Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers

Responses to Frequently Asked Questions (Revised)*

Guidance for Industry

Comments may be submitted at any time for Agency consideration. Electronic comments may be submitted to http://www.regulations.gov. Alternatively, submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD, 20852. All comments should be identified with Docket No. [FDA-2012-D-1083].

For questions regarding this guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

Additional copies are available online at http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/default.htm. You may send an e-mail request to SmallBiz.Tobacco@fda.hhs.gov to receive an electronic copy of this guidance. You may send a request for hard copies to U.S. Food and Drug Administration, Center for Tobacco Products, Attn: Office of Small Business Assistance, Document Control Center, Bldg. 71, Rm. G335, 10903 New Hampshire Ave., Silver Spring, MD 20993-2000.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Tobacco Products

December 2016

* This is a revision to the third edition of this guidance, which issued in May 2015. Revisions are noted by date at the end of the guidance.
Table of Contents

I. INTRODUCTION .........................................................................................................1
II. RESPONSES TO FREQUENTLY ASKED QUESTIONS........................................2
I. INTRODUCTION

This guidance provides information in response to frequently asked questions that the Center for Tobacco Products (CTP) is receiving from retailers and other interested stakeholders regarding civil money penalties and no-tobacco-sale orders for violations of Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301 et seq.) requirements relating to tobacco products in retail outlets. In particular, the guidance provides information about CTP’s enforcement of the requirement that tobacco products may not be sold or distributed in violation of regulations issued under section 906(d) of the FD&C Act, including restrictions on the sale and distribution of cigarettes, smokeless tobacco, and covered tobacco products in title 21 of the Code of Federal Regulations (CFR) part 1140 and about procedures CTP follows when it initiates administrative enforcement actions. Additional information on civil money penalties and no-tobacco-sale orders can be found in FDA’s guidance for FDA and tobacco retailers Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers (CMP and NTSO Guidance).

The penalty schedule mentioned in this document is only for violations by a retail outlet of rules issued under section 906(d) of the FD&C Act. CTP may seek other general or enhanced penalties under section 303(f)(9) of the FD&C Act for other kinds of violations not addressed in

---

1 This guidance was prepared by the Office of Compliance and Enforcement and Office of Regulations in the Center for Tobacco Products at FDA.

this document. A no-tobacco-sale order may be imposed only for repeated violations at a
particular outlet of restrictions on the sale and distribution of tobacco products promulgated
under section 906(d) of the FD&C Act.

FDA’s guidance documents, including this guidance, do not establish legally enforceable
responsibilities. Instead, guidances describe the Agency’s current thinking on a topic and should
be viewed only as recommendations, unless specific regulatory or statutory requirements are
cited. The use of the word should in Agency guidances means that something is suggested or
recommended, but not required.

II. RESPONSES TO FREQUENTLY ASKED QUESTIONS

This section provides responses to questions that retailers and other interested stakeholders have
asked CTP regarding civil money penalties and no-tobacco-sale orders.

1. What is a civil money penalty?

A civil money penalty (CMP) is a monetary penalty assessed for a violation of the law. FDA is
authorized to assess CMPs for violations of the 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.

2. What is a no-tobacco-sale order (NTSO)?

Section 303(f)(8) of the FD&C Act authorizes FDA to impose a no-tobacco-sale order on a
person found to have committed repeated violations of restrictions promulgated under section
906(d) of the FD&C Act at a particular retail outlet. The term no-tobacco-sale order refers to an
order prohibiting the sale of tobacco products at a retail outlet indefinitely or for a specified
duration under section 303(f)(8) of the FD&C Act. “Repeated violations” means at least 5
violations of particular requirements over a 36-month period at a particular retail outlet that
constitute a repeated violation (section 103(q)(1)(A) of the Family Smoking Prevention and
Tobacco Control Act (Tobacco Control Act)).

3. What is a complaint?

A complaint is a legal document that identifies the statutory and/or regulatory violations CTP is
alleging as the basis for a CMP, an NTSO, or both. The complaint also identifies the amount of
the CMP and/or duration of the NTSO that CTP is seeking. CTP’s filing of a complaint for a
CMP and/or NTSO, or both, 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. CTP serves a copy of the complaint on the retailer or other appropriate person.

4. How will the respondent be notified of a CMP or NTSO?

CTP may serve the complaint by either of the following methods:
Contains Nonbinding Recommendations

- certified or registered mail or similar mail delivery service (e.g., UPS), with a return receipt reflecting receipt (21 CFR § 17.7(a)(1)); or
- personal delivery to an individual respondent, or if the respondent is a corporation or unincorporated business, personal delivery to the respondent’s officer, managing agent, or general agent (21 CFR § 17.7(a)(2)).

