

FDA's Center for Tobacco Products Begins Fining Retailers for Violations – What You Need to Know

Introduction

The Food and Drug Administration (“FDA”) has begun pursuing civil money penalties (*i.e.*, fines) against retailers who are found to have violated FDA’s tobacco regulations. This document is intended to provide tobacco retailers the information they need so they know how to respond if they are assessed a fine, as well as how they might minimize the severity of penalties that are assessed against them.

Background

The Family Smoking Prevention and Tobacco Control Act (“Tobacco Control Act”), signed into law by President Obama in 2009, contains a number of restrictions intended to limit the sale of tobacco products to minors. To ensure that retailers are complying with these restrictions, FDA has been conducting undercover inspections of retail outlets. These inspections currently cover the Tobacco Control Act’s:

- *Prohibition on underage sales* – Retailers may not sell tobacco to anyone under 18 years of age;
- *Age verification requirement* – Retailers must verify the age of purchasers under the age of 27;
- *Prohibition of free samples of tobacco products* – Retailers may not offer free samples of cigarettes or smokeless tobacco;
- *Restrictions regarding gifts/discounted items* – Retailers are prohibited from offering any free cigarette or smokeless tobacco products. Further, retailers are prohibited from offering any benefit to a customer in return for purchasing cigarettes or smokeless tobacco (except for free matches) unless that benefit is discounted cigarettes or smokeless tobacco. At the same time, retailers may not offer discounted cigarettes or smokeless tobacco in return for any non-tobacco purchase (such as gasoline). FDA has indicated to NACS, however, that customers may *redeem* “loyalty points” by buying cigarettes or smokeless tobacco, but retailers may not count purchases of cigarettes or smokeless tobacco as points in such a loyalty or affinity program;
- *Self-service displays* – Retailers must remove any self-service display of cigarettes or smokeless tobacco (including vending machines) unless only customers over the age of 18 are permitted to enter the premises;
- *Products Using Tobacco Brand Names/Logos*– Retailers are prohibited from selling any item other than cigarettes, smokeless tobacco, or roll-your-own paper,

which bears the brand name, logo, symbol, or any other indicia of product identification identifiable with those used for any brand of cigarettes or smokeless tobacco.

The FDA recently published an updated draft guidance intended to help industry comply with these requirements. The updated Draft Guidance is *available at* <http://www.fda.gov/downloads/TobaccoProducts/GuidanceComplianceRegulatoryInformation/UCM248241.pdf>.

Statute's Penalty Schedule

The Tobacco Control Act contains a penalty structure whereby penalties gradually increase in severity with succeeding violations. For example, the fine for a third violation is harsher than the fine for a second violation. This was intended to provide retailers with an opportunity to correct problems as they are discovered and prevent the regulator from imposing draconian penalties when retailers have not had an opportunity to make such corrections. Additionally, the statute provides for less severe penalties when the retailer has in place an adequate training program for employees. These lower penalties include a Warning Letter for the first violation (rather than a fine) and lower fines for subsequent violations than would be levied in the absence of a training program. Importantly, FDA has yet to institute any regulations regarding these training programs, and is thus subjecting *all* retailers to the reduced penalty schedule as though they had an adequate training program in place. The following chart is the penalty schedule contained in the Tobacco Control Act:

FDA Compliance Check Violation	FDA Penalty/Fine without approved training program	FDA Penalty/Fine with approved training program
1st Violation	\$250	Warning letter
2nd Violation within 12 months	\$500	\$250
3rd Violation within 24-months	\$1,000	\$500
4th violation within 24 months	\$2,000	\$2,000
5th violation within 36 months	\$5,000	\$5,000
6th or subsequent violation within 48 months as determined by the Secretary on a case-by-case basis	\$10,000	\$10,000
“Repeated and serious violations of the Act relating to minors.”	No Sale Order	No Sale Order

Source: *The Family Smoking Prevention and Tobacco Control Act – Public Law 111-31*

Until recently, all violations resulted in a Warning Letter from FDA. However, after sending retailers a Warning Letter, FDA conducts at least one follow-up inspection. If the retailer is found to violate any regulations at such a follow-up inspection, the retailer will receive a civil money penalty complaint from the FDA. The complaint will notify the retailer of the specific issue(s) observed, the specific provisions of the law that have been violated, and the amount of the monetary penalty being assessed. The complaint will also include a cover letter with detailed instructions about how the retailer can respond to the complaint.

