Civil Money Penalties and No-Tobacco-Sale Orders For Tobacco Retailers (Revised) *

Guidance for Industry

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For questions regarding this draft guidance, contact the Center for Tobacco Products at (Tel) 1-877-CTP-1373 (1-877-287-1373) Monday-Friday, 9 a.m. – 4 p.m. EDT.

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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***This is the seventh revision to the first edition of this guidance, which issued in March 2011. Revisions are noted by date at the end of the guidance.**

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Contains Nonbinding Recommendations

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

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Guidance for Industry[1]

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 document is intended to describe CTP's current policies with respect to civil money penalties and no-tobacco-sale orders for retailers who violate Federal Food, Drug, and Cosmetic Act ("FD&C Act") (21 U.S.C. 301 et seq.) requirements relating to tobacco products, including the requirement that tobacco products may not be sold or distributed in violation of the restrictions on the sale and distribution of cigarettes,[2] smokeless tobacco, and covered tobacco products, which are codified at title 21 of the Code of Federal Regulations (CFR) part 1140. When this guidance document was finalized in March 2011, several provisions in the Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act" or "TCA") (Public Law 111-31) that relate to civil money penalties and no-tobacco-sale orders went into effect. Section 103(q)(3) of the TCA.

The guidance document discusses:

- Definitions
- How does CTP intend to identify violations of the FD&C Act relating to tobacco products?
- Does good-faith reliance on the presentation of a false government-issued ID constitute a violation of minimum-age requirements for the sale of tobacco products?

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

[2] Unless otherwise stated, the requirements applicable to cigarettes also apply to cigarette tobacco (section 900(4) of the FD&C Act and 21 CFR § 1140.3). Additionally, the definition of "cigarette" includes roll-your-own tobacco (Section 900(3) of the FD&C Act; 21 C.F.R. § 1140.3).

- When may CTP decide to seek civil money penalties and/or no-tobacco-sale orders?
- Procedures that apply if CTP seeks civil money penalties and/or no-tobacco-sale orders
- What amount of civil money penalty may be assessed for a violation of the FD&C Act relating to tobacco products (including a violation of regulations issued under Section 906(d) of the FD&C Act)?
- What factors must be considered when imposing a no-tobacco-sale order, and how long may such an order run?

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.

II. BACKGROUND

On June 22, 2009, President Obama signed the 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.

Civil Money Penalties. The Tobacco Control Act provides for civil money penalties for violations of FD&C Act requirements that relate to tobacco products. Section 303(f)(9) of the FD&C Act. Of special importance to retailers, these violations include the sale or distribution of tobacco products in a manner that violates regulations issued under Section 906(d) of the FD&C Act, including the sale or distribution of cigarettes, smokeless tobacco, and covered tobacco products in violation of the restrictions set forth in 21 CFR part 1140.[3]

Maximum civil money penalty amounts are set by the FD&C Act, as amended by the TCA, and take into account the requirements that are violated, the number of violations, and several other factors.

[3] Section 102(a)(1)(A) of the TCA provides that the statutorily required final rule, ultimately issued as "Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents" (75 FR 13225) (March 19, 2010) (codified at 21 CFR part 1140) is deemed to be issued under Chapter IX of the FD&C Act. Section 906(d) of the FD&C Act provides the authority in Chapter IX for regulations restricting the sale or distribution of tobacco products, and FDA accordingly understands this regulation to have been issued under Section 906(d) of the FD&C Act.

21 CFR part 1140 was amended by the rule "Deeming Tobacco Products to be Subject to the Federal Food, Drug, and Cosmetic Act, as Amended by the Family Smoking Prevention and Tobacco Control Act; Restrictions on the Sale and Distribution of Tobacco Products and Required Warning Statements for Tobacco Products" (81 FR 28973) (May 10, 2016) (the Deeming Rule). In the Deeming Rule, under section 906(d), FDA established certain restrictions on the sale and distribution of covered tobacco products.

