

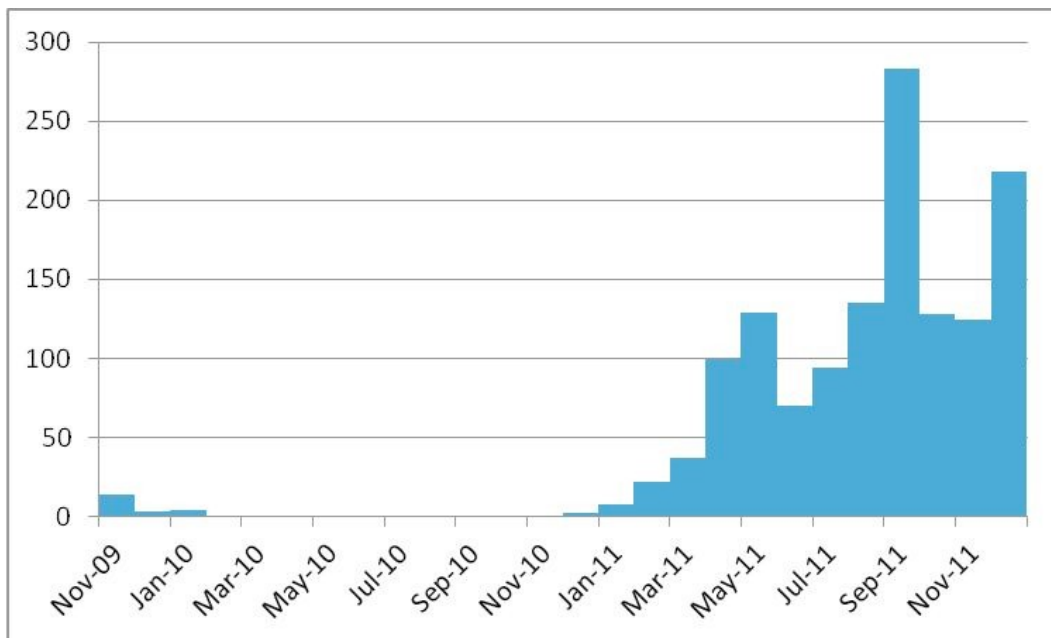
Update on Tobacco Warning Letters

January 30, 2012 by Sheppard Mullin

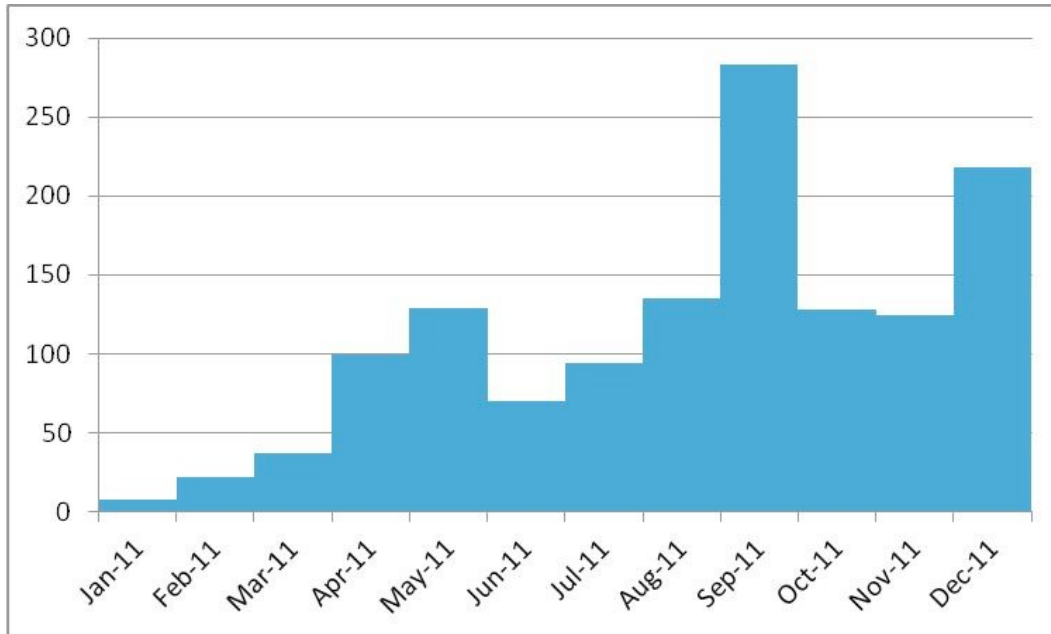
Welcome to the first monthly update on FDA's enforcement over regulated tobacco products. This update will examine trends in Warning Letters, and cover some unique Warning Letters and enforcement actions that have occurred in the previous month. As the first post regarding tobacco products, we will begin with a summary of tobacco related Warning Letters issued by the FDA to date.^[1]

