

DISCLAIMER: ALL SELLERS OF COVERED TOBACCO PRODUCTS, AS DEFINED IN 21 C.F.R. § 1140.3, SHOULD BE AWARE OF THE NEW FDA REGULATIONS EFFECTIVE AUGUST 8, 2016. A BRIEF SUMMARY OF THOSE REGULATIONS AS THEY PERTAIN TO THE FDA'S PHOTO IDENTIFICATION REQUIREMENTS FOR INTERNET PURCHASES APPEARS BELOW. PLEASE BE AWARE THAT THIS IS ONLY A SUMMARY AND ANALYSIS OF CERTAIN PROVISIONS OF THESE REGULATIONS, DOES NOT PURPORT TO BE COMPLETE, AND IS NOT A SUBSTITUTE FOR LEGAL ADVICE. PLEASE SEEK YOUR OWN LEGAL COUNSEL IF YOU HAVE ANY QUESTIONS REGARDING THOSE REGULATIONS.

Interpretation of Regulations

On August 8, 2016, new FDA regulations concerning the sale of cigarettes, smokeless tobacco and other covered tobacco products, which include e-cigarettes, became effective. Retailers must now make sure their practices are in compliance or risk being in violation and accruing penalties associated with these violations, as outlined below. Based on the language of the regulations and the FDA's commentary, these regulations require Internet retailers of covered tobacco products to verify a purchaser's age by means of photographic identification, unless the person is over 26 years old.

Under the regulations, no retailer may sell covered tobacco products to any person younger than 18 years of age. 21 CFR § 1140.14(b)(1). Further, except for persons over the age of 26 and for mail-order sales, each retailer must verify by means of photographic identification containing the bearer's date of birth that no person purchasing the product is younger than 18 years of age. 21 CFR § 1140.14(b)(2)(i).

Some commentators suggest that the FDA's exception from the photo ID requirements for mail-order sales includes Internet sales. However, the FDA's own explicit commentary, as well as other interpretative language in the commentary, affirm that photographic identification is indeed required for Internet purchases of covered tobacco products.

In its commentary regarding the new regulations, the FDA states that it "does not intend for section 1140.14(b)(3) [prohibiting retailers from selling covered tobacco products with the assistance of any electronic or mechanical device, such as a vending machine] to prohibit the sale of tobacco products via the Internet, but the sale of covered tobacco products via any medium, including the Internet, must only be to persons 18 years of age or older. **Therefore, any sale of covered tobacco products over the Internet must comply with the minimum age and identifications requirements in this rule.**" 81 FR 29057 (emphasis added). Here, the FDA explicitly states that Internet sales must comply with not only the minimum age requirements but also the identification requirements.

Further, the FDA's commentary that accompanies the new rules in several places makes a distinction between mail-order sales and Internet sales. *See, e.g.*, 89 FR 29016 ("In addition, as stated in § 1140.16, retailers of newly deemed tobacco products may not sell covered tobacco products (through any medium, including the Internet) to individuals under 18 years of age. FDA will continue to actively enforce the minimum age restriction **for mail order and Internet sales**, which will help to reduce youth access to the nicotine and tobacco containing components, without which they cannot use the other components of ENDS.") (emphasis added); *see also* 89 FR 29059 ("Several comments also recommended that FDA require retailers to verify the age of purchasers of newly deemed tobacco products using methods similar to those



found in the Prevent All Cigarette Trafficking (PACT) Act of 2009 (which ensures the collection of Federal, State, and local tobacco taxes on cigarettes and smokeless tobacco **sold via the Internet or mail order sales**.)” (emphasis added).

As such, the new regulations require Internet sales to comply with the photo identification requirements that it imposes on direct, face-to-face purchases.

Penalties for Violations of FDA Regulations

A civil monetary penalty (CMP) is a fine assessed by the FDA for a violation of law. The FDA is authorized to seek a CMP for violations relating to tobacco products. The FDA is also authorized to issue a no-tobacco-sale order (NTSO) to a person found to have committed repeated violations of restrictions at a particular retail outlet. The NTSO prohibits the sale of tobacco products at a retail outlet indefinitely or for a specified period of time. “Repeated violations” means at least 5 violations of particular requirements over a 36-month period at a particular retail outlet that constitute a repeated violation.

In the case of the first violation, the FDA’s policy is to send a Warning Letter. Violations discovered during subsequent inspections or compliance check will result in the FDA seeking a CMP not to exceed the following:

- In the case of a second violation within a 12-month period, \$250;
- In the case of a third violation within a 24-month period, \$500;
- In the case of a fourth violation within a 24-month period, \$2,000;
- In the case of a fifth violation within a 36-month period, \$5,000; and
- In the case of a sixth or subsequent violation within a 48-month period, \$11,000 as determined by the FDA on a case-by-case basis.

If there have been repeated violations at the outlet and a NTSO would be appropriate in light of the factors, the FDA also generally seeks a NTSO. The FDA’s policy is to count as only one violation any violations found from the first inspection, regardless of how many violations were noted in the Warning Letter; however, for subsequent inspections, the FDA may count any or all violations and its general policy is to count all of them individually for purposes of the above fines.

To start