- Maximum penalties for violating regulations issued under Section 906(d) of the FD&C Act, including the restrictions on the sale and distribution of cigarettes, smokeless tobacco, and covered tobacco products in 21 CFR part 1140, are set forth at Section 103(q)(2) of the TCA and have since been adjusted for inflation.[4] The first time a retailer with an approved training program violates the regulations issued under Section 906(d) of the FD&C Act, there is no penalty; instead, CTP will send the retailer a Warning Letter. The maximum civil money penalty amounts for such retailers range from $250 (for a second violation in a 12-month period) to $10,000 (for a sixth or each subsequent violation at the same retail location within a 48-month period).[5] *Id.*

- In general, penalties for violating other FD&C Act requirements relating to tobacco products may not exceed $15,000 for each violation or $1,000,000 for all violations adjudicated in a single proceeding.[6] Section 303(f)(9)(A) of the FD&C Act. For example, a violation of the FD&C Act involving the manufacture, sale, and/or distribution of a new tobacco product that lacks the required marketing authorization could be subject to a penalty under Section 303(f)(9)(A). A tobacco product that lacks the required marketing authorization is adulterated and misbranded. See Sections 910, 902(6)(A), and 903(a)(6) of the FD&C Act. Violations of certain provisions may be subject to enhanced penalties. Section 303(f)(9)(B) of the FD&C Act.

In determining the amount of civil money penalty under the relevant statutory limits, the following factors must be considered: the nature, circumstances, extent, and gravity of the violation or 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. CTP considers a violation involving the manufacture, sale, and/or distribution of an unauthorized tobacco product to be egregious in terms of the nature and gravity of the violation. FDA may consider bringing an action for enhanced penalties under Section 303(f)(9)(B)(i) if there is evidence of an intentional violation of a requirement of section 902(6)(A) (among other provisions).

No-Tobacco-Sale Orders. The Tobacco Control Act also adds Section 303(f)(8) to the FD&C Act, authorizing FDA to impose a no-tobacco-sale order against a person found to have committed repeated violations of restrictions promulgated under Section 906(d) of the FD&C Act at a particular retail outlet. "Repeated violations" is defined 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 TCA.

In determining the duration of a no-tobacco-sale order, the same factors listed above for civil money penalties must be considered, and also whether employers have taken certain steps to

[4] The Civil Money Penalty amounts listed in this guidance 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. No. 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, Pub. L. No. 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.
[5] *Id*.
[6] *Id*.

promote compliance with the FD&C Act. Section 303(f)(5)(B) of the FD&C Act, Section 103(q)(1)(G) of the TCA.

Special Considerations and Mitigating Penalties. Section 103(q)(1)(F) of the TCA explains that good-faith reliance on a false government-issued photographic identification that contains a date of birth does not constitute a violation of any minimum age requirement for the sale of tobacco products, provided that an employer takes effective steps to prevent such violations. Also relevant are Section 103(q)(1)(G) of the TCA and Section 303(f)(5)(B) of the FD&C Act, which are discussed above. Additionally, if a retailer has violated a restriction promulgated under section 906(d), the amount of any penalties that the retailer has paid to a State for the same violation will be considered for purposes of mitigating the civil penalty. Section 103(q)(2)(C) of the TCA.

Procedures. CTP must provide for timely and effective notice of each alleged violation at a particular retail outlet before conducting a follow-up compliance check at that outlet, and must provide notice of all previous violations at a particular outlet before a person can be charged with a violation at that outlet. Section 103(q)(1)(B) & (D) of the TCA. Civil money penalties and no-tobacco-sale orders may only be imposed after an opportunity for a hearing pursuant to the procedures established through regulations of the FDA for assessing civil money penalties (which are currently codified at 21 CFR part 17). Section 103(q)(1)(C) of the TCA, Section 303(f)(5)(A) of the FD&C Act. A retailer can request that such a hearing be conducted by telephone or at the nearest FDA regional or field office (or, in a no-tobacco-sale order case, at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such a facility is available). Section 303(f)(8) of the FD&C Act, Section 103(q)(1)(C) of the TCA. A procedure for expedited administrative appeal of an alleged violation must also be provided. Section 103(q)(1)(C) of the TCA.

Effective Date. Section 103(q)(3) of the TCA provides that several provisions that relate to civil money penalties and no-tobacco-sale orders will take effect upon issuance of the guidance described in Section 103(q)(1) of the TCA. When this guidance document was finalized in March 2011, the conditions in Section 103(q)(3) of the TCA were satisfied and the provisions it identifies went into effect.

