

Determination of the Period Covered by a No-Tobacco-Sale Order and Compliance With an Order

Guidance for Tobacco Retailers

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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.

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Guidance for Tobacco Retailers¹

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 the approach 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 describes FDA’s current thinking with respect to imposing a no-tobacco-sale order (NTSO) on a retailer who has committed repeated violations of restrictions promulgated under section 906(d) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 301 et seq.), including FDA’s “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents,” codified at 21 CFR part 1140. It supplements FDA’s current policies as described in FDA’s guidance for FDA and tobacco retailers, *Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers*. This guidance discusses, among other things, the factors FDA will consider in determining the period of time covered by an NTSO and a retailer’s compliance with an NTSO. Additional information regarding procedures FDA follows when it initiates a civil money penalty (CMP) or an NTSO action may be found in FDA’s guidance for industry and FDA staff, *Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers: Responses to Frequently Asked Questions* (CMP and NTSO FAQs guidance).

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.

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

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39 **II. BACKGROUND**

40
41 On June 22, 2009, President Obama signed the Family Smoking Prevention and Tobacco Control
42 Act (Tobacco Control Act) into law. The Tobacco Control Act amended the FD&C Act to give
43 FDA important new authority to regulate the manufacture, marketing, and distribution of tobacco
44 products to protect the public health generally and to reduce tobacco use by minors. Section
45 906(d) of the FD&C Act authorizes FDA to issue regulations that restrict the sale and
46 distribution of tobacco products if FDA determines such regulations would be appropriate for the
47 protection of the public health. Section 303(f)(8) of the FD&C Act authorizes FDA to impose an
48 NTSO against a person found to have committed repeated violations, at a particular retail outlet,
49 of restrictions on the sale and distribution of tobacco products promulgated under section 906(d)
50 of the FD&C Act, such as FDA’s “Regulations Restricting the Sale and Distribution of
51 Cigarettes and Smokeless Tobacco to Protect Children and Adolescents.”

52
53 In addition to its authority to seek NTSOs, FDA has the authority to seek CMPs from retailers
54 for violations of the FD&C Act and implementing regulations. FDA may pursue a CMP and an
55 NTSO separately or together. Further, FDA has authority to pursue other enforcement actions
56 for FD&C Act violations based on the individual circumstances, including injunctions, criminal
57 prosecution, and seizures.

58 59 **III. DISCUSSION**

60 61 **A. What definitions apply to this guidance?**

62
63 For purposes of this guidance, FDA intends to use the following definitions.

64
65 **No-tobacco-sale order (NTSO):** The term “no-tobacco-sale order” refers to an order
66 prohibiting the sale of tobacco products at a retail outlet indefinitely or for a specified period of
67 time under section 303(f)(8) of the FD&C Act.

68
69 **Person:** The term “person” is not limited to a natural person, but includes individual,
70 partnership, corporation, and association (section 201(e) of the FD&C Act).

71
72 **Retailer:** The term “retailer” means any person, government, or entity who sells tobacco
73 products to individuals for personal consumption, or who operates a facility where self-service
displays of tobacco products are permitted (section 900(14) of the FD&C Act).

74
75 **Repeated violation:** For purposes of section 303(f)(8) of the FD&C Act, which relates
76 to NTSOs, the Tobacco Control Act defines the term “repeated violation” to mean “at least 5
77 violations of particular requirements over a 36-month period at a particular retail outlet that
78 constitute a repeated violation...” (section 103(q)(1)(A) of the Tobacco Control Act).

79
80 **Tobacco product:** The term “tobacco product” means “any product made or derived
81 from tobacco that is intended for human consumption, including any component, part, or
82 accessory of a tobacco product (except for raw materials other than tobacco used in
manufacturing a component, part, or accessory of a tobacco product).” This term does not

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83 include an article that is a drug, a device, or a combination product as defined in the FD&C Act
84 (section 201(rr) of the FD&C Act).

85

B. When may FDA seek an NTSO?

87

88 FDA conducts inspections at retail outlets to evaluate compliance with the requirements of the
89 FD&C Act and implementing regulations relating to tobacco products. If FDA finds that a
90 retailer has committed “repeated violations” of the restrictions on the sale and distribution of
91 tobacco products promulgated under section 906(d) of the FD&C Act (including restrictions
92 codified at part 1140) at a particular retail outlet, then FDA may seek to impose an NTSO on that
93 retailer prohibiting the sale of tobacco products at that outlet. FDA considers there to be
94 “repeated violations” for purposes of section 303(f)(8) if:

- 95 • There are at least five violations of requirements issued under section 906(d) of the
96 FD&C Act at a particular outlet;
- 97 • Each of the five violations represents the second or subsequent violation of a particular
98 requirement; and
- 99 • Each of the five violations occurs within 36 months.

