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Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Re: Docket No. FDA-2010-D-0431
Draft Guidance for FDA and Tobacco Retailers: Civil Money Penalties And No-Tobacco-Sale Orders for Tobacco Retailers
Comments from the Campaign for Tobacco-Free Kids

To Whom It May Concern:

This draft guidance on money penalties and no-tobacco-sale orders for tobacco product retailers that violate the federal Tobacco Control Act or related rules has the same major flaw as the previously circulated Tobacco Retailer Training Program Draft Guidance. It states that FDA intends to apply the lower maximum civil money penalties schedule in the Tobacco Control Act to all retailers who violate any of the rules issued pursuant to Section 906(d) of the Tobacco Control Act– which the law applies exclusively to retailers with FDA-approved training programs –even if they do not have any training program of any kind.

That stated intention directly contradicts the Tobacco Control Act, which explicitly states that the lower maximum penalties may apply only to retailers with an approved training program. [Section 103(q)(2)(A)] FDA does not have the legal authority under the Tobacco Control Act to reduce the maximum penalty amounts for any retailer that does not have an FDA approved training program. FDA also should not take this approach because it would be inappropriate as a matter of policy.

For retailers without an approved training program that violate any of the rules issued pursuant to Section 906(d), FDA is, of course, free to determine what penalty amounts it will apply *within the applicable maximum penalties for retailers without approved training programs*. But FDA does not have the authority to reduce the maximum applicable penalties across-the-board, before the violations occur, for all future retailers who violate the regulations, regardless of the individual circumstances of those violations.

Besides not being permitted by the Tobacco Control Act, such an across-the-board, anticipatory reduction of applicable maximum penalties would open the door to retailer abuses. Among other things, it would give all retailers a free pass for their first violation – regardless of how intentional or gross the violation was, and even if the retailer had made no attempt at all to train its staff to comply with the regulation or had even trained them how to evade compliance – subjecting the violating retailer, at most, to a warning letter. At the same time, the economic risk to retailers for second and third violations would be cut in half. Because FDA is still developing

its monitoring and enforcement mechanisms for retailer compliance, the chances that a retailer which violates the regulation will be caught is still relatively low. Coupling that lower risk of being caught with sharply reduced maximum penalties is inviting retailer carelessness if not intentional misconduct.

Until final regulations are issued to establish formal standards for approved retailer programs to qualify for the lower statutory penalties, FDA must inform retailers that, by law, the penalty amount maximums for retailers without approved training programs must apply to all retailer violations of the regulations prohibiting sales or distributions to youth. To be fair, however, FDA could also notify retailers that FDA will consider whether or not a violating retailer has made a good faith effort to train its staff to comply with the regulations in determining the final penalty amount that will actually be applied. FDA might also state that only those violating retailers that have absolutely no good faith training program at all will be subject to possibly having to pay the very highest penalties allowed under the applicable maximums.

But no retailers should qualify for the lower penalties meant only for those retailers with FDA-approved training program unless they actually have a bona fide employee training program and there has been at least some individualized fact finding to confirm its quality and its consistent application.

Other Concerns and Suggestions

- As in any other guidance that mentions the statutory definitions of "tobacco product" or any specific type of tobacco product, this guidance should make it clear that FDA will apply those Tobacco Control Act provisions and regulations that apply only to "cigarettes" but not to cigars to any and all rolls for smoking containing tobacco that fit the "cigarette" definition, even if the cigarettes are labeled as "little cigars" or "filtered cigars." Similarly, FDA should state clearly that it will apply and law or rule pertaining to roll-your-own tobacco for cigarettes to any and all RYO tobacco for cigarettes, even if it is labeled as "RYO tobacco for cigars" or as "pipe tobacco." [1]

FDA should also issue a new rule to eliminate any confusion over the scope of the definitions it uses for any type of tobacco product and to block any related efforts by tobacco product manufacturers to manipulate their products or their packaging or labeling to evade compliance. In the meantime, FDA should at least put manufacturers and retailers on notice that it will not ignore or tolerate any efforts to escape the definitions through false labeling or other improper means. One good way to do that is to make sure all related guidance documents explicitly mention these issues and clearly state that FDA will be interpreting and applying the existing definitions aggressively to ensure that no tobacco products evade compliance with the Tobacco Control Act or any related rules.