III. DISCUSSION

A. Definitions

CTP intends to use the following definitions in implementing no-tobacco-sale order provisions and civil money penalty provisions relating to tobacco products.

1. **Civil money penalty**: The term "civil money penalty" means a penalty assessed under Section 303(f)(9) of the FD&C Act for violations of the FD&C Act.

2. **Component or part**: The term "component or part" means any software or assembly of materials intended or reasonably expected: (1) To alter or affect the tobacco product's performance, composition, constituents, or characteristics; or

(2) To be used with or for the human consumption of a tobacco product. Component or part excludes anything that is an accessory of a tobacco product.

3. **Accessory**: The term "accessory" means any product that is intended or reasonably expected to be used with or for the human consumption of a tobacco product; does not contain tobacco and is not made or derived from tobacco; and meets either of the following: (1) Is not intended or reasonably expected to affect or alter the performance, composition, constituents, or characteristics of a tobacco product; or (2) Is intended or reasonably expected to affect or maintain the performance, composition, constituents, or characteristics of a tobacco product but (i) Solely controls moisture and/or temperature of a stored product; or (ii) Solely provides an external heat source to initiate but not maintain combustion of a tobacco product.

4. **Covered tobacco product**: The term "covered tobacco product" means any tobacco product deemed to be subject to the FD&C Act under 21 CFR § 1100.2, but excludes any component or part that is not made or derived from tobacco.

5. **No-tobacco-sale order**: 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. It is a prohibited act under the FD&C Act to violate a no-tobacco-sale order. Section 301(oo) of the FD&C Act.

6. **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.

7. **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.

8. **Repeated violation**: For purposes of Section 303(f)(8) of the FD&C Act, which relates to no-tobacco-sale orders, the TCA 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 TCA. FDA understands this to mean that there is a "repeated violation" 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.

Thus, if there are six violations for selling cigarettes or smokeless tobacco to a minor (21 CFR §1140.14(a)(1)) at the same outlet, and the last five of the violations take place at the outlet within 36 months, that would constitute a "repeated violation" for purposes of Section 303(f)(8) of the FD&C Act. Or, if there are four violations of 21 CFR § 1140.14(a)(1), two violations for failing to verify photographic identification (21 CFR §1140.14(a)(2)(i)), and two violations of 21 CFR § 1140.14(a)(4) (selling a quantity of cigarettes or smokeless tobacco that is less than the minimum/smallest package size) at a retail outlet, and the last three violations of 21 CFR § 1140.14(a)(1), and the second violation each of 21 CFR §§ 1140.14(a)(2)(i) and (a)(4) take place within 36 months, that would constitute a "repeated violation" for purposes of Section 303(f)(8) of the FD&C Act. In each of these examples, the first violation of a requirement would not count toward the total, but each second or subsequent violation would. CTP also understands that each of the violations that counts toward the total must fall within a 36-month period, but that an initial violation (i.e., a first violation of a provision, which does not count toward the total of five required) may fall outside the 36-month period. CTP counts as a "repeated violation" an action that violates the same textual regulation, regardless of whether the specific citation for such violation has changed.[7]

9. **Tobacco product**: The term "tobacco product" means any product made or derived from tobacco or containing nicotine from any source 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). The term "tobacco product" does not mean an article that under the Federal Food, Drug, and Cosmetic Act is: a drug (section 201(g)(1)); a device (section 201(h)); a combination product (section 503(g)); or a food under section 201(f) if such article contains no nicotine, or no more than trace amounts of naturally occurring nicotine (section 201(rr) of the FD&C Act). Thus, the term is not limited to products containing tobacco or nicotine, but also includes components, parts, and accessories of tobacco products, whether they are sold for further manufacturing or for consumer use. For example, tobacco, papers, and filters are tobacco products, whether they are sold to consumers for use with roll-your-own tobacco or are sold for further manufacturing into a product sold to a consumer, such as a cigarette.

B. How does CTP intend to identify violations of the FD&C Act relating to tobacco products?

CTP intends to conduct compliance check inspections to identify violations of FD&C Act requirements relating to tobacco products, including the sale or distribution of cigarettes, smokeless tobacco, and covered tobacco products in violation of the restrictions in 21 CFR part 1140. Such inspections may be conducted by FDA officers or employees,

[7] 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.

officers or employees of other federal departments or agencies, or certain state officers or employees commissioned by FDA. Section 702 of the FD&C Act.