Generally, CTP will address the complaint to the establishment where the violation occurred or the retailer’s registered agent. If CTP cannot reach the retailer or its agent through any of these methods, CTP intends to reach the retailer through other means.

5. Who is the respondent?

The respondent is the party against whom the complaint is filed, whom CTP is charging with violating an FD&C Act tobacco-related provision. The respondent will be listed in the heading of the complaint and in certain accompanying documents. When CTP seeks CMPs or NTSOs for retailer violations of 21 CFR part 1140, CTP generally names the owner of the retail outlet as the respondent in the complaint, rather than an employee or clerk. The owner of a retail outlet who is named as respondent will be liable for any CMP that is imposed for violations at the outlet.

Note that the term retailer includes the owner of a physical or on-line retail outlet that otherwise meets the definition in section 900 of the FD&C Act or part 1140 of the CFR.

6. Why did CTP serve this complaint?

CTP is alleging that the respondent is responsible for violations of tobacco-related provisions of the FD&C Act and/or implementing regulations, and is initiating a CMP or NTSO action, or both, against the respondent. The first time CTP identifies violation(s) at a retail outlet, it generally issues a Warning Letter that describes each violation identified. If CTP identifies violation(s) at a retail outlet during a follow-up compliance check, or at a subsequent inspection at that retail outlet, it generally seeks a CMP. Additionally, if a retailer has committed five repeated violations within a 36-month period, CTP may seek an NTSO. See CMP and NTSO Guidance.

7. How does CTP initiate CMPs or NTSOs, and what are the respondent’s options?

CTP will initiate a CMP or NTSO action, or both, by filing an administrative complaint and serving a copy of the complaint on the tobacco retailer or other appropriate person or entity, usually by sending the documents via UPS. If the respondent is served with a complaint for CMP and/or NTSO, or both, the respondent can usually choose from the following options, as applicable:

1. pay the penalty sought in the complaint (no contest);
2. enter into an agreement for the NTSO sought in the complaint (no contest); or
3. file an answer and contest some or all of the Agency’s allegations (see 21 CFR § 17.9).
8. What if the respondent decides to pay the penalty sought in a CMP?

If the respondent decides to pay the CMP and the payment has been received and processed, CTP will file a Notice of Settlement Agreement with the ALJ and send a copy of the filed Notice of Settlement Agreement to the respondent. The ALJ then issues an order closing the administrative action. Although paying the penalty closes the current CMP action, it does not excuse the retailer from any future violations. For information about the CMP schedule, see “43. How does CTP determine the amount of the CMP that it will seek in the complaint for violations of 21 CFR part 1140?”

9. What if the respondent does not contest the no-tobacco-sale order?

The ALJ will enter an NTSO. The respondent will be subject to the NTSO for the duration specified in the order.

10. What if the respondent chooses to contest the complaint?

If the respondent chooses to contest the matter, the party must file an answer to the complaint, as described in 21 CFR § 17.9, within 30 days after date of service of the complaint. The respondent may also request an extension of time to file an answer, which is allowed by the ALJ only when “good cause” is shown (see 21 CFR § 17.9(c)). For more information, see “15. Can the respondent have more time to file an answer, and how does the respondent request an extension of time to file an answer?”

If the respondent files an answer in a timely manner, the party is entitled to a hearing according to the procedures established in FDA’s regulations governing CMP proceedings (21 CFR part 17). For more information, see “23. If the respondent is served with a complaint, does the party have a right to a hearing?”

The respondent and/or the respondent’s representative(s) may engage in settlement discussions with CTP regarding the CMP. For information about settlement discussions, see “20. Can the case be settled without having a hearing?”

11. What is an answer and what is its purpose?

An answer is a legal document that contains the respondent’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 CMP or the duration of the NTSO should be less than the amount sought in the complaint. An answer also serves as a request for hearing unless the respondent states otherwise (see 21 CFR § 17.9(a)). Detailed

---

3 In computing this period, begin with the day following the act or event, and include the last day of the period, unless such day is a Saturday, Sunday, or Federal holiday, in which event the time includes the next business day (see 21 CFR § 17.30(a)).

4 See CMP and NTSO Guidance.
Contains Nonbinding Recommendations

12. If the respondent was named as the owner of a retail outlet in the complaint but was not the owner when the violations occurred, is there anything that the respondent needs to do in response to the complaint?

