

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**

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Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers Responses to Frequently Asked Questions

Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff responsible for this guidance as listed on the title page.

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 1140² 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.

² 75 FR 13225, March 19, 2010; 81 FR 28973, May 10, 2016 ("Deeming Rule").

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

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

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47 **II. RESPONSES TO FREQUENTLY ASKED QUESTIONS**

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

51

52 **1. What is a *civil money penalty*?**

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54 A *civil money penalty* (CMP) is a monetary penalty assessed for a violation of the law. FDA is
55 authorized to assess CMPs for violations of the FD&C Act relating to tobacco products under
56 section 303(f)(9) of the FD&C Act (21 U.S.C. 333(f)(9)). FDA’s regulations governing CMP
57 procedures are established in 21 CFR part 17.

58

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

60

61 Section 303(f)(8) of the FD&C Act authorizes FDA to impose a no-tobacco-sale order on a
62 person found to have committed repeated violations of restrictions promulgated under section
63 906(d) of the FD&C Act at a particular retail outlet. The term no-tobacco-sale order refers to an
64 order prohibiting the sale of tobacco products at a retail outlet indefinitely or for a specified
65 duration under section 303(f)(8) of the FD&C Act. “Repeated violations” means at least 5
66 violations of particular requirements over a 36-month period at a particular retail outlet that
67 constitute a repeated violation (section 103(q)(1)(A) of the Family Smoking Prevention and
68 Tobacco Control Act (Tobacco Control Act)).

69

70 **3. What is a *complaint*?**

71

72 A *complaint* is a legal document that identifies the statutory and/or regulatory violations CTP is
73 alleging as the basis for a CMP, an NTSO, or both. The complaint also identifies the amount of
74 the CMP and/or duration of the NTSO that CTP is seeking. CTP’s filing of a complaint for a
75 CMP and/or NTSO, or both, officially opens an administrative enforcement action. Once the
76 complaint is filed, it is assigned to an administrative law judge (ALJ) who will preside over the
77 case. CTP serves a copy of the complaint on the retailer or other appropriate person.

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

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81 CTP may serve the complaint by either of the following methods:

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- 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).

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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.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 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).⁴ 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.

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169 information on where and how to file an answer will be provided with the complaint. For
170 information about what the answer must contain, see “**17. What must be included in an**
171 **answer?**”
172

173 **12. If the respondent was named as the owner of a retail outlet in the complaint but was not**
174 **the owner when the violations occurred, is there anything that the respondent needs to**
175 **do in response to the complaint?**
176

177 If the respondent was not the owner of the retail outlet at the time the violations occurred, the
178 respondent should still submit an answer to the complaint and raise any applicable defenses.
179

180 CTP recommends that the respondent submit evidence with the answer to show that it was not
181 the owner at the time the violation was observed, e.g., evidence of legal sale of the
182 establishment, lease contract, or other evidence to show a change of ownership. If the evidence
183 provided is sufficient to show that the respondent was not responsible for the violations, then
184 CTP will withdraw or amend the complaint.
185

186 **13. How does the respondent submit an answer?**
187

188 Detailed information on where and how to file an answer will be provided with the complaint.
189

190 **14. How long does the respondent have to submit an answer?**
191

192 The answer must be filed within 30 days of the date of service of the complaint. The answer is
193 considered filed when it is received, not when it is mailed (see 21 CFR § 17.9(a)).
194

195 **15. Can the respondent have more time to file an answer, and how does a respondent**
196 **request an extension of time to file an answer?**
197

198 If the respondent is unable to file an answer within the time allowed, the respondent must file an
199 extension request not later than 30 days after service of the complaint. The request must explain
200 why the respondent is unable to file the answer in the time allowed and why an extension should
201 be granted. If the respondent shows good cause for an extension, the ALJ may grant up to 30
202 additional days to file an answer (see 21 CFR § 17.9(c)). Note that a request for extension is *not*
203 automatically granted and is *only* granted for good cause shown. Detailed information on where
204 and how to file an extension request will be provided with the complaint.
205

206 **16. What type of proof does the respondent need to submit with an extension request?**
207

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

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217 The answer must:

218

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

226

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

231

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

234

235 **18. What happens if the respondent's answer does not contain all the elements required by** 236 **21 CFR § 17.9(b)?**

237

238 If the respondent's answer does not contain all of the elements that are required by 21 CFR
239 § 17.9(b), the ALJ may choose not to accept the answer. If that happens, the respondent could
240 ask the ALJ for permission to amend his or her answer in the particular case. The ALJ may
241 choose not to grant the respondent permission to amend an incomplete answer.