C. Does good-faith reliance on the presentation of a false government-issued ID constitute a violation of minimum-age requirements for the sale of cigarettes, smokeless tobacco, and covered tobacco products?

With respect to minimum-age requirements for the sale of cigarettes, smokeless tobacco, and covered tobacco products, including regulations issued under section 906(d) of the FD&C Act, good faith reliance on the presentation of a false government issued photographic identification that contains a date of birth does not constitute a violation if the retailer has taken effective steps to prevent such violations, 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)(F) of the TCA.

D. When may CTP decide to seek civil money penalties and/or no-tobacco-sale orders?

Although CTP is generally not required to issue a Warning Letter before taking further regulatory action, the first time CTP identifies violation(s) at a retail outlet, it generally intends to issue a Warning Letter that describes each violation.

Warning Letters will be sent by certified mail, registered mail, or personal delivery to: (1) the retailer, at the establishment where the inspection occurred; or (2) the retailer's registered agent. If CTP cannot reach the retailer or its agent through any of the methods described in the previous sentence, CTP intends to attempt to reach the retailer through other means, for example, the retailer at an address otherwise identified by the State or CTP.

CTP intends, in Warning Letters, to remind the retailer that failure to comply with the requirements of the FD&C Act relating to tobacco products may result in further FDA enforcement action, including civil money penalties, a no-tobacco-sale order, and/or injunction. CTP also intends that these letters will provide contact information and seek the retailer's response to the alleged violations.

After CTP has issued a Warning Letter with respect to a retail outlet, it intends to conduct a follow-up compliance check of that outlet without further notice to the retailer or retail outlet.

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 intends to seek a civil money penalty to the extent it is appropriate. If there have been repeated violations at the outlet and a no-tobacco-sale order would be appropriate in light of the factors discussed below in Section G, CTP also generally intends to seek a no-tobacco-sale order.

E. Procedures that apply if CTP seeks a civil money penalty and/or a no-tobacco-sale order

CTP will only charge a person with a violation at a particular retail outlet after providing notice to the retailer of all previous violations identified by CTP at that outlet. Section 103(q)(1)(D) of the TCA.

Civil money penalties and no-tobacco-sale orders are initiated by CTP filing a Complaint and serving the Complaint upon the respondent (the tobacco retailer or other appropriate person). Upon being served with a complaint for the CMP, 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).

If a respondent chooses to contest the matter, it must file an Answer to the Complaint, pursuant to 21 CFR § 17.9, within 30 days of the date of service of the Complaint. The Answer must admit or deny each of the allegations made in the Complaint, and also include any and all defenses to the action and reasons or explanations why the penalty and assessment should be less than the amount requested by the Complaint. If the respondent timely files an Answer, it is entitled to a hearing according to the procedures established in FDA's regulations governing civil money penalty proceedings, codified in 21 CFR part 17. If the respondent does not file a timely Answer, the Administrative Law Judge (ALJ) may enter an order of default, finding the respondent liable for the violations alleged in the Complaint.

After submitting an Answer, a respondent or its representatives may engage in settlement discussions with CTP regarding the civil money penalty and/or the no-tobacco-sale order. Respondents may present relevant mitigating factors or arguments for CTP to consider reducing the penalty amount or duration of the no-tobacco-sale order. If CTP and the respondent arrive at an agreed upon settlement of a Complaint seeking a civil money penalty, respondent will pay that amount and the case is concluded. If CTP and the respondent arrive at an agreed settlement of a Complaint seeking a no-tobacco-sale order, respondent will sign a settlement agreeing to the terms of the NTSO and will be expected to comply with its terms unless or until it is terminated. Even if charges are resolved through a settlement agreement, any violations that occurred will be counted in determining the total number of violations for purposes of subsequent enforcement actions.

Cases that are not settled or defaulted will be decided by an ALJ through motions for summary decision filed by either or both parties, or after an administrative hearing conducted according to the procedures in 21 CFR part 17. Under Section 103(q)(1)(C) of the TCA, a retailer can make a request to the presiding ALJ that a hearing be held by telephone or at the nearest FDA regional or field office. For cases involving no-tobacco-sale orders, the retailer can make a request to the presiding ALJ that a hearing be held by telephone, at the nearest FDA regional or field office, or at a Federal, State, or county facility within 100 miles from the location of the retail outlet, if such facility is available. Upon request, for appropriate cause, the ALJ may expedite the schedule for various aspects of the hearing.