[1] For more on RYO tobacco falsely qualifying as "pipe tobacco" to evade proper taxation and regulation, see the comments submitted to FDA by Matthew Myers, Campaign for Tobacco-Free Kids, Docket No. FDA-2009-N-0294-1035, posted December 31, 2009, Hhttp://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a6fc38H.

- At page 7, the draft guidance lists the following four effective steps retailers potentially subject to penalties must have taken to avoid having a good-faith reliance on the presentation of a false government-issued ID constitute a violation:

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

    FDA should clarify that taking these four steps to avoid any such violation must include providing employees with basic training on how to distinguish between valid and false government-issued IDs.

    More generally, FDA should provide more information about what each of these steps must entail to qualify retailers for preferential treatment. Even if FDA cannot provide more detailed guidance at this point, FDA could at least point out that the written policy in step 1 must unequivocally state that sales to persons under the age of 18 are illegal and unacceptable and that all tobacco product sales to any person who looks like they might possibly be less than 27 years old must provide a valid government-issued photo ID prior to any sale being completed. Similarly, FDA could clarify that step 2 includes informing employees of all of the restrictions and requirements that apply to retailers in the Tobacco Control Act and the related final rule, as well as to all state and local laws and rules applicable to retail tobacco product sales; that the disciplinary sanctions in step 3 must include firing any employee who repeatedly sells tobacco products to minors; and that step 4 must educate employees as to what types of photographic identification are acceptable (government-issued IDs with the bearer's birth date) and which are not (e.g., IDs that have no birth date or no name or contact information or are not government issued).

- On page 8, the text should be revised to say that if a no-tobacco-sale order is issued pursuant to a settlement agreement between FDA and a retailer, unless or until it is terminated the retailer shall be *required under penalty of law* to comply with the order (not just "expected" to comply). That same section could also be improved by providing some guidance as to the parameters for any such settlements, making it clear that retailers that have clearly engaged in a violation cannot escape all significant penalties simply by entering into a settlement agreement, and to ensure that the possibility of a settlement agreement does not weaken the financial incentives not to engage in violations. Similarly, this section should clearly establish that any violation that leads to a settlement agreement will still count as a violation in the event that the retailer engages in any future violations and might qualify for increased penalties because of numerous past violations.

The Appendix, below, offers proposed revised text for the guidance document that would make all of the changes suggested herein.

With these changes, this guidance document should present retailers with the kind of clear and accurate penalty information needed to foster compliance. As detailed in related comments submitted previously by the Campaign for Tobacco-Free Kids, available research shows that retailers reduce their tobacco product sales to youth and otherwise improve their compliance

with applicable laws and regulations when faced with clear standards, significant financial incentives, and effective enforcement.[2]

Sincerely,

Matthew L. Myers
President
Campaign for Tobacco-Free Kids

APPENDIX

PROPOSED CHANGES TO THE EXISTING GUIDANCE DOCUMENT TEXT

The following shows the relevant existing text from the draft guidance with the text proposed to be eliminated lined out and the proposed new text underlined.

To Apply the Penalty Maximums Mandated by the Tobacco Control Law

Changes to page 9:

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

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 FDCA*. 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), and another for retailers that do not have an approved training program (Section 103(q)(2)(A)(ii) of the TCA)[3]. FDA intends to promulgate regulations establishing standards for approved retailer training programs. Until it does, the agency intends to seek penalties within the range provided by Section 103(q)(2)(A)(ii) of the TCA (for retailers without an approved training program), ~~whether or not the retailer has implemented a training program~~ but FDA will reduce

[2] Comments submitted to FDA by Matthew L. Myers, President, Campaign for Tobacco-Free Kids, Docket No. FDA-2009-N-0569-0011, posted January 8, 2010, Hhttp://www.regulations.gov/search/Regs/home.html#documentDetail?R=0900006480a7889dH.

the penalties within those ranges for any retailers that had established an ongoing employee training program directed at preventing sales to youth prior to the violation, with larger reductions for those with more comprehensive and rigorously enforced programs, and only those retailers that had no employee training program in place all prior to the violation will be subject to possibly having to pay the very highest penalties allowed under the applicable maximums. Those penalties shall not exceed:

1. in the case of the first violation, $250~~.00 together with the issuance of a warning letter to the retailer~~;
2. in the case of a second violation within a 12-month period, $500~~250~~;
3. in the case of a third violation within a 24-month period, $1000~~500~~;
4. in the case of a fourth violation within a 24-month period, $2,000;
5. in the case of a fifth violation within a 36-month period, $5,000; and
6. 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.

