
- Receives evidence.
- Issues rulings on admissibility of the evidence.
- Regulates the course of the hearing and conduct of the parties.
- Rules on procedural and other motions.
- Determines whether the retailer is liable for the violations in the Complaint.
- Determines the appropriate amount of the CMP or duration of the NTSO.

ADMINISTRATIVE LAW JUDGE (ALJ)



- ALJ is not responsible for conducting settlement negotiations.
- The settlement process with FDA/CTP and the hearing process can occur simultaneously.

WHAT HAPPENS ONCE A HEARING IS REQUESTED

“ACKNOWLEDGMENT AND PRE-HEARING ORDER”



- Issued by the ALJ once Answer is filed.
- Title and format can vary depending on the ALJ assigned.
- Tells the retailer and FDA/CTP the procedures for presenting evidence and arguments.
- Sets important dates for the case.

PRE-HEARING ORDER



Department of Health and Human Services

DEPARTMENTAL APPEALS BOARD

Civil Remedies Division

In the Case of:)
)
Center for Tobacco Products,)
)
Complainant)
)
- v. -)
)
XYZ LLC)
d/b/a ABC Tobacco Store,)
)
Respondent.)

Date: December 1, 2017

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

ACKNOWLEDGMENT AND PRE-HEARING ORDER

This acknowledges receipt by the Departmental Appeals Board, Civil Remedies Division of Respondent's November 15, 2017 Answer. The case has been docketed under the

PRE-HEARING ORDER, SPECIFICALLY



- Notifies parties of the name and contact information of the staff attorney assisting the ALJ;
- Summarizes documents that the parties must file;
- Establishes due dates for filing documents;
- Provides format requirements that both parties must follow when filing documents.

- Process by which a retailer or FDA makes a written request to the other party for production of documents.
- Sample language from a Pre-Hearing Order:

12. Discovery

The parties may request copies of documents relevant to this case. The requesting party must serve the request for documents no later than **January 8, 2018**. A party receiving such a request must provide the requested documents no later than 30 days after the request has been made. 21 C.F.R. § 17.23(a). Neither the request for production of documents, nor the documents provided in response to a request, should be filed with the Civil Remedies Division except as specified below.

A party may file a motion for a protective order with the Civil Remedies Division within 10 days of receiving a request for the production of documents. The motion should indicate that the party takes issue with some or all of the opposing party's request for documents, and that a memorandum in support of their motion will be filed when responsive documents not at issue are produced.

PRE-HEARING ORDER: PRE-HEARING EXCHANGE



- Pre-Hearing Order: requires that the Retailer and FDA/CTP submit a Pre-Hearing Exchange.
- The Pre-Hearing Order may require an Informal Brief from the Retailer and FDA/CTP.
- The Pre-Hearing order will require the Retailer and FDA/CTP to submit a list of witnesses and exhibits; sworn, written direct testimony of any witness; and any documents the party intends to use during the hearing.

LANGUAGE ACCESS SERVICES OR TRANSLATIONS



- DAB provides free language access services throughout the process.
- Also available by calling the DAB at (844) 880-5720.

PRE-HEARING ORDERS



- Read through all the requirements in the Pre-Hearing Order.
- Contact the ALJ's staff attorney, listed on the Pre-Hearing Order, if there are any questions about the ALJ's orders.
- Submitting an Answer is only the first step towards requesting a hearing. Additional steps are required before the ALJ will schedule a hearing date.

PRE-HEARING CONFERENCE



- Telephone conference.
- Date, time, and conference call number provided through a separate order from the ALJ.
- ALJ will:
 - Clarify issues to be determined at the hearing;
 - Identify witnesses who will be questioned during the hearing;
 - Set time and date for the hearing.

WHAT HAPPENS AT THE HEARING

WHO ATTENDS THE HEARING?

- The ALJ;
- Staff attorney assigned to assist the ALJ;
- Counsel from FDA's Office of Chief Counsel (on behalf of the Center for Tobacco Products);
- Representatives from the Center for Tobacco Products;
- The Respondent (the retailer);
- The Respondent's attorney, if there is one;
- Witnesses for both sides; and
- A court reporter to record the hearing.



TELEPHONE HEARING



- Hearings conducted over the telephone via conference call.
- Contact the ALJ's staff attorney if a telephone hearing is impractical.

Document Evidence

- Must be included in pre-hearing exchange that is filed prior to the hearing.
- Can include photographs, videos, reports, and sworn witness statements.
- Also referred to as exhibits.

Witness Testimony

- Made under oath.
- Witnesses must submit sworn direct testimony in writing prior to the hearing.
- The retailer will be permitted to pose questions to FDA's/CTP's witnesses.
- FDA/CTP can pose questions to the retailer's witnesses.

PRESIDING ALJ



- Presiding ALJ determines what evidence and exhibits are admissible in the hearing.
- ALJ will not make a final decision at the hearing.
- A written final decision is issued after the hearing is conducted.

WHAT HAPPENS AFTER THE HEARING

- Written transcript of the hearing produced after hearing is complete and ALJ accepted the evidence into the record.
- Each side is allowed to review the written transcript.

- Both parties permitted to submit a Post-Hearing Brief.
- Submitted after the hearing is completed.
- Summarizes arguments or legal issues regarding the facts of the case.
- ALJ sets the due date after the transcript becomes available.

WHAT IS IN AN INITIAL DECISION?

A decision finding:

- Whether the allegations in the complaint are true;
- Whether the retailer's actions violated the law;
- Whether the retailer is liable for the charged CMP or NTSO; and
- If the retailer is liable, what is the appropriate amount of CMP or duration of NTSO.

If the retailer is found liable for a CMP:

- Will set forth amount of the penalty.
- When the decision becomes final and binding on both parties.

If the retailer is found liable for a NTSO:

- Will set forth the number of days that the NTSO will be in effect.
- FDA/CTP will send the retailer a letter of the dates the NTSO will be in effect.

If the ALJ finds the retailer is not liable for the alleged violations:

- No assessed CMP amount or NTSO duration.

APPEALING ALJ'S INITIAL DECISION



Right to appeal

- Appeal must be filed within thirty (30) days after the date that the Initial Decision is issued.
- Information on how to appeal included with Initial Decision.

- Requesting a hearing, by filing an Answer;
- ALJ, the presiding officer in the case;
- Pre-Hearing Order, Discovery, Pre-Hearing Exchange, and the Pre-Hearing Conference;
- Hearing and Evidence Presentation;
- Transcripts, Post-Hearing Briefs, Initial Decisions, and Appeals.

WHAT'S NEXT?

Additional webinars:

- Introduction to CMP and NTSO Complaints
- How to Pay Your CMP Using the Online Payment Portal
- How to File an Answer and Consequences for Not Filing An Answer
- The Settlement Process

HOW TO FIND THE WEBINARS



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