If the respondent was not the owner of the retail outlet at the time the violations occurred, the respondent should still submit an answer to the complaint and raise any applicable defenses. CTP recommends that the respondent submit evidence with the answer to show that it was not the owner at the time the violation was observed, e.g., evidence of legal sale of the establishment, lease contract, or other evidence to show a change of ownership. If the evidence provided is sufficient to show that the respondent was not responsible for the violations, then CTP will withdraw or amend the complaint.

13. How does the respondent submit an answer?

Detailed information on where and how to file an answer will be provided with the complaint.

14. How long does the respondent have to submit an answer?

The answer must be filed within 30 days of the date of service of the complaint. The answer is considered filed when it is received, not when it is mailed (see 21 CFR § 17.9(a)).

15. Can the respondent have more time to file an answer, and how does a respondent request an extension of time to file an answer?

If the respondent is unable to file an answer within the time allowed, the respondent must file an extension request not later than 30 days after service of the complaint. The request must explain why the respondent is unable to file the answer in the time allowed and why an extension should be granted. If the respondent shows good cause for an extension, the ALJ 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. Detailed information on where and how to file an extension request will be provided with the complaint.

16. What type of proof does the respondent need to submit with an extension request?

An ALJ may grant an extension only “for good cause shown.” This means that the respondent must provide a good and sufficient reason for being unable to provide an answer within the 30 days provided by the regulations. If the ALJ does not grant the request, then the answer remains due in the original 30-day timeframe. Thus, it is recommended that the respondent make all requests early and continue to prepare the answer while waiting for the ALJ’s response (see 21 CFR § 17.9(c)).
17. What is included in an answer?

The answer must:

- admit or deny each of the allegations listed in the complaint. If an allegation is not specifically denied, it will be considered admitted (see 21 CFR § 17.9(b)(1));
- state any defenses the respondent plans to use (see 21 CFR § 17.9(b)(2));
- provide any reasons the respondent believes that civil money penalties and/or NTSO duration should be less than sought in the complaint (see 21 CFR § 17.9(b)(3)); and
- if respondent is represented by counsel, state counsel’s name, address and telephone number (see 21 CFR § 17.9(b)(4)).

The respondent should also provide an e-mail address and a facsimile number for counsel, if available. If the respondent is not represented by counsel, CTP suggests providing the name, address, telephone number, facsimile number, and e-mail address of the respondent, as applicable.

In addition, the respondent can use the answer to request to participate in settlement discussions with CTP prior to going to hearing.

18. What happens if the respondent’s answer does not contain all the elements required by 21 CFR § 17.9(b)?

If the respondent’s answer does not contain all of the elements that are required by 21 CFR § 17.9(b), the ALJ may choose not to accept the answer. If that happens, the respondent could ask the ALJ for permission to amend his or her answer in the particular case. The ALJ may choose not to grant the respondent permission to amend an incomplete answer.

19. What if the respondent does not agree with the charges in the complaint, the CMP amount, or the duration of the NTSO?

If the respondent wishes to contest the charges, the CMP amount, and/or the duration of the NTSO, the party should file an answer to the complaint (see 21 CFR § 17.9(a)). The information that must be included in an answer is detailed in question 17 above. A respondent may file an answer and admit the allegations and request a lower CMP amount and/or shorter NTSO duration than sought in the complaint, but the respondent should explain his or her reasons why the CMP amount or the NTSO duration should be modified.

20. Can the case be settled without having a hearing?

If the respondent does not agree with the allegations, wants to contest the amount of the CMP or the duration of the NTSO that CTP is seeking, or has other concerns related to the case, the party should file an answer. When a respondent files an answer, the respondent may request settlement discussions with CTP. Settlement discussions are often an efficient method of resolving a contested case. The respondent may present evidence and arguments as to why he or she should not be subject to a CMP, an NTSO, or both, or mitigating factors that should reduce
the CMP amount and/or the NTSO duration. If the respondent and CTP do not agree on a
settlement, the respondent can still have a hearing. Cases that are not settled will be decided by
an ALJ either through motions for summary decision filed by one or both parties, or after an
administrative hearing conducted according to the procedures in 21 CFR part 17.

If the respondent and CTP arrive at an agreed upon settlement of a complaint seeking a no-
tobacco-sale order, the respondent will sign a settlement agreeing to the terms of the NTSO and
will be expected to comply with its terms unless or until it is terminated. Even if charges are
resolved through a settlement agreement, any violations that occurred will be counted in
determining the total number of violations for purposes of subsequent enforcement actions.