242

243 **19. What if the respondent does not agree with the charges in the complaint, the CMP** 244 **amount, or the duration of the NTSO?**

245

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

252

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

254

255 If the respondent does not agree with the allegations, wants to contest the amount of the CMP or
256 the duration of the NTSO that CTP is seeking, or has other concerns related to the case, the party
257 should file an answer. When a respondent files an answer, the respondent may request
258 settlement discussions with CTP. Settlement discussions are often an efficient method of
259 resolving a contested case. The respondent may present evidence and arguments as to why he or
260 she should not be subject to a CMP, an NTSO, or both, or mitigating factors that should reduce

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261 the CMP amount and/or the NTSO duration. If the respondent and CTP do not agree on a
262 settlement, the respondent can still have a hearing. Cases that are not settled will be decided by
263 an ALJ either through motions for summary decision filed by one or both parties, or after an
264 administrative hearing conducted according to the procedures in 21 CFR part 17.

265

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

271

21. Who will be involved in the settlement conference, and where will it take place?

272

273 The respondent and the respondent's attorney (as applicable), may participate in the settlement
274 conference. CTP generally expects to be represented by at least one of its representative and/or
275 an attorney from FDA's Office of Chief Counsel. CTP's policy is to conduct settlement
276 conferences by telephone.

277

22. What kind of mitigating factors does CTP consider?

278

279 The respondent may present relevant mitigating factors for CTP to consider for reducing the
280 CMP amount. A list of the types of factors that may be relevant will be sent to the retailer prior
281 to settlement discussions. Mitigating factors may include the following:

282

- 283 • nature, circumstances, extent, and gravity of the violation(s)
- 284 • ability to pay
- 285 • effect on ability to continue to do business
- 286 • any history of prior violations
- 287 • degree of culpability
- 288 • amount of any penalties paid by the retailer to a State for the same violation
- 289 • retailer's implementation of an employee training program
- 290 • other relevant matters

291

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

293

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

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305 **23. If the respondent is served with a complaint, does the party have a right to a hearing?**
306

307 Yes. Filing an answer in response to a complaint seeking a CMP or imposition of an NTSO, or
308 both, serves as a request for a hearing unless the respondent states otherwise (see 21 CFR
309 § 17.9(a)). If the respondent files an answer in a timely manner,⁵ the respondent is entitled to
310 have the matter proceed under the procedures established in FDA’s regulations governing CMP
311 proceedings, which can be found in 21 CFR part 17 and includes the option to have a hearing
312 unless the case is resolved on a motion for summary decision without the need for a hearing.
313 CTP must use these procedures for NTSOs as well (section 303(f)(8) of the FD&C Act).
314

315 **24. What is an administrative hearing?**
316

317 CTP files a complaint seeking assessment of a CMP or imposition of an NTSO, or both, with an
318 ALJ, who is a fair and impartial decision-maker. The ALJ will determine whether the violations
319 alleged in the complaint occurred. If the ALJ finds that the respondent is liable for the violations
320 alleged, the ALJ will determine the appropriate CMP amount to assess and/or the appropriate
321 duration for an NTSO. If the respondent chooses to have a hearing, it will be an administrative
322 hearing before the ALJ. Prior to a hearing, the parties must exchange their direct written
323 testimony (declarations from its witnesses and all evidence supporting the parties’ positions)
324 violations). During the hearing, the parties have the opportunity to cross-examine the other
325 parties’ witnesses and raise legal issues. (See 21 CFR §§ 17.25, 17.33, 17.37).
326

327 **25. Who would hear the case if a hearing is held, and where would the hearing be held?**
328

