Guidance for Industry and FDA Staff

Civil Money Penalties for Tobacco Retailers

Responses to Frequently Asked Questions

DRAFT GUIDANCE

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Guidance for Industry and FDA Staff[1]

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This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the FDA staff responsible for implementing this guidance. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

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 the issuance of civil money penalties 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 FDA's regulations restricting the sale and distribution of cigarettes and smokeless tobacco to protect children and adolescents (21 CFR part 1140)[2] and about procedures the Agency follows when it initiates enforcement actions.

The penalty schedule mentioned in this document is only for violations of rules issued under section 906(d) of the FD&C Act by a retail outlet. FDA 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 this document.

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

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

[2] 75 FR 13225, March 19, 2010.

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 our responses to questions that retailers and other interested stakeholders have asked CTP regarding the issuance of civil money penalties.

1. What is a *civil money penalty* (CMP)?

A *civil money penalty* (CMP) is a fine assessed for a violation of law. FDA is authorized to seek 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 concerning CMPs are established in 21 CFR part 17.

2. What is a *complaint*?

A *complaint* is a legal document that identifies the statutory or regulatory violations FDA is alleging as the basis for a CMP, as well as the amount of the penalty that FDA is seeking. FDA's filing of a complaint for a CMP officially opens an administrative enforcement action. FDA serves a copy of the complaint on the retailer or other appropriate person and files a copy with the FDA Division of Dockets Management. (See § 17.5.) FDA also files a copy with the administrative law judge (ALJ) who will preside over the case.

3. How will the respondent be notified of a CMP?

FDA may serve the complaint by either of the following methods:

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

Generally, FDA will address the complaint to the corporate address of the owner of the retail establishment as provided in state records, if that address appears reliable, and mail a copy to the establishment where the violations were observed.

4. Who is the *respondent*?

The *respondent* is the party against whom the complaint is filed, whom FDA is charging with violating a tobacco-related provision in the FD&C Act. The respondent will be listed in the heading of the complaint and in certain accompanying documents. When FDA seeks CMPs for retailer violations of 21 CFR part 1140, FDA 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* in part 1140 and as used in the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) includes the owner of a physical or on-line retail outlet that otherwise meets the statutory or regulatory definition.

5. Why did FDA serve this complaint?

FDA is alleging that the respondent is responsible for violations of tobacco-related provisions of the FD&C Act and/or implementing regulations, and is pursuing a CMP action against the respondent. The first time FDA identifies violation(s) at a retail outlet, it generally issues a Warning Letter that describes each violation identified. If FDA 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. *See* the guidance for FDA and tobacco retailers on *Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers* (CMPs guidance).

6. How does FDA initiate CMPs, and what are the respondent's options?

FDA will initiate a CMP action by filing a complaint with the FDA Division of Dockets Management and will serve a copy of the complaint on the tobacco retailer or other appropriate person or entity, usually by sending the documents via UPS. FDA also files a copy with the ALJ. If the respondent is served with a CMP complaint, the respondent can usually choose from two options:

(1) pay the penalty sought in the complaint (no contest); or
(2) file an answer and contest some or all of the Agency's allegations (see § 17.9).

7. What if the respondent decides to pay the penalty?

If the respondent decides to pay the penalty and the payment has been received and processed, the Agency will close its docket with the FDA Division of Dockets Management, file a Request for Case Closure with the ALJ, and send a copy to the respondent. Paying the penalty closes the current CMP action but does not excuse the retailer from any future violations.

8. 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 § 17.9, within 30 days of the date of service of the complaint.[3] 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 § 17.9(c)). For more information, see **"Can the respondent have more time to file an answer, and how does the respondent request an extension of time to file an answer?"**

[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 § 17.30(a)).

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 (part 17).[4] For more information, see "**If the respondent is served with a complaint, does the party have a right to a hearing?"**

After submitting an answer, the respondent and/or the respondent's representative(s) may engage in settlement discussions with FDA regarding the CMP. For information about settlement discussions, see **"Can the case be settled without having a hearing?"**

9. 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 penalty and assessment should be less than the amount requested by the complaint. An answer also serves as a request for hearing unless the respondent states otherwise (see § 17.9(a)). Detailed information on where and how to file an answer will be provided with the complaint. For information about what the answer must contain, see **"What must be included in an answer?"**

10. 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 party should still submit an answer to the complaint and raise any applicable defenses.

It is recommended that the respondent submit evidence with the answer to show that the respondent was not the owner at the time the violation was observed by FDA, 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 FDA will withdraw or amend the complaint.

11. How does the respondent submit an answer?

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

12. 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 § 17.9(a)).

[4] See the CMPs Guidance.

13. 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 § 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.