21. Who will be involved in the settlement conference, and where will it take place?
The respondent and the respondent’s attorney (as applicable), may participate in the settlement
conference. CTP generally expects to be represented by at least one of its representative and/or
an attorney from FDA’s Office of Chief Counsel. CTP’s policy is to conduct settlement
conferences by telephone.

22. What kind of mitigating factors does CTP consider?
The respondent may present relevant mitigating factors for CTP to consider for reducing the
CMP amount. A list of the types of factors that may be relevant will be sent to the retailer prior
to settlement discussions. 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
• other relevant matters

See 21 U.S.C. 333(f)(5)(B) and section 103(q)(2)(C) of the Tobacco Control Act.

For more information about how CMP amounts are determined, including information on
“mitigating factors,” see CMP and NTSO Guidance. If the respondent and CTP arrive at an
agreed upon settlement of a complaint seeking a CMP, the respondent should pay that amount
and, once the payment is processed, CTP will file a Notice of Settlement Agreement asking the
ALJ to close the case. Please note that, as a term of settlement, CTP requires the respondent to
both acknowledge that the violations occurred as alleged in the complaint and waive its ability to
contest those violations in the future. Even if the case is resolved through settlement, any
violations alleged in that case may be counted in determining the total number of violations for
purposes of subsequent enforcement actions. See CMP and NTSO Guidance.
23. If the respondent is served with a complaint, does the party have a right to a hearing?

Yes. Filing an answer in response to a complaint seeking a CMP or imposition of an NTSO, or both, serves as a request for a hearing unless the respondent states otherwise (see 21 CFR § 17.9(a)). If the respondent files an answer in a timely manner, the respondent is entitled to have the matter proceed under the procedures established in FDA’s regulations governing CMP proceedings, which can be found in 21 CFR part 17 and includes the option to have a hearing unless the case is resolved on a motion for summary decision without the need for a hearing. CTP must use these procedures for NTSOs as well (section 303(f)(8) of the FD&C Act).

24. What is an administrative hearing?

CTP files a complaint seeking assessment of a CMP or imposition of an NTSO, or both, with an ALJ, who is a fair and impartial decision-maker. The ALJ will determine whether the violations alleged in the complaint occurred. If the ALJ finds that the respondent is liable for the violations alleged, the ALJ will determine the appropriate CMP amount to assess and/or the appropriate duration for an NTSO. If the respondent chooses to have a hearing, it will be an administrative hearing before the ALJ. Prior to a hearing, the parties must exchange their direct written testimony (declarations from its witnesses and all evidence supporting the parties’ positions) violations). During the hearing, the parties have the opportunity to cross-examine the other parties’ witnesses and raise legal issues. (See 21 CFR §§ 17.25, 17.33, 17.37).

25. Who would hear the case if a hearing is held, and where would the hearing be held?

Cases that proceed to hearing are heard by an ALJ. An ALJ is the presiding officer in an administrative hearing and has authority, among other things, to regulate the course of the hearing, receive and rule on the way evidence can be used at the hearing, rule on procedural and other motions, decide the case, in whole or in part, and issue a decision (see 21 CFR § 17.19). The ALJ also has the authority to set the hearing date, time, and location, and may determine that the hearing will be conducted in person, via videoconferencing, or via teleconferencing. Upon the respondent’s request, the ALJ may order that the hearing be conducted by telephone, at the nearest regional or field office of the FDA or, in a no-tobacco sale order case, at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available. (see section 303(f)(8) of the FD&C Act).

26. Who will be at the hearing?

An ALJ presides over the hearing. Counsel from FDA’s Office of the Chief Counsel on behalf of CTP, representatives from CTP, the respondent, and if represented, the attorney for the respondent, may be present at the hearing. Witnesses may also be present for some or all of the hearing, depending on the nature of the case. The hearing is open to the public unless otherwise ordered by the ALJ (see 21 CFR § 17.33(d)).

5 For further information on the length of time to submit an answer, see “How long does the respondent have to submit an answer?”
27. What evidence will the respondent have to bring to the hearing?

At least 30 days before the hearing or at the time specified by the ALJ, the CTP and the respondent will exchange the following documents:

- List of all proposed exhibits (an “exhibit” includes the written direct testimony of any proposed witnesses, if any). **Please note that there is no oral direct testimony permitted at a hearing**;
- Copies of each proposed exhibit;
- Lists of all proposed witnesses, if any;
- Copies of any prior written statement by any proposed witnesses; and
- Other requirements that the ALJ may require.