329 Cases that proceed to hearing are heard by an ALJ. An ALJ is the presiding officer in an
330 administrative hearing and has authority, among other things, to regulate the course of the
331 hearing, receive and rule on the way evidence can be used at the hearing, rule on procedural and
332 other motions, decide the case, in whole or in part, and issue a decision (see 21 CFR § 17.19).
333

334 The ALJ also has the authority to set the hearing date, time, and location, and may determine that
335 the hearing will be conducted in person, via videoconferencing, or via teleconferencing. Upon
336 the respondent’s request, the ALJ may order that the hearing be conducted by telephone, at the
337 nearest regional or field office of the FDA or, in a no-tobacco sale order case, at a Federal, State,
338 or county facility within 100 miles from the location of the retail outlet, if such a facility is
339 available. (see section 303(f)(8) of the FD&C Act).
340

341 **26. Who will be at the hearing?**
342

343 An ALJ presides over the hearing. Counsel from FDA’s Office of the Chief Counsel on behalf
344 of CTP, representatives from CTP, the respondent, and if represented, the attorney for the
345 respondent, may be present at the hearing. Witnesses may also be present for some or all of the
346 hearing, depending on the nature of the case. The hearing is open to the public unless otherwise
347 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?”

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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

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391 which the party resides or transacts business (section 303(f)(6) of the FD&C Act; 21 CFR
392 § 17.51).

393 394 **31. Who is responsible for paying a CMP or complying with an NTSO?**

395
396 The party found liable by the ALJ is responsible for paying the CMP or complying with the
397 NTSO. The retailer is typically the named respondent and can be either a person or a business
398 entity (see 21 CFR § 17.3(b)).

399 400 **32. Where does the CMP money go?**

401
402 All CMP payments are deposited in the Treasury of the United States as miscellaneous receipts
403 (see 21 CFR § 17.54).

404 405 **33. What happens if the respondent is served with a complaint and does not respond by the** 406 **time an answer is due?**

407
408 If service was proper and the respondent does not pay the CMP or file a timely answer to a
409 complaint seeking a CMP and/or an NTSO, or both, the ALJ will assume that the facts alleged in
410 the complaint are true and, if those facts establish liability, the ALJ will issue an initial decision,
411 through a default order, imposing the requested CMP and/or NTSO.

412 413 **34. What is a default order?**

414
415 If a respondent is served with a complaint seeking a CMP and/or NTSO, or both, and does not
416 pay the penalty and/or agree to an NTSO or also does not file an answer in a timely manner, the
417 ALJ will assume that the facts alleged in the complaint are true and if those facts establish
418 liability, will issue an initial decision, called a default order, imposing the requested CMP and/or
419 NTSO. If the complaint seeks a CMP, the amount of the CMP imposed by the ALJ will be either
420 (1) the maximum amount of penalties provided for by law for the violations alleged; or (2) the
421 amount sought in the complaint, whichever amount is smaller (see 21 CFR § 17.11(a)). If a
422 complaint seeks an NTSO, the ALJ will impose an NTSO for the duration sought in the
423 complaint. For permanent NTSOs, the initial decision must allow the respondent, after a
424 specified period of time, to request compromise, modification, or termination of the NTSO. The
425 initial decision becomes final and binding 30 days after it is issued.⁶

426
427 By failing to file a timely answer, the respondent waives any right to a hearing and any right to
428 contest the CMP amount or NTSO duration that is imposed by the ALJ, unless the party can
429 demonstrate that there were extraordinary circumstances that prevented the filing of an answer.

430 431 **35. If the ALJ enters an initial default order against the respondent, can the respondent** 432 **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)).