Overall, there have been 1,370 Warning Letters issued by the Center for Tobacco Products since the Family Smoking Prevention and Tobacco Control Act was passed in 2009. The majority of Warning Letters were issued as the result of state contract inspections of retailers. The remaining 45 Warning Letters were issued directly by the Center for Tobacco Products to Internet retailers and manufacturers.

Tobacco Warning Letters Issued to Date:



Tobacco Warning Letters Issued in 2011



The most common violation among brick-and-mortar retailers is the sale of a tobacco product to a minor, which is prohibited by 21 C.F.R. § 1140.14(a). This violation is often combined with a violation for the failure to check for identification, which is a requirement of 21 C.F.R. § 1140.14(b)(1). These violations arise out of the undercover purchases made by minors who are accompanied by state contract inspectors. FDA has also given considerable attention to the use of self-service displays and vending machines, which are prohibited in establishments that permit anyone under the age of 18 to enter. Inspections of facilities that do not permit anyone under the age of 18 to enter are generally conducted only by the state contract inspector, and do not include a minor. The following table provides totals for violations found among all state contract inspections.

Violation	Explanation	Number of Warning Letters	Percent
21 C.F.R. § 1140.10	Failure to follow FDA regulations in 21 C.F.R. part 1140.	359	27.1%
21 C.F.R. § 1140.14(a)	Sale to a minor.	1036	78.2%
21 C.F.R. § 1140.14(b)(1)	Failure to check identification.	688	51.9%
21 C.F.R. §§ 1140.14(d) or 1140.16(b)	Sale of individual cigarettes.	27	2.0%
21 C.F.R. § 1140.14(e)	Failure to remove displays, advertising and labeling in violation of the regulations.	287	21.7%
21 C.F.R. § 1140.16(c)	Use of a self-service display.	148	11.2%
21 C.F.R. § 1140.34(b)	Offer of a gift or item with purchase.	9	0.7%
21 C.F.R. §§ 1140.14(c) and 1140.16(c)	Use of a vending machine.	125	9.4%

In addition, four (4) Warning Letters cited brick-and-mortar retailers for selling cigarettes that contained a characterizing flavor, and forty-four (44) brick-and-mortar retailers were notified regarding the use of modified risk language in labeling.

Warning Letters issued directly by the Center for Tobacco Products, and not as the result of a state contract inspection, were primarily sent to Internet retailers. These Warning Letters generally concerned the sale of cigarettes with a characterizing flavor (39 of 45 Warning Letters), and the use of modified risk language in advertising and labeling (19 of 45 Warning Letters). Two manufacturers were cited for sponsoring an event, and one was cited for offering a free gift or item for the sale of a tobacco product.

The FDA has taken a hard line against cigarettes containing a characterizing flavor, and it is not surprising to see the agency continuing to monitor the Internet for such products. Use of modified risk language, even if explaining a change in product name, has also been a focus of the FDA with regards to Internet retailers and manufacturers.

Warning Letters regarding the offer of a free gift or item generally involved a free item, most commonly a lighter. One Warning Letter, however, involved a rewards program, which offered a check to customers in exchange for providing proof of purchase of specially marked tobacco products.^[2] This is the first public Warning Letter to address the issue of a rewards program (as opposed to a free item), and it remains to be seen what attention the FDA will give to more general rewards programs.

Based on this data, retailers should review their training policies and procedures, and be on the lookout for state contract inspections with an undercover minor. There are a number of programs available, and counsel may be retained to assist with implementing such programs.

Next month will include an examination of trends seen between different states.

^[1] This includes all Warning Letters posted by the FDA as of January 13, 2012

^[2] FDA, Warning Letter issued to Pinkerton Tobacco Company LP (Nov. 28, 2011).