For additional information on the exchange of information between the parties, witnesses, and evidence, please see 21 CFR §§ 17.25, 17.37, and 17.39.

28. What happens if the ALJ rules the respondent is not liable for any of the violations listed in the complaint?

If the ALJ determines that the respondent is not liable for any of the violations alleged in the complaint, the ALJ will issue an initial decision or a summary decision in the respondent’s favor (see 21 CFR § 17.45(c)). CTP may appeal the decision to the entity designated by the Commissioner of Food and Drugs to hear the appeal, currently the Departmental Appeals Board (DAB) at the Department of Health and Human Services (see 21 CFR § 17.47).

29. What happens if the ALJ rules that the respondent is liable for some or all of the violations listed in the complaint?

If the ALJ finds that the respondent is liable, the respondent will owe the CMP amount and/or be subject to the NTSO, as set forth in the ALJ’s initial decision, unless the respondent files a notice of appeal electronically to DAB or if hard copy to both DAB and FDA’s Division of Dockets Management, within 30 days after the date the ALJ’s order issues (see 21 CFR §§ 17.45(a), 17.45(b)(3), 17.47).

30. If the respondent is not satisfied with the ALJ’s decision, does the party have a right to appeal?

Yes, the respondent has the right to appeal an ALJ’s initial decision to the DAB. The respondent may appeal to the DAB by filing a notice of appeal with the electronically to DAB or if hard copy to both DAB and FDA’s Division of Dockets Management within 30 days of the decision. See 21 CFR § 17.47 for further information.

If the respondent is not satisfied with the result on appeal, the respondent may appeal a decision of the DAB to the U.S. Court of Appeals for the District of Columbia or any other circuit in
which the party resides or transacts business (section 303(f)(6) of the FD&C Act; 21 CFR § 17.51).

31. Who is responsible for paying a CMP or complying with an NTSO?

The party found liable by the ALJ is responsible for paying the CMP or complying with the NTSO. The retailer is typically the named respondent and can be either a person or a business entity (see 21 CFR § 17.3(b)).

32. Where does the CMP money go?

All CMP payments are deposited in the Treasury of the United States as miscellaneous receipts (see 21 CFR § 17.54).

33. What happens if the respondent is served with a complaint and does not respond by the time an answer is due?

If service was proper and the respondent does not pay the CMP or file a timely answer to a complaint seeking a CMP and/or an NTSO, or both, the ALJ will assume that the facts alleged in the complaint are true and, if those facts establish liability, the ALJ will issue an initial decision, through a default order, imposing the requested CMP and/or NTSO.

34. What is a default order?

If a respondent is served with a complaint seeking a CMP and/or NTSO, or both, and does not pay the penalty and/or agree to an NTSO or also does not file an answer in a timely manner, the ALJ will assume that the facts alleged in the complaint are true and if those facts establish liability, will issue an initial decision, called a default order, imposing the requested CMP and/or NTSO. If the complaint seeks a CMP, the amount of the CMP imposed by the ALJ will be either (1) the maximum amount of penalties provided for by law for the violations alleged; or (2) the amount sought in the complaint, whichever amount is smaller (see 21 CFR § 17.11(a)). If a complaint seeks an NTSO, the ALJ will impose an NTSO for the duration sought in the complaint. For permanent NTSOs, the initial decision must allow the respondent, after a specified period of time, to request compromise, modification, or termination of the NTSO. The initial decision becomes final and binding 30 days after it is issued.6

By failing to file a timely answer, the respondent waives any right to a hearing and any right to contest the CMP amount or NTSO duration that is imposed by the ALJ, unless the party can demonstrate that there were extraordinary circumstances that prevented the filing of an answer.

35. If the ALJ enters an initial default order against the respondent, can the respondent contest it later?

6 If the respondent misses the deadline to file an answer or seek an extension, the respondent may file a motion requesting the ALJ to reopen the case, but this motion requires, among other things, a showing of extraordinary circumstances (21 CFR § 17.11(c)).
When the respondent receives a default order, it will become final 30 days after the date of the initial order. The respondent can dispute the initial order only if extraordinary circumstances are shown and a motion to re-open is filed during the 30-day period between the dates of the initial order and the final order (see 21 CFR § 17.11(c)–(d)).

36. What happens if the respondent receives a valid and final order to pay but does not comply?

If the respondent does not comply with a valid and final order by paying the required amount, FDA may pursue further action through the U.S. Department of Justice.