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434 When the respondent receives a default order, it will become final 30 days after the date of the
435 initial order. The respondent can dispute the initial order only if an extraordinary circumstances
436 are shown and a motion to re-open is filed during the 30-day period between the dates of the
437 initial order and the final order (see 21 CFR § 17.11(c)–(d)).
438

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

441
442 If the respondent does not comply with a valid and final order by paying the required amount,
443 FDA may pursue further action through the U.S. Department of Justice.
444

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

447
448 CTP has developed two different categories of compliance check inspections:
449 (1) undercover buy (UB) inspections, primarily to determine a retailer's compliance with
450 the age and photo identification requirements relating to the sale of tobacco products;
451 and
452 (2) advertising and labeling (A&L) inspections, to determine a retailer's compliance with
453 tobacco product requirements other than age and photo identification.
454

455 In UB inspections, minors (supervised by FDA-commissioned state inspectors) attempt to
456 purchase tobacco products, and the inspectors, who generally accompany the minors, collect
457 evidence, record inspection results, and draft narrative reports and other documents describing
458 their inspectional observations. UB inspections are generally conducted without notice to the
459 retailer. FDA-commissioned state inspectors follow the same procedures when conducting A&L
460 inspections, except that A&L inspections are conducted without a minor and the inspectors
461 generally present the retailer with a Notice of Inspection (Form FDA 482). For inspections that
462 identify potential violations, the information recorded by the inspectors is transmitted to CTP for
463 review and evaluation.
464

465 Generally, the initial inspection of a retail establishment is either a UB or an A&L inspection.
466 After a Warning Letter is issued, CTP creates a compliance follow-up inspection assignment of
467 the establishment in two parts. UB and A&L inspections at a retail establishment are performed
468 separately (usually on different days) to verify a retailer's compliance with the FD&C Act's
469 requirements relating to regulated tobacco products. The inspection is done in two parts because
470 inspectors often announce themselves and ask questions of the retailer during the A&L part of
471 the inspection.
472

38. How does CTP determine that violations occurred?

474
475 In general, FDA-commissioned inspectors and minors conduct inspections of tobacco retail
476 outlets. The inspectors visit the retail outlets, collect relevant evidence, and report potential
477 violations to CTP for further review. Generally, an explanation of the violations observed during

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478 the inspection at the respondent's retail outlet will be included in any Warning Letter or
479 complaint.

480

39. Does CTP have evidence of the violations?

482

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

490

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

492

493
494 Shortly after any inspection in which a retailer sells tobacco products to a minor, CTP issues a
495 Notice of Compliance Check Inspection informing the retailer of the sale and explaining that
496 CTP will make a final determination regarding whether there has been a violation of federal law.
497 The information included in the Notice of Compliance Check Inspection generally will include:

498

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

505

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

506

507
508 Yes. In accordance with 21 CFR § 17.23, no later than 60 days prior to the hearing, or at another
509 time specified by the ALJ, the respondent may request relevant inspection documents.
510 Additionally, at least 30 days prior to the hearing, or at another time specified by the ALJ, the
511 respondent and CTP are required to exchange various types of evidence, including witness lists,
512 copies of prior written statements of proposed witnesses, and copies of proposed hearing exhibits
513 (see 21 CFR § 17.25(a)). CTP intends to include some evidentiary documents with the
514 complaint and cover letter it sends to the respondent when it initially files a case. Once a case is
515 closed, certain documents become publicly available. For additional information on the
516 exchange of information between the parties, witnesses, and evidence, see 21 CFR §§ 17.25,
517 17.37, and 17.39.

518

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

519

520
521 The Tobacco Control Act provides that the amount of a civil penalty for violations of part 1140
522 shall not exceed certain amounts, depending on the number of previous violations, the time
523 period in which the violations occurred, and other factors (see section 103(q)(2)(A) of the

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524 Tobacco Control Act; 21 CFR § 17.2 (referencing penalty table in 45 CFR § 102.3)). The
525 Tobacco Control Act also established two schedules for the maximum civil money penalties for
526 violations of regulations issued under section 906(d) of the FD&C Act, including violations of
527 part 1140.

