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

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Guidance for Tobacco Retailers

DRAFT GUIDANCE

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For questions regarding this draft guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

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U.S. Department of Health and Human Services
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Guidance for Tobacco Product Retailers[1]

This draft guidance, when finalized, will represent the Food and Drug Administration's (FDA's or Agency's) current thinking on this topic.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 using the contact information on the title page of this guidance.

I. INTRODUCTION

This draft guidance, when finalized, will describe FDA's current thinking with respect to imposing a no-tobacco-sale order (NTSO) on a retailer who has committed repeated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 This draft guidance discusses, among other things, the factors FDA will consider in determining the period of time covered by an NTSO and a retailer's compliance with an NTSO.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

[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.

cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

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

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

III. DISCUSSION

A. What definitions apply to this guidance?

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

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

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

Retailer: The term "retailer" means any person, government, or entity who sells tobacco 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).

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

Tobacco product: The term "tobacco product" means "any product made or derived from tobacco that is intended for human consumption, including any component, part, or 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 include an article that is a drug, a device, or a combination product as defined in the FD&C Act (section 201(rr) of the FD&C Act).

B. When may FDA seek an NTSO?

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

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

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

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

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

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

whether a retailer has taken effective steps to prevent the sale of tobacco products in violation of the minimum age requirements, including:

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

See Section 103(q)(1)(G) of the TCA and Section 303(f)(5) of the FD&C Act.

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

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

FDA also considered how similar penalties are addressed at the state level. FDA found that the number of violations that triggers a state's imposition of a similar penalty and the length of time that state laws and regulations allow for suspension of the sale of tobacco products at a retailer

[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.

vary greatly among the states. The periods covered by similar penalties at the state level range from days to indefinite revocation of a retailer's license. FDA's decision to pursue a maximum of 30 days for an initial NTSO and a maximum of 6 months for a second NTSO is consistent with the increasing periods authorized by many states' laws and regulations. FDA also found that many states may suspend or revoke a retailer's license after multiple violations. Thus, FDA's approach to have a third NTSO that permanently prohibits the sale of tobacco products is not inconsistent with states revocation of a retailer's license after repeated violations of laws relating to the sale of tobacco products.

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

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

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

D. How does FDA initiate and impose NTSOs?

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

E. What happens after an NTSO has been imposed?

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

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

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

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

2. How will FDA monitor compliance with an NTSO?

FDA may conduct unannounced compliance checks at a retail establishment during the period covered by the NTSO to ensure the establishment is complying with the terms of the order. If FDA determines that there has been another violation of the FD&C Act or its implementing regulations during a compliance check, FDA may choose to initiate a subsequent enforcement action during the period a retailer is subject to an NTSO.

3. What happens if a retailer violates an NTSO?

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

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

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

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

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

G. What compliance assistance is available to retailers?

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

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