100

101 FDA’s current policy is to consider each retail location to be a separate retail outlet when
102 determining if there are repeated violations that provide grounds for FDA to seek an NTSO. A
103 retail chain may receive multiple separate CMP and NTSO complaints for violations of part
104 1140, but for purposes of counting violations for CMPs and NTSOs, each retail outlet would be
105 treated individually.

106

C. What is the period of time an NTSO will cover?

108

109 In determining the period to be covered by an NTSO or amount of a CMP, FDA must take into
110 account the nature, circumstances, extent, and gravity of the violations and, with respect to the
111 violator, ability to pay, effect on ability to continue to do business, any history of prior such
112 violations, the degree of culpability, and such other matters as justice may require (section
113 303(f)(5)(B) of the FD&C Act).

114

115 The following table shows the maximum period of time FDA intends to seek when imposing an
116 NTSO on a retailer. This maximum period takes into account the number of NTSOs previously
117 imposed on the retailer. In general, FDA intends to file a complaint seeking the maximum time
118 period. However, based on information that may subsequently become available to FDA,
119 including information provided by the retailer in an answer to the complaint or during a
120 settlement conference or hearing, FDA may reduce the time period taking into consideration the
121 factors described above and information regarding whether the retailer has taken effective steps
122 to prevent selling tobacco products to minors. In determining whether to impose the NTSO or
123 reduce the period of time FDA seeks to impose in the NTSO, FDA will generally consider
124 whether a retailer has taken effective steps to prevent the sale of tobacco products in violation of
125 the minimum age requirements, including:

- 126 • adopting and enforcing a written policy against sales to minors;
- 127 • informing its employees of all applicable laws;
- 128 • establishing disciplinary sanctions for employee noncompliance; and

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- 129 • requiring its employees to verify age by way of photographic identification or electronic
130 scanning device.

131 See section 103(q)(1)(G) of the Tobacco Control Act and section 303(f)(5) of the FD&C Act.

132

Number of NTSOs received by Retailer	Maximum Period of Time for NTSO
First NTSO	30 Calendar Days
Second NTSO	6 Months
Third (and subsequent) NTSO	Permanent NTSO

133

134 The Tobacco Control Act does not establish specific periods of time to be covered by an NTSO,
135 but does allow for an NTSO to permanently prohibit a retailer from selling tobacco products
136 (section 303(f)(5)(B) of the FD&C Act). FDA believes that imposing NTSOs on a schedule with
137 gradually increasing periods of time, as laid out above, is appropriate based on the following
138 considerations. First, if there are grounds for imposing an NTSO, the retailer has already
139 engaged in repeated violations of the law and regulations restricting the sale and distribution of
140 tobacco products, and therefore has a prior history of violations. Second, the restrictions
141 codified in part 1140 are intended to protect the public health, especially children and
142 adolescents, and FDA therefore considers repeated violations of these restrictions to be very
143 serious. Nearly 9 out of 10 adult daily smokers smoked their first cigarette by age 18 (87
144 percent).² If the current trajectory of smoking rates continues, 5.6 million children alive today
145 will die prematurely as a result of smoking.³ Third, FDA believes that imposing NTSOs where
146 the periods of time gradually increase, starting with a maximum of 30 days and then a maximum
147 of 6 months before issuing an order permanently prohibiting the sale of tobacco products, strikes
148 an appropriate balance between considerations related to the number, extent, and gravity of the
149 violations on one hand, and the retailer’s ability to continue to do business on the other hand.
150 The increasing periods of time for which FDA intends to impose NTSOs are also consistent with
151 the scheme of increasing CMPs for violations laid out in the Tobacco Control Act.

152

153 FDA also considered how similar penalties are addressed at the state level. FDA found that the
154 number of violations that triggers a state’s imposition of a similar penalty and the length of time
155 that state laws and regulations allow for suspension of the sale of tobacco products at a retailer
156 vary greatly among the states. The periods covered by similar penalties at the state level range
157 from days to indefinite revocation of a retailer’s license. FDA’s decision to pursue a maximum
158 of 30 days for an initial NTSO and a maximum of 6 months for a second NTSO is consistent
159 with the increasing periods authorized by many states’ laws and regulations. FDA also found
160 that many states may suspend or revoke a retailer’s license after multiple violations. Thus,
161 FDA’s approach to have a third NTSO that permanently prohibits the sale of tobacco products is

² U.S. Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress. A Report of the Surgeon General. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, National Center for Chronic Disease Prevention and Health Promotion, Office on Smoking and Health, 2014, p. 708.