528
529 In determining the amount of the CMP that will be sought, CTP will use the lower schedule for
530 all retailers until regulations are developed that establish standards for retailer training programs.
531 This lower schedule, as set out in section 103(q)(2)(A) of the Tobacco Control Act codified at
532 FD&C Act Section 303 note, is:⁷

- 533
534 ...the amount of the civil penalty shall not exceed—
- 535 (I) in the case of the first violation, \$0.00. together with the issuance of a
536 warning letter to the retailer;⁸
 - 537 (II) in the case of a second violation within a 12-month period, \$250;
 - 538 (III) in the case of a third violation within a 24-month period, \$500;
 - 539 (IV) in the case of a fourth violation within a 24-month period, \$2,000;
 - 540 (V) in the case of a fifth violation within a 36-month period, \$5,000; and
 - 541 (VI) in the case of a sixth or subsequent violation within a 48-month period,
542 \$10,000 as determined by the Secretary on a case-by-case basis.
- 543

544 **43. How does CTP determine the amount of the CMP that it will seek in the complaint for** 545 **violations of 21 CFR part 1140?**

546
547 The first time that CTP finds a violation at a retail outlet, its policy is to send a warning letter
548 rather than seeking a CMP. If CTP identifies violation(s) at a retail outlet during a follow-up
549 compliance check or a subsequent inspection at that retail outlet, CTP generally intends to seek
550 civil money penalties to the extent they are appropriate. If there have been repeated violations at
551 the outlet and a no-tobacco-sale order would be appropriate in light of the factors discussed in
552 questions 2 and 6 above, CTP also generally intends to seek a no-tobacco-sale order. See CMP
553 and NTSO Guidance.

554
555 To determine the amount of CMP it will seek, CTP counts violations of the part 1140 regulations
556 and consults a charging schedule provided in the Tobacco Control Act. CTP counts only one
557 regulation violation from the first inspection at a retail outlet, regardless of the number of
558 regulation violations that were noted and included in a Warning Letter. For any subsequent
559 inspections, CTP may count any or all violations and its general policy is to count all of them
560 individually.
561

⁷ The Civil Money Penalty amounts listed in this document reflect the amounts listed in the statute. FDA is required to update these amounts annually to reflect inflation by the Federal Civil Penalties Inflation Adjustment Act of 1990 (Pub. L. 101-410, 104 Stat. 890 (1990) (codified as amended at 28 U.S.C. 2461 note 2(a)), as amended by the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 (Sec. 701 of the Bipartisan Budget Act of 2015, Public Law 114-74, November 2, 2015). For the most up to date amounts, please see 45 CFR §102.3 or the CTP website at:

<http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm232109.htm>.

⁸ Although the penalty for the first violation is \$0.00, consistent with the statute CTP will issue a warning letter.

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562 Once CTP has counted violations at a retail outlet for the 48-month period that precedes the most
563 recent violation(s), it consults the following charging schedule to determine the amount it will
564 seek in a complaint:

565
566

Number of Violations	CMP ⁹
1	\$0.00 (CTP will issue a 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

567 Thus, if the respondent receives a Warning Letter after the first inspection that notes four
568 violations, and CTP notes two more violations during a follow-up inspection within 24 months,
569 CTP would generally count three of the violations (one for the first inspection and two for the
570 second), and seek \$500 under its policy.
571

572 To provide another, more detailed, example:
573

- 574 • A Warning Letter was issued for selling cigarettes or smokeless tobacco to a minor (21
575 CFR 1140.14(a), now 21 CFR 1140.14(a)(1)) and failing to verify photographic
576 identification (21 CFR 1140.14(b)(1), now 21 CFR 1140.14(a)(2)(i)) during an inspection
577 on January 1, 2011.¹⁰
- 578 • A two-part follow-up inspection at the same retail outlet, conducted on June 1 and June 7,
579 2011, observed violations for:
 - 580 ○ selling to a minor;
 - 581 ○ failing to verify photographic identification; and
 - 582 ○ offering free samples of cigarettes (21 CFR 1140.16(d)(1)).
- 583 • Thus, CTP has observed five violations at the retail outlet.
- 584 • Under its current policy, CTP would generally count four of the violations in determining
585 the amount it will seek: one from the Warning Letter and three from the follow-up
586 inspection.
- 587 • Applying these facts to the charging schedule, CTP would seek a CMP of \$2,000 in the
588 complaint.