37. Are the FDA inspections that result in CMPs different from the kinds of inspections that result in Warning Letters?

CTP has developed two different categories of compliance check inspections:

1. undercover buy (UB) inspections, primarily to determine a retailer’s compliance with the age and photo identification requirements relating to the sale of tobacco products; and
2. advertising and labeling (A&L) inspections, to determine a retailer’s compliance with tobacco product requirements other than age and photo identification.

In UB inspections, minors (supervised by FDA-commissioned state inspectors) attempt to purchase tobacco products, and the inspectors, who generally accompany the minors, collect evidence, record inspection results, and draft narrative reports and other documents describing their inspectional observations. UB inspections are generally conducted without notice to the retailer. FDA-commissioned state inspectors follow the same procedures when conducting A&L inspections, except that A&L inspections are conducted without a minor and the inspectors generally present the retailer with a Notice of Inspection (Form FDA 482). For inspections that identify potential violations, the information recorded by the inspectors is transmitted to CTP for review and evaluation.

Generally, the initial inspection of a retail establishment is either a UB or an A&L inspection. After a Warning Letter is issued, CTP creates a compliance follow-up inspection assignment of the establishment in two parts. UB and A&L inspections at a retail establishment are performed separately (usually on different days) to verify a retailer’s compliance with the FD&C Act’s requirements relating to regulated tobacco products. The inspection is done in two parts because inspectors often announce themselves and ask questions of the retailer during the A&L part of the inspection.

38. How does CTP determine that violations occurred?

In general, FDA-commissioned inspectors and minors conduct inspections of tobacco retail outlets. The inspectors visit the retail outlets, collect relevant evidence, and report potential violations to CTP for further review. Generally, an explanation of the violations observed during
the inspection at the respondent’s retail outlet will be included in any Warning Letter or complaint.

39. Does CTP have evidence of the violations?

Yes. FDA-commissioned inspectors are instructed to collect evidence, as appropriate, to document violations found during retail compliance check inspections. CTP sends a Warning Letter or files a complaint alleging a violation only when CTP determines that the evidence shows that there has been a violation. Some examples of evidence may include: photographs taken during an inspection, including photographs of the tobacco products purchased by minors; written statements from inspectors describing their observations; and physical evidence collected during an inspection.

40. What steps will CTP take after an inspection involving a minor reveals a potential violation?

Shortly after any inspection in which a retailer sells tobacco products to a minor, CTP issues a Notice of Compliance Check Inspection informing the retailer of the sale and explaining that CTP will make a final determination regarding whether there has been a violation of federal law. The information included in the Notice of Compliance Check Inspection generally will include:

- Name of the establishment;
- Date and approximate time of the inspection;
- Characteristics regarding the clerk who sold to the minor, if known;
- Notification of a potential violation;
- Photograph of establishment taken at the time of inspection, if available; and
- Address of the establishment.

41. Can a respondent see the evidence held by CTP?

Yes. In accordance with 21 CFR § 17.23, no later than 60 days prior to the hearing, or at another time specified by the ALJ, the respondent may request relevant inspection documents. Additionally, at least 30 days prior to the hearing, or at another time specified by the ALJ, the respondent and CTP are required to exchange various types of evidence, including witness lists, copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits (see 21 CFR § 17.25(a)). CTP intends to include some evidentiary documents with the complaint and cover letter it sends to the respondent when it initially files a case. Once a case is closed, certain documents become publicly available. For additional information on the exchange of information between the parties, witnesses, and evidence, see 21 CFR §§ 17.25, 17.37, and 17.39.

42. What is the schedule of maximum penalties for violations of part 1140?

The Tobacco Control Act provides that the amount of a civil penalty for violations of part 1140 shall not exceed certain amounts, depending on the number of previous violations, the time period in which the violations occurred, and other factors (see section 103(q)(2)(A) of the
Tobacco Control Act; 21 CFR § 17.2 (referencing penalty table in 45 CFR § 102.3)). The Tobacco Control Act also established two schedules for the maximum civil money penalties for violations of regulations issued under section 906(d) of the FD&C Act, including violations of part 1140.

In determining the amount of the CMP that will be sought, CTP will use the lower schedule for all retailers until regulations are developed that establish standards for retailer training programs. This lower schedule, as set out in section 103(q)(2)(A) of the Tobacco Control Act codified at FD&C Act Section 303 note, is:7

…the amount of the civil penalty shall not exceed—
(I) in the case of the first violation, $0.00, together with the issuance of a warning letter to the retailer;8
(II) in the case of a second violation within a 12-month period, $250;
(III) in the case of a third violation within a 24-month period, $500;
(IV) in the case of a fourth violation within a 24-month period, $2,000;
(V) in the case of a fifth violation within a 36-month period, $5,000; and
(VI) in the case of a sixth or subsequent violation within a 48-month period, $10,000 as determined by the Secretary on a case-by-case basis.