³ U.S. Department of Health and Human Services. The Health Consequences of Smoking: 50 Years of Progress, p. 667.

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162 not inconsistent with states revocation of a retailer's license after repeated violations of laws
163 relating to the sale of tobacco products.

164
165 An NTSO that permanently prohibits an individual retail outlet from selling tobacco products
166 must allow the retail outlet, after a specified period of time, to request that FDA compromise,
167 modify, or terminate the order (section 303(f)(5)(B) of the FD&C Act). In determining whether
168 to compromise, modify, or terminate any NTSO, FDA must consider whether a retailer has taken
169 effective steps to prevent violations of the minimum age requirements for the sale of tobacco
170 products, including

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

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

177

D. How does FDA initiate and impose NTSOs?

179

180 Before entry of an NTSO, a person is entitled to a hearing pursuant to the procedures established
181 through FDA's regulations for assessing CMPs (section 303(f)(8) of the FD&C Act). Thus,
182 FDA will follow the procedures set forth in 21 CFR part 17. The CMP and NTSO FAQs
183 guidance provides answers to frequently asked questions regarding the procedures FDA follows
184 when it initiates a CMP or an NTSO action. Among other information, the CMP and NTSO
185 FAQs guidance describes options retailers have for responding to a complaint.

186

E. What happens after an NTSO has been imposed?

188

1. What steps could a retailer take to ensure compliance with an NTSO?

190

191 The NTSO will state the period of time during which the retailer cannot sell tobacco products.
192 While an NTSO is in effect, a retailer may want to consider taking additional action to ensure
193 that no tobacco products are sold in the establishment. These actions could include, for example:

- 194 • *Drapes/curtains over the products:* A retailer may cover its tobacco products with
195 drapes, curtains, or some other covering so the tobacco products cannot be accessed
196 for sale or distribution.
- 197 • *Removal of products:* A retailer may remove the tobacco products from the area of the
198 store that is visible to the customers or from the store entirely.

199

200 The retailer may use other approaches to ensure that no regulated tobacco products are being
201 sold at the retail establishment during the period covered by the NTSO. FDA recommends that
202 the retailer explain the means by which it intends to comply with the terms of the NTSO.

203

2. How will FDA monitor compliance with an NTSO?

205

206 FDA may conduct unannounced compliance checks at a retail establishment during the period
207 covered by the NTSO to ensure the establishment is complying with the terms of the order. If

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208 FDA determines that there has been another violation of the FD&C Act or its implementing
209 regulations during a compliance check, FDA may choose to initiate a subsequent enforcement
210 action during the period a retailer is subject to an NTSO.

211

212 3. *What happens if a retailer violates an NTSO?*

213

214 The sale of tobacco products in violation of an NTSO is a prohibited act under section 301(oo) of
215 the FD&C Act. Thus, if the retailer sells tobacco products in violation of an NTSO, the retailer
216 may be subject to further enforcement actions such as criminal prosecution or injunction.

217

218 4. *What happens after an NTSO has been lawfully fulfilled?*

219

220 FDA may visit the retail establishment after the terms of the NTSO have been met to assess
221 compliance with the FD&C Act and implementing regulations after the retailer resumes tobacco
222 sales. If violations are observed during such inspections, FDA may assess a CMP or impose an
223 NTSO, or both, or initiate other enforcement actions, as appropriate. Compliance with the terms
224 of an NTSO or a subsequent nonviolative inspection does not eliminate any past violations from
225 the retailer's history. That is, past violations may be used to support additional enforcement
226 actions, including subsequent NTSOs.

227

228 **F. How can a consumer learn which retailers have received NTSOs?**

229

230 FDA maintains information regarding which retailers have violated laws or regulations relating
231 to tobacco products on the Center for Tobacco Products (CTP) Web site. The CTP Web site
232 includes a searchable database to review the results of compliance check inspections. When an
233 NTSO is imposed on a retailer, FDA intends to post the information on the CTP Web site.

234

235 **G. What compliance assistance is available to retailers?**

236

237 Small businesses may contact CTP by email at smallbiz.tobacco@fda.hhs.gov or by phone at 1-
238 877-CTP-1373.

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