



March 2013

In February, FDA announced new tobacco retailer guidance, titled [Guidance for FDA and Tobacco Retailers Civil Money Penalties and No-Tobacco-Sale Orders for Tobacco Retailers](#). This draft guidance provides responses to questions FDA has regularly received concerning the issuance of civil money penalties for violations of regulations related to tobacco products in retail outlets. The draft guidance also provides additional information on the complaint procedure used for civil money penalties.

The FDA is increasing its enforcement of Tobacco Control Act provisions impacting retailers. Data for 2012 (January-August) shows more than 67,000 store inspections generating more than 2,800 Warning Letters.

That is a large increase compared to the 35,000 store inspections and 1,700 Warning Letters issued in 2011, according to FDA enforcement data at www.fda.gov.

There were also 378 civil money penalties issued in 2012, compared to zero in 2010 and just 8 in 2011.

Approximately 95% of retail stores have passed the inspections.

As with all draft guidance, retailers are permitted to submit comments on the draft for 60 days after the publication in the Federal Register.

Retailers can submit electronic comments on the guidance to <http://www.regulations.gov> or submit written comments to:

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

In addition to comment submission, there are steps retailers can take to prepare for an inspection, and, more importantly, ensure you and your staff members are compliant every day.

What Retailers Can Do

While the FDA's involvement is new to the industry, retailer responsibilities do not differ greatly from those that existed before FDA's involvement. Some simple steps to take are:

JT International U.S.A., Inc.

Glenpointe Centre West 500 Frank W. Burr Blvd. Suite 24
Teaneck, NJ 07666, USA
800 966 9709

[**jti.com**](http://jti.com)

- **Create a written Age Verification Policy.** FDA and state regulations require anyone appearing to be under age 27 to be asked for photo identification and for employees to make a good faith effort to verify the ID's authenticity.
- **Train your employees.** Your employees are often at the register completing the sale of cigarettes. They are your best defense against underage tobacco sales. Ensure all of your employees are trained on the laws and regulations. Institute follow-up education sessions to guarantee your employees retain this critical information.
- **If cited for a violation and receive a FDA Warning Letter, do not ignore it.** Even though FDA's present guidance states that a first offense will generally only result in a Warning Letter, this policy is subject to change or exception and failure to respond may be factored into FDA's penalty for any later violation.
- **Engage with the FDA.** The FDA hosts training materials for retailers on their website, including archived webcasts; check www.fda.gov for more details.

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If you have any questions regarding the Tobacco Control Act or any new FDA regulations or requirements, please contact the FDA Center for Tobacco Products at 1-877-287-1373 or email AskCTP@fda.hhs.gov. If you have any questions regarding state laws and guidelines, it is recommended that you contact a legal professional.

JTI USA remains committed to the responsible marketing and sales of our products through our dedicated distributors and retailers. We continue to ensure that our products and marketing materials meet current regulatory requirements. We care about your business. However, this communication is not intended to replace or be considered as legal advice or opinion. Any questions or concerns regarding your individual compliance with any regulations or laws should be directed to your attorney or the regulating agency.