In advance of a hearing, parties are required to exchange exhibits and written direct testimony. 21 CFR §§ 17.25 and 17.37. Parties can choose to "rest" after this exchange, or request an opportunity to cross-examine the opposing party at an oral hearing and/or submit legal briefs. After resting, or after an oral hearing and/or further briefing, the ALJ will render an initial decision based on the evidence submitted. 21 CFR § 17.45.

After the ALJ renders an initial decision, either party can appeal to the Department of Health and Human Services (DHHS) Departmental Appeals Board (DAB), pursuant to 21 CFR § 17.47. 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 which the respondent resides or transacts business. Section 303(f)(6) of the FD&C Act, 21 U.S.C. 333(f)(6).

F. What amount of civil money penalty may be assessed for a violation of the FD&C Act relating to tobacco products (including a violation of regulations issued under Section 906(d) of the FD&C Act)?

The TCA provides that civil money penalties may not exceed certain limits, and requires a number of factors to be considered in determining the penalty under those limits.

Statutory limits. Statutory limits vary according to the requirements that are violated, the number of violations, and other factors.

- *For violations of regulations issued under Section 906(d) of the FD&C Act*. The statute provides two schedules of maximum penalties for violations of such regulations -- one for retailers with an approved training program (Section 103(q)(2)(A)(i) of the TCA, codified at FD&C Act Section 303 note), and another for retailers that do not have an approved training program (Section 103(q)(2)(A)(ii) of the TCA).[8] FDA intends to promulgate regulations establishing standards for approved retailer training programs. Until it does, CTP intends to seek penalties within the range provided by Section 103(q)(2)(A)(i) of the TCA (for retailers with an approved training program), whether or not the

[8] For more information about the retailer training program, please see Guidance for Industry "Tobacco Retailer Training Programs," available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-retailer-training-programs.

retailer has implemented a training program. Those penalty amounts shall not exceed: [9]

I. in the case of the first violation, $0.00 together with the issuance of a Warning Letter to the retailer;[10]

II. in the case of a second violation within a 12-month period, $250;

III. in the case of a third violation within a 24-month period, $500;

IV. in the case of a fourth violation within a 24-month period, $2,000;

V. in the case of a fifth violation within a 36-month period, $5,000; and

VI. in the case of a sixth or subsequent violation within a 48-month period, $10,000 as determined by the Secretary on a case-by-case basis.

- *Violations of other FD&C Act requirements relating to tobacco products*. In general, penalties for violating other FD&C Act requirements relating to tobacco products may not exceed $15,000 for each violation or $1,000,000 for all violations adjudicated in a single proceeding.[11] Section 303(f)(9)(A) of the FD&C Act. For example, a violation of the FD&C Act involving the manufacture, sale, and/or distribution of a new tobacco product that lacks the required marketing authorization could be subject to a penalty under Section 303(f)(9)(A). A tobacco product that lacks the required marketing authorization is adulterated and misbranded. See Sections 910, 902(6)(A), and 903(a)(6) of the FD&C Act. Violations of certain FD&C Act provisions are subject to enhanced penalties. Section 303(f)(9)(B) of the FD&C Act.

Other factors that must be considered in determining the amount of civil money penalty. In determining the amount of a civil money penalty, the following factors must be considered: the nature, circumstances, extent, and gravity of the violation or 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. CTP considers a violation involving the manufacture, sale, and/or distribution of an unauthorized tobacco product to be egregious in terms of the nature and gravity of the violation. FDA may consider bringing an action for enhanced penalties under Section 303(f)(9)(B)(i) if there is evidence of an intentional violation of a requirement of section 902(6)(A) (among other provisions).

[9] *Supra* note 4.
[10] Although the penalty for the first violation is $0.00, consistent with the statute, CTP will issue a Warning Letter.
[11] *Supra* note 4.

If a retailer has violated a restriction promulgated under section 906(d), the amount of any penalties that the retailer has paid to a State for the same violation will be considered for purposes of mitigating the civil penalty. Section 102(q)(2)(C) of the TCA.