43. How does CTP determine the amount of the CMP that it will seek in the complaint for violations of 21 CFR part 1140?

The first time that CTP finds a violation at a retail outlet, its policy is to send a warning letter rather than seeking a CMP. If CTP identifies violation(s) at a retail outlet during a follow-up compliance check or a subsequent inspection at that retail outlet, CTP generally intends to seek civil money penalties to the extent they are appropriate. If there have been repeated violations at the outlet and a no-tobacco-sale order would be appropriate in light of the factors discussed in questions 2 and 6 above, CTP also generally intends to seek a no-tobacco-sale order. See CMP and NTSO Guidance.

To determine the amount of CMP it will seek, CTP counts violations of the part 1140 regulations and consults a charging schedule provided in the Tobacco Control Act. CTP counts only one regulation violation from the first inspection at a retail outlet, regardless of the number of regulation violations that were noted and included in a Warning Letter. For any subsequent inspections, CTP may count any or all violations and its general policy is to count all of them individually.

---

8 Although the penalty for the first violation is $0.00, consistent with the statute CTP will issue a warning letter.
Once CTP has counted violations at a retail outlet for the 48-month period that precedes the most recent violation(s), it consults the following charging schedule to determine the amount it will seek in a complaint:

<table>
<thead>
<tr>
<th>Number of Violations</th>
<th>CMP</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>$0.00 (CTP will issue a warning letter)</td>
</tr>
<tr>
<td>2 within a 12-month period</td>
<td>$250</td>
</tr>
<tr>
<td>3 within a 24-month period</td>
<td>$500</td>
</tr>
<tr>
<td>4 within a 24-month period</td>
<td>$2,000</td>
</tr>
<tr>
<td>5 within a 36-month period</td>
<td>$5,000</td>
</tr>
<tr>
<td>6 within a 48-month period</td>
<td>$10,000</td>
</tr>
</tbody>
</table>

Thus, if the respondent receives a Warning Letter after the first inspection that notes four violations, and CTP notes two more violations during a follow-up inspection within 24 months, CTP would generally count three of the violations (one for the first inspection and two for the second), and seek $500 under its policy.

To provide another, more detailed, example:

- A Warning Letter was issued for selling cigarettes or smokeless tobacco to a minor (21 CFR 1140.14(a), now 21 CFR 1140.14(a)(1)) and failing to verify photographic identification (21 CFR 1140.14(b)(1), now 21 CFR 1140.14(a)(2)(i)) during an inspection on January 1, 2011.10
- A two-part follow-up inspection at the same retail outlet, conducted on June 1 and June 7, 2011, observed violations for:
  - selling to a minor;
  - failing to verify photographic identification; and
  - offering free samples of cigarettes (21 CFR 1140.16(d)(1)).
- Thus, CTP has observed five violations at the retail outlet.
- Under its current policy, CTP would generally count four of the violations in determining the amount it will seek: one from the Warning Letter and three from the follow-up inspection.
- Applying these facts to the charging schedule, CTP would seek a CMP of $2,000 in the complaint.

44. What does the ALJ consider in determining the amount of the CMP to be assessed?

In contested cases, when the ALJ determines that violations have occurred, the ALJ decides the amount of the CMP to be assessed. The statute requires that the ALJ consider the penalty

---

9 Supra note 7.
10 Certain of FDA’s tobacco regulations in 21 C.F.R. Part 1140 relating to the sale and distribution of cigarettes and smokeless tobacco, such as minimum age and identification requirements, were renumbered as a result of the Deeming Rule, but the text of those regulations remains substantively the same.
schedule in the statute as well as any evidence of “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,
- the 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 21 U.S.C. 333(f)(5)(B) and section 103(q)(2)(C) of the Tobacco Control Act; 21 CFR § 17.34. For more information about how CMP amounts are determined, including information on mitigating factors, see CMP and NTSO Guidance.

45. What does the ALJ consider in determining whether to impose an NTSO, the duration of an NTSO, and whether to compromise, modify, or terminate an NTSO?

In contested cases, when the ALJ determines that five or more repeated violations have occurred in a 36-month period, the ALJ decides the duration of the NTSO.

In determining the duration of an NTSO, the ALJ must take into account the nature, circumstances, extent, and gravity of the violations and, with respect to the violator, effect on ability to continue to do business, any history of prior violations, the degree of culpability, and such other matters as justice may require (section 303(f)(5)(B) of the FD&C Act).

