

GUIDANCE: DETERMINATION OF THE PERIOD COVERED BY A NO-TOBACCO-SALE ORDER (NTSO) AND COMPLIANCE WITH AN ORDER



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September 2, 2015

AGENDA

- Legal Authority and Background
- When FDA May Seek an NTSO
- How FDA Seeks an NTSO and Retailer Rights
- Period of Time Covered by an NTSO
- Compliance with an NTSO

FAMILY SMOKING PREVENTION AND TOBACCO CONTROL ACT

- Signed into law on June 22, 2009
- The Food and Drug Administration (FDA) was given the authority to regulate tobacco products under the new law.
- Section 303(f)(8) of the FD&C Act authorizes FDA to impose a No-Tobacco-Sale Order (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 .
- 21 Code of Federal Regulations part 1140

RETAILER VIOLATIONS

- Sale of a tobacco product to a minor
- Failure to verify age by means of photo ID during the sale of a tobacco product
- Using a vending machine to sell tobacco products in a non-age restricted facility
- Selling/offering for sale single cigarettes
- Failure to remove a violative display/advertising/labeling
- Selling cigarette packages containing fewer than 20 cigarettes
- Using a self-service display of cigarettes, cigarette tobacco, smokeless tobacco, or roll-your-own tobacco in a non-age restricted facility
- Distributing free samples, except for smokeless tobacco in a qualified adult-only facility

RETAILER INSPECTION ENFORCEMENT

Warning Letter - notifies the retailer of a violation or violations, does not seek a monetary fine, and provides the retailer the opportunity to voluntarily comply with the law.

Civil Money Penalty - a monetary fine assessed against a retailer for 2 or more violations of the provisions of the FD&C Act or its implementing regulations governing the sale of tobacco products.

NTSO - an order prohibiting the sale of tobacco products at a retail outlet indefinitely or for a specified period of time.

GUIDANCE FOR INDUSTRY

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

Contains Nonbinding Recommendations

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

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.

DEFINITIONS

Person

- A “person” is not limited to a natural person, but includes individuals, partnerships, corporations, and associations.

Retailer

- Any person, government, or entity who sells tobacco products to individuals for personal consumption.

Repeated Violation

- “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)

WHAT IS AN NTSO?

- An NTSO is 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.
- This means that if a retail outlet is under an NTSO, the retailer may not sell any tobacco products regulated by the FDA during the period time covered by the NTSO.

WHEN MAY FDA SEEK AN NTSO?

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- FDA may seek an NTSO when:
 - There are at least five violations of requirements issued under section 906(d) of the FD&C Act at a particular retail 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.

COUNTING REPEATS – EXAMPLE 1

OV = Original Violation

X = Repeat Violation

Charged Violation	Dates of Violative Inspections				Number of Repeated Violations
	August 2013	February 2014	November 2014	June 2015	
Sale of tobacco to a minor	OV	X	X	X	3
Failure to verify age by photo ID		OV	X	X	2
<u>FDA Action</u>	Warning Letter	First CMP	Second CMP	Current Complaint	Total: 5 Repeated Violations

COUNTING REPEATS – EXAMPLE 2

OV = Original Violation

X = Repeat Violation

Charged Violation	Dates of Violative Inspections				Number of Repeated Violations
	May 2012	January 2013	October 2014	June 2015	
Sale of tobacco to a minor	OV	X	X	X	3
Failure to verify age by photo ID		OV	X		1
Sale/offering for sale single cigarettes	OV	X		X	2
<u>FDA Action</u>	Warning Letter	First CMP	Second CMP	Current Complaint	Total: 6 Repeated Violations

HOW DOES FDA SEEK AN NTSO AND WHAT ARE MY RIGHTS?

NTSO PROCESS

- FDA files a Complaint requesting an NTSO
- Retailer may:
 - agree to comply with the NTSO sought in the complaint (no contest);
 - file an answer and contest some or all of the Agency's allegations;
 - once an answer has been filed, the retailer may contact CTP to discuss settlement.

If the retailer does not settle or file an answer, a default judgment against the retailer may be ordered

- For more information on the procedures, see FDA's guidance titled "Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers Responses to Frequently Asked Questions"

PERIOD OF TIME COVERED BY AN NTSO

WHAT IS THE PERIOD OF TIME AN NTSO WILL COVER?

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

MITIGATING FACTORS

According to Section 303(f)(5)(B) of the FD&C Act, mitigating factors can include:

- Nature, circumstances, extent, and gravity of the violations
- Ability to pay, effect on ability to continue to do business, any history of prior such violations, the degree of culpability
- Other matters as justice may require

MITIGATING FACTORS CONTINUED

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.

COMPLIANCE WITH AN NTSO

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The NTSO will state the period of time during which the retailer cannot sell tobacco products.

Example actions retailers may, but are not required to, take during an NTSO:

- Drapes/curtains over the products
- Removal of products

WHAT HAPPENS IF A RETAILER VIOLATES AN NTSO?

FDA may conduct unannounced compliance check inspections during the period covered by the NTSO.

The sale of tobacco products in violation of an NTSO is a prohibited act under section 301(o) of the FD&C Act.

Further Enforcement Actions Include:

- Criminal Prosecution
- Injunction

STEPS AFTER AN NTSO IS LAWFULLY FULFILLED

- Future compliance check inspections
- If violations are observed during future compliance check inspections, FDA may assess a CMP or impose a subsequent NTSO for a longer duration, or both, or initiate other enforcement actions, as appropriate.
- Compliance with the terms of an NTSO or a subsequent non-violative 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.

ADDITIONAL RESOURCES

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

For additional information on retailer compliance with regulations and the law, see FDA guidance documents titled:

“Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers”

and

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

These documents and other information are located on CTP’s website at <http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation>

THE END



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