What You Should Know: How to Respond to a Civil Money Penalty

Retailers who receive a civil money penalty complaint must respond to FDA within 30 calendar days of receiving the complaint. There are 5 options when responding to a complaint from FDA, and retailers are entitled to an attorney at *any stage* of this process. Retailers who decide to do anything other than simply admitting guilt and paying the fine might find it particularly useful to avail themselves of legal counsel.

1. *Pay the fine in full* – The FDA must receive payment within 30 calendar days to avoid a default judgment. Once the penalty is paid, the case is closed.
2. *Request a conference with FDA to negotiate* – The retailer may file an answer to the complaint and request a settlement conference to negotiate the amount of the fine assessed. If the retailer requests a settlement conference, the FDA will respond with

details about the conference (time, location, etc.). If an agreement is reached at the settlement conference, the retailer will pay the settlement amount and the case is closed. If an agreement is not reached, the matter will be referred to an Administrative Law Judge for a hearing. The answer and request for a conference must be received by FDA within 30 calendar days of the retailer receiving the complaint. Settlement conferences may occur in person or over the phone.

3. *Request a hearing before an Administrative Law Judge* – The retailer may file an answer to the complaint and request a hearing before an Administrative Law Judge. The retailer will receive details about the hearing once it is scheduled. Hearings may be conducted in person, via phone, or from an FDA branch office with video conferencing capabilities. Retailers have the right to inspect relevant FDA documents during this process, and call witnesses to testify. The answer and request for hearing must be received by FDA within the 30 calendar days. Retailers dissatisfied with the result of a hearing may appeal to the Department of Health and Human Services’ Departmental Appeals Board. This Board does not conduct hearings, but analyzes cases based on briefs each side submits. Once the Board renders a decision, dissatisfied retailers may petition a federal district court to overturn it.
4. *Request an extension of time to respond* - The Administrative Law Judge has discretion to grant an extension of up to 30 additional calendar days for “good cause.” If a retailer thinks additional time may be required to respond, the request for an extension should be filed promptly. Unless the request is filed *and granted* within the initial 30-day timeframe, the retailer will be subject to a default judgment.

If a retailer does not respond in any of the above ways within the 30-day period, the retailer waives the right to a hearing and the right to contest the amount of the fine. The Administrative Law Judge will enter a default judgment against the retailer for the full amount of the penalty and the retailer will have to pay immediately.

In deciding how best to respond to a civil money penalty, retailers are advised to consider the following:

- **One Violation Impacts the Penalty for Future Violations** – As discussed above, if a retailer is found to have committed a violation, it means any subsequent violations will be harsher than they otherwise would. This could lead to fines exceeding \$10,000 and ultimately a No-Tobacco-Sale order. This should be kept in mind as retailers consider whether to simply pay a relatively small \$250 fine and “move on.”
- **Currently, No Fine Should be Issued Without a Prior Warning Letter** – Because FDA is currently subjecting all retailers to the lower penalty schedule, no retailer should be fined unless he or she has already received a Warning Letter from FDA. If no such letter has been received, this is grounds for appealing the fine.
- **Only One “Violation” Can Result From Any Single FDA Inspection** – There is a fundamental disagreement on the law between industry and FDA regarding the issue of

multiple violations: NACS maintains that the Tobacco Control Act's graduated penalty structure and its stipulation that "a person may not be charged with a violation at a particular retail outlet unless [FDA] has notified the retailer of all previous violations at that outlet" clearly limits the number of violations—and thus the severity of penalties assessed—resulting from a single inspection to one. FDA appears to have a policy whereby they will penalize for multiple violations resulting from a single inspection. This could lead to a \$10,000 fine and/or imposition of a no tobacco sale order resulting from a single inspection. Such a result is not justifiable under the plain language of the law.

NACS urges all tobacco retailers to be aware of this disagreement and immediately contact NACS if they are fined for multiple violations discovered during a single inspection. This may present an opportunity for the industry to file a legal challenge to FDA's misreading of the law. More specifically, as it currently stands, no tobacco retailer should be fined an amount greater than \$250 as their first civil money penalty, and no retailer should be fined an amount greater than \$500 as their second civil money penalty. Moreover, no retailer should be fined *any amount* unless he or she has already received a Warning Letter from FDA.

If any of these situations take place, please contact NACS immediately and consider hiring counsel.