In determining whether to impose a no-tobacco-sale order, or compromise, modify, or terminate a previously issued no-tobacco-sale order, the ALJ must consider whether a retailer has taken the effective steps to prevent violations of the minimum age requirements for the sale of tobacco products, including:

- adopting and enforcing a written policy against sales to minors;
- informing its employees of all applicable laws;
- establishing disciplinary sanctions for employee noncompliance; and
- requiring its employees to verify age by way of photographic identification or electronic scanning device.

Section 103(q)(1)(G) of the Tobacco Control Act.

Provisions allowing the outlet, after a specified period of time, to request that the Secretary compromise, modify, or terminate the order must be included in an NTSO that permanently prohibits an individual retail outlet from selling tobacco products (section 303(f)(5)(B) of the FD&C Act).

46. If the respondent has already paid a CMP, can the respondent be assessed another one?
Yes, CTP is continuing to conduct inspections. If CTP identifies violation(s) at a retail outlet during a follow-up compliance check, or at a subsequent inspection at that retail outlet, it generally intends to seek civil money penalties to the extent they are appropriate. If there have been repeated violations at the outlet and a no-tobacco-sale order would be appropriate, as discussed in “2. What is a no-tobacco-sale order (NTSO)?” and “6. Why did CTP serve this complaint?,” CTP also generally intends to seek a no-tobacco-sale order. See CMP and NTSO Guidance.

Whether the respondent receives another complaint for CMP, and the amount of the CMP sought, will depend on the number of violations observed at the outlet, the timing of the violations, and other factors. See CMP and NTSO Guidance for additional information.

47. What happens if the respondent does not have any violations in follow-up inspection?

If no violations are observed in a follow-up inspection, the retail outlet will appear on the CTP inspection database as having no violations observed. The inspection database can be found at the following website http://www.accessdata.fda.gov/scripts/oce/inspections/oce_insp_searching.cfm.

An FDA-commissioned inspector may visit the retail outlet again in the future to evaluate continued compliance. If violations are observed during future inspections, CTP may seek to impose additional CMPs. If there have been repeated violations at the outlet and a no-tobacco-sale order would be appropriate as discussed in “2. What is a no-tobacco-sale order (NTSO)?” and “6. Why did CTP serve this complaint?,” CTP also generally intends to seek a no-tobacco-sale order. Additionally, if violations are observed during future inspections, CTP may initiate other enforcement actions in Federal court.

The respondent’s violation history does not reset to zero violations if there is a nonviolative inspection, and, in regard to CMPs, proceeds according to the schedule listed in “42. What is the schedule of maximum civil money penalties for violations of part 1140?”

48. How does CTP count violations at a retail outlet that is part of a chain when it seeks CMPs under part 1140?

CTP’s current policy is to consider each retail location to be a separate retail outlet for purposes of counting CMP violations under the schedule of maximum penalties described above. A retail chain may receive multiple separate CMP complaints for violations of part 1140, but for purposes of counting violations for CMPs, each retail outlet would be treated individually. Similarly, under this policy, a chain could also expect to receive separate Warning Letters for each outlet where violations are found.
Document History:

- December 2013 – First edition of final guidance was issued.
- June 2014 – Pages 12-13 were updated with new Civil Money Penalty amounts that reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act; references to CTP’s address updated throughout the document.
- May 2015 – Questions and answers were updated to include no-tobacco-sale order procedures, which are the same as those used in the Civil Money Penalties process (section 303(f)(8) of the FD&C Act). Minor editorial changes and clarifications were made.
- December 2016 - Throughout the document, non-substantive edits have been made to improve the general clarity of the document and “FDA” has been replaced with “CTP” where appropriate to clarify that CTP is the Complainant in CMP/NTSO actions; Page 1 was updated to include “covered tobacco products” in the list of tobacco products regulated under 21 CFR part 1140; Footnote 2 was edited to include the Federal Register citation for the Deeming Rule that amended 21 CFR part 1140; Page 3 was updated to reflect CTP’s current practice regarding where and to which entity it sends complaints; Page 7 was edited to reflect the fact that an ALJ may also decide a case on the basis of a motion for summary decision; Page 8 was edited to remove former question 23 because it repeated the same information contained in current question 45; Pages 13-14 were updated to reflect the statutory CMP amounts and remove the specific citations from the example; Footnotes 7 and 9 were updated to reflect amendments to the Civil Money Penalty Inflation Adjustment Act and to include reference to the current CMP amounts listed on the CTP website.