589
590 **44. What does the ALJ consider in determining the amount of the CMP to be assessed?**
591

592 In contested cases, when the ALJ determines that violations have occurred, the ALJ decides the
593 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.

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594 schedule in the statute as well as any evidence of “mitigating factors.” Mitigating factors may
595 include the following:

- 596 • nature, circumstances, extent, and gravity of the violation(s),
- 597 • ability to pay,
- 598 • effect on ability to continue to do business,
- 599 • any history of prior violations,
- 600 • degree of culpability,
- 601 • the amount of any penalties paid by the retailer to a State for the same violation,
- 602 • retailer’s implementation of an employee training program, and
- 603 • other relevant matters.

604
605 See 21 U.S.C. 333(f)(5)(B) and section 103(q)(2)(C) of the Tobacco Control Act; 21 CFR
606 § 17.34. For more information about how CMP amounts are determined, including information
607 on mitigating factors, see CMP and NTSO Guidance.

608 609 **45. What does the ALJ consider in determining whether to impose an NTSO, the duration** 610 **of an NTSO, and whether to compromise, modify, or terminate an NTSO?**

611
612 In contested cases, when the ALJ determines that five or more repeated violations have occurred
613 in a 36-month period, the ALJ decides the duration of the NTSO.

614
615 In determining the duration of an NTSO, the ALJ must take into account the nature,
616 circumstances, extent, and gravity of the violations and, with respect to the violator, effect on
617 ability to continue to do business, any history of prior violations, the degree of culpability, and
618 such other matters as justice may require (section 303(f)(5)(B) of the FD&C Act).

619
620 In determining whether to impose a no-tobacco-sale order, or compromise, modify, or terminate
621 a previously issued no-tobacco-sale order, the ALJ must consider whether a retailer has taken the
622 effective steps to prevent violations of the minimum age requirements for the sale of tobacco
623 products, including:

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

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

630
631 Provisions allowing the outlet, after a specified period of time, to request that the Secretary
632 compromise, modify, or terminate the order must be included in an NTSO that permanently
633 prohibits an individual retail outlet from selling tobacco products (section 303(f)(5)(B) of the
634 FD&C Act).

635 636 **46. If the respondent has already paid a CMP, can the respondent be assessed another one?** 637

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

645
646 Whether the respondent receives another complaint for CMP, and the amount of the CMP
647 sought, will depend on the number of violations observed at the outlet, the timing of the
648 violations, and other factors. See CMP and NTSO Guidance for additional information.

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

650
651
652 If no violations are observed in a follow-up inspection, the retail outlet will appear on the CTP
653 inspection database as having no violations observed. The inspection database can be found at
654 the following website

655 http://www.accessdata.fda.gov/scripts/oc/inspections/oc_insp_searching.cfm.

656
657 An FDA-commissioned inspector may visit the retail outlet again in the future to evaluate
658 continued compliance. If violations are observed during future inspections, CTP may seek to
659 impose additional CMPs. If there have been repeated violations at the outlet and a no-tobacco-
660 sale order would be appropriate as discussed in “**2. What is a no-tobacco-sale order (NTSO)?**”
661 and “**6. Why did CTP serve this complaint?**,” CTP also generally intends to seek a no-tobacco-
662 sale order. Additionally, if violations are observed during future inspections, CTP may initiate
663 other enforcement actions in Federal court.

664
665 The respondent’s violation history does not reset to zero violations if there is a nonviolative
666 inspection, and, in regard to CMPs, proceeds according to the schedule listed in “**42. What is the**
667 **schedule of maximum civil money penalties for violations of part 1140?**”

668 669 **48. How does CTP count violations at a retail outlet that is part of a chain when it seeks** 670 **CMPs under part 1140?**

671
672 CTP’s current policy is to consider each retail location to be a separate retail outlet for purposes
673 of counting CMP violations under the schedule of maximum penalties described above. A retail
674 chain may receive multiple separate CMP complaints for violations of part 1140, but for
675 purposes of counting violations for CMPs, each retail outlet would be treated individually.
676 Similarly, under this policy, a chain could also expect to receive separate Warning Letters for
677 each outlet where violations are found.

678
679
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681 **Document History:**

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