14. 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 § 17.9(c)).

15. 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 § 17.9(b)(1));
- state any defenses the respondent plans to use (see § 17.9(b)(2));
- provide any reasons the respondent believes that penalties should be less than requested in the complaint (see § 17.9(b)(3)); and
- if respondent is represented by counsel, state counsel's name, address and telephone number (see § 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, FDA 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 the FDA prior to going to hearing.

16. What happens if the respondent's answer does not contain all the elements required by § 17.9(b)?

If the respondent's answer does not contain all of the elements that are required by § 17.9(b), the ALJ may choose not to accept the answer. The ALJ may choose not to grant permission to

amend the respondent's answer so that it is complete. The respondent will have to ask the ALJ for permission to amend the answer in the particular case.

17. What if the respondent does not agree with the penalty amount and/or charges in the complaint?

If the respondent wishes to contest the charges and/or the penalty amount, the party should file an answer to the complaint (see § 17.9(a)). The answer should admit or deny each of the allegations made in the complaint, and also include any and all defenses to the action and reasons or explanations why the penalty and assessment should be less than the amount requested by the complaint (see § 17.9(b)). If the respondent files an answer and admits to the allegations, the party may ask for a lower penalty amount than requested in the complaint but should explain the reasons for the belief that the penalty should be lower.

18. 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 that FDA is seeking, or has other concerns related to the case, the party should file an answer. At that time, the respondent may request settlement discussions with FDA. Settlement discussions are often an efficient method of resolving a contested case. The respondent may present evidence and arguments as to why the party should not be liable for a CMP or mitigating factors that should reduce the amount of the CMP. If the respondent and FDA do not agree on a settlement, the respondent can still have a hearing.

19. 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. FDA generally expects to be represented by a CTP representative and/or an FDA attorney. FDA policy is to conduct settlement conferences by telephone, and to call the respondent at a time that the parties have agreed upon.

20. What kind of mitigating factors does the FDA consider?

The respondent may present relevant mitigating factors for FDA to consider for reducing the penalty amount. A list of 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
- 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 the CMPs Guidance.

If the respondent and FDA arrive at an agreed settlement of a complaint seeking a CMP, the respondent should pay that amount and, once the payment is processed, the case is closed. Even if the case is resolved through settlement, any violations that occurred may be counted in determining the total number of violations for purposes of subsequent enforcement actions.[5]

21. If the respondent is served with a complaint, does the party have a right to a hearing?

Yes. Filing an answer serves as a request for a hearing unless the respondent states otherwise (see § 17.9(a)). If the respondent files an answer in a timely manner,[6] the respondent is entitled to a hearing according to the procedures established in FDA's regulations governing CMP proceedings, which can be found in part 17.

22. What is an administrative hearing?

When FDA issues a complaint for a CMP, and a respondent contests it by filing an answer, the case is referred to an ALJ for a fair and impartial determination regarding whether to impose a CMP and, if so, how much the penalty should be. FDA will present its evidence, and the respondent has an opportunity to contest the charges and allegations or seek a reduction in penalty. (See §§ 17.25, 17.33.) The matter is heard and decided by an ALJ who is part of the Departmental Appeals Board of the Department of Health and Human Services and is not employed by the FDA.

23. 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, who is part of the Departmental Appeals Board of the Department of Health and Human Services and is not employed by the FDA. 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 § 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, a hearing may be conducted by telephone, at the nearest regional or field office of the FDA, or 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).

[5] See the CMPs Guidance.

[6] For further information on the length of time to submit an answer, see "How long does the respondent have to submit an answer?"

24. Who will be at the hearing?

An ALJ presides over the hearing. Counsel for the FDA, 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 § 17.33(d)).

25. What evidence will the respondent have to bring to the hearing?

At least 30 days before the hearing or the time specified by the ALJ, the FDA/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);
- 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, as provided by the ALJ.

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

26. What might the ruling look like if the ALJ rules in the respondent's favor?

If the ALJ rules in the respondent's favor, the ruling may include that:

- ALJ finds the respondent liable for some or all of the violations alleged, but reduces the amount of the CMP imposed; or
- ALJ finds that the respondent is not liable for any of the violations alleged in the CMP complaint.

27. 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 listed in the complaint, the ALJ will issue an initial decision or a summary decision in the respondent's favor (see § 17.45(c)). FDA may appeal the decision, in which case the appeal will be decided by the Departmental Appeals Board (see § 17.47).

28. What happens if the ALJ rules that the respondent is liable for violations listed in the complaint?

If the ALJ finds that the respondent is liable, the party will owe the amount stated by the ALJ, which could be the full amount sought or a reduced amount, unless the respondent files a notice of appeal within 30 days (see §§ 17.45(a), 17.45(b)(3)).