To Alert Retailers to FDA's Interpretation of Applicable Definitions

Insert into page 6 after item A.6:

7. [Insert definition of "cigarette" including roll-your-own tobacco for cigarettes.]

8. [Insert definition of "smokeless tobacco product"]

Note: In its interpretation and application of the definitions for "cigarette," "roll-your-own tobacco," and "smokeless tobacco product," FDA will include any tobacco product that fits into the statutory definitions regardless of how the products are packaged or labeled. For example, FDA will include as a "cigarette" any roll for smoking containing tobacco that fits the statutory definition, even if it is labeled as a "little cigar" or "filtered cigar." Similarly, FDA will include as "roll-your-own tobacco for cigarettes" any tobacco intended or expected to be used by consumers as roll-your-own tobacco for cigarettes even if it is labeled as " roll-your-own tobacco for cigars" or as "pipe tobacco" or has no label or markings at all.

To Provide Additional Guidance on the Effective Steps Retailers Can Take to Avoid Violations for Selling to Youth and to Avoid No-Tobacco-Sale Orders

Revise the text on page 7, as follows:

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 tobacco products?**

With respect to minimum-age requirements for the sale of tobacco products, including regulations issued under 906(d), 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 –

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

Section 103(q)(1)(F) of the TCA.

FDA intends to issue further guidance on how retailers can take each of these steps effectively so that no violation can occur based on a good faith reliance on the presentation of a false government issued photographic identification that contains a date of birth. Until then, FDA shall apply the following minimum standards for each of these steps:

1. The written policy against sales to minors must state that sales to persons under the age of 18 are illegal and never acceptable and that all tobacco product sales to any person who looks like they might possibly be 26 years old or less must provide a valid government-issued photo ID that includes their date of birth prior to any sale being completed;
2. Employees must be informed about not only all of the restrictions and requirements relating to retailers in the Tobacco Control Act and related final rules but also any state or local laws applicable to the sale of tobacco products;
3. The disciplinary sanctions must include terminating the employment of any staff person who repeatedly makes sales to persons under the age of 18 or otherwise repeatedly fails to follow the written policy against sales to minors and related procedures;
4. Employees must be given at least some basic training on how to distinguish between valid and false government-issued photographic identification that includes the bearer's date of birth, and must be informed that identification that does not include a photograph of the bearer, does not include the bearer's birth date, or is not government-issued is never acceptable.

Revise the text on page 11 as follows:

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~~-no~~-sale order is imposed, FDA will also consider these factors in deciding whether to compromise, modify, or terminate the order. *Id.*

FDA intends to issue further guidance on how retailers can take each of these steps effectively to obtain the related protections. Until then, these four steps must satisfy the minimum standards outlined on page 6, under item C.

To Set Minimum Standards for Settlement Agreements and to Clarify that No-Tobacco-Sale Orders Pursuant to a Settlement Agreement Must be Followed by the Retailer.

Revise the text on page 8 as follows:

After submitting an Answer, a respondent and its representatives may engage in discussions with FDA regarding the civil money penalty and/or the no-tobacco-sale order through a written submission or a mediation process. Respondents may present relevant mitigating factors or arguments for FDA to consider reducing the penalty amount or terms of the order. But in no event shall a settlement agreement reduce the penalty amount or terms of the order to such an extent that the final penalty or order no longer constitutes a significant financial disincentive to engaging in the violation. If FDA and the respondent arrive at an agreed settlement of a Complaint seeking a civil money penalty, respondent will pay that amount and the case is concluded. If FDA and the respondent arrive at an agreed settlement of a Complaint seeking a no-tobacco-sale order, respondent will receive a copy of the order and ~~will be expected to~~ must fully comply with its terms unless or until it is terminated. Any violation resolved through a settlement agreement shall still count as a violation for the purposes of determining whether repeated violations by that retailer have occurred within the relevant time periods for establishing higher penalties.