Finally, CTP may also take into account whether a retailer has implemented a training program in determining whether to seek less than the maximum allowed. Additional information about such programs may be found in FDA's Guidance for Industry, "Tobacco Retailer Training Programs."[12]

G. What factors must the ALJ consider when imposing a no-tobacco-sale order, and how long may such an order run?

If there are repeated violations[13] of a restriction promulgated under Section 906(d) of the FD&C Act at a particular retail outlet, a no-tobacco-sale order may be imposed to prohibit the sale of tobacco products at that outlet. Section 303(f)(8) of the FD&C Act, Section 103(q)(1)(A) of the TCA.

As noted above, CTP generally does not intend to seek a no-tobacco-sale order the first time that an inspection identifies violations at a retail outlet, and instead intends to send a Warning Letter.

In determining whether a no-tobacco-sale order may be imposed, it is necessary to 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 TCA. If a no-tobacco-sale order is imposed, the ALJ will also consider these factors in deciding whether to compromise, modify, or terminate such order. *Id.*

In determining the duration of a no-tobacco-sale order, the same factors that are relevant to determining the amount of a civil money penalty must be considered, that is: the nature, circumstances, extent, and gravity of the violation or 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.

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[12] For more information about the retailer training program, please see Guidance for Industry "Tobacco Retailer Training Programs," available at: https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-retailer-training-programs.

[13] Defined to mean at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation - *see* Definitions above.

If a no-tobacco-sale order permanently prohibits an individual retail outlet from selling tobacco products, the order must include provisions that allow the outlet, after a specified period of time, to request that the ALJ compromise, modify, or terminate the order. *Id*.

Document History:

- March 2011 – First edition of guidance was issued.
- July 2012 – Footnote 2 was revised to change the first citation from Section 102(q)(1)(A) of the Tobacco Control Act to Section 102(a)(1)(A); the table of contents was reformatted.
- November 2012 - Page 4 was revised to correct a citation from 303(5)(A) to 303(f)(5)(A).
- September 2013 - Footnote 2 was revised to reflect the fact that the guidance was finalized.
- June 2014 - Pages 3 and 9 were updated with new Civil Money Penalty amounts that reflect inflation, as required by the Federal Civil Penalties Inflation Adjustment Act; footnotes 2 and 3 were updated to clarify that the guidances are now final; footnote 4 was edited to clarify that the guidance is now final; pages 5 and 10 were edited to change the phrase "tobacco-no-sale order" to "no-tobacco-sale order."
- December 2016 - Throughout the document: "FDCA" has been replaced with "FD&C Act," "FDA" has been replaced with "CTP" where appropriate to clarify that CTP is the Complainant in CMP/NTSO actions, and non-substantive edits have been made to improve the general clarity of the document; Pages 1-3 and 6 have been edited to reflect that some of the restrictions in 21 CFR part 1140 now apply to covered tobacco products; Footnote 3 has been edited to reflect the fact that 21 CFR part 1140 has been revised by the Deeming Rule; Pages 3 and 9-10 have been updated to reflect the statutory CMP amounts; Footnotes 4-6, 9, and 11 have been updated to reflect amendments to the Civil Money Penalty Inflation Adjustment Act and to include reference to the CTP website for current amounts; Pages 4-5 have been edited to include definitions for the terms "accessory," "component or part," and "covered tobacco product;" page 6 was updated to reflect CTP's current practice regarding where and to which entity it sends Warning Letters and to provide additional detail regarding CTP's interpretation of what constitutes a "repeated violation"; Page 9 was edited to reflect the fact that an ALJ may also enter a default judgment against a respondent who fails to file a timely Answer and/or decide a case on the basis of a motion for summary decision.
- March 2023 – The definition of "tobacco product" is updated to reflect statutory amendments made by the Consolidated Appropriations Act, 2022 (Pub. L. 117-103). Among other things, the legislation amends the definition of "tobacco product" in section 201(rr) of the FD&C Act to include products "containing nicotine from any source."
- August 2023 - Pages 3 and 10 were updated with clarifying language related to violations of the FD&C Act involving the manufacture, sale, and/or distribution of a new tobacco product that lacks the required marketing authorization.