29. 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 initial decision to the Departmental Appeals Board (DAB). The respondent may appeal to the DAB by filing a notice of appeal with the DAB and the FDA Division of Dockets Management within 30 days of the relevant decision. See § 17.47 for further information.

If the respondent is not satisfied with the result on appeal, the party 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; § 17.51).

30. What happens if the respondent pays a CMP?

If the respondent decides to pay the penalty and the payment has been received and processed, the Agency will close its docket with the FDA Division of Dockets Management, file a Request for Case Closure with the ALJ, and send a copy to the respondent. Paying the penalty closes the current CMP action but does not excuse the retailer from any future violations.

31. Who is responsible for the fine?

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

32. Where does the money collected from the CMPs go?

All CMP payments are deposited in the Treasury of the United States as miscellaneous receipts (see § 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 penalty or 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, the ALJ will issue an initial decision imposing a CMP called a Default Order. See next question for further information.

34. What is a default order?

If the respondent is served with a complaint and does not pay the penalty or file an answer in a timely manner, the ALJ will assume that the fact s alleged in the complaint are true; if those facts establish liability, the ALJ will issue an initial decision imposing a CMP. The amount of CMP imposed will be either (1) the maximum amount of penalties provided for by law for the

violations alleged or (2) the amount asked for in the complaint, whichever amount is smaller (see § 17.11(a)). The decision becomes final and binding 30 days after it is issued.[7]

By failing to file an answer in a timely manner, the respondent waives any right to a hearing and any right to contest the amount of the penalties imposed 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?

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 an extraordinary circumstance can be 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 § 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?

FDA 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 inspections 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, the main differences being 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.

[7] If the respondent misses the deadline to file an answer or seek an extension, the respondent may file a motion asking the ALJ to reopen the case, but this motion requires, among other things, a showing of extraordinary circumstances (§ 17.11(c)).

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. A UB inspection and an A&L inspection 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 FDA 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 the FDA 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 CMP complaint.

39. Does FDA have proof of the violations?

FDA inspectors are instructed to collect evidence, as appropriate, to document violations found during retail compliance check inspections. FDA sends a Warning Letter or CMP complaint alleging a violation only when FDA determines that the evidence supports a determination that there has been a violation. Some examples of evidence include: photographs taken during an inspection; written statements from inspectors describing their observations; and physical evidence collected during an inspection.

40. Can a respondent see the evidence held by the FDA?

Yes. In accordance with § 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 the FDA 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 § 17.25(a)). FDA intends to include some evidentiary documents with the complaint and cover letter it sends to the respondent when it initially files the 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 §§ 17.25, 17.37, and 17.39.

41. 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; § 17.2). The Tobacco Control Act also established two schedules for the maximum civil money penalties that can be assessed 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 penalty the Agency will seek, 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, is:

> …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;
>
> (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.

42. How does CTP determine the amount of the CMP that it will seek in the complaint for violations of 21 CFR 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 penalty. If CTP finds violations on a subsequent inspection of the same outlet, it will generally seek a CMP.

To determine the amount of penalty it will seek, CTP counts violations and consults a charging schedule within the scope of the schedule provided in the Tobacco Control Act.

CTP counts only one violation from the first inspection that finds one or more violations at an outlet, regardless of the number of 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.

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:

Number of Violations	CMP
1	$0.00 w/ warning letter
2 within a 12-month period	$250
3 within a 24-month period	$500
4 within a 24-month period	$2,000
5 within a 36-month period	$5,000
6 within a 48-month period	$10,000

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 to a minor (§ 1140.14(a)) and failing to verify photographic identification during an inspection on January 1, 2011. (§ 1140.14(b)).
- 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 (§ 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.

43. 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 penalty to be assessed. The statute requires that the ALJ consider the penalty 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, and
- 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 the CMPs Guidance.

44. If the respondent has already paid a CMP, can the party be assessed another one?

Yes, FDA is continuing to conduct inspections, and if FDA finds violations on a subsequent inspection, it generally seeks a CMP. Whether the respondent receives another complaint for CMP, and the amount of the CMP being sought, will depend on the number of violations observed at the outlet, the timing of the violations, and other factors. Generally, FDA intends to wait until a CMP action is closed before initiating a subsequent CMP action. See the CMPs Guidance for additional information.

45. 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 FDA 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.

FDA may visit the retail outlet again in the future to assess continued compliance. If violations are observed during future inspections, FDA can assess CMPs or initiate other enforcement actions. The respondent's violation history does not reset to zero violations if there is a nonviolative inspection, but proceeds according to the schedule listed under **"What is the schedule of maximum fines for violations of part 1140?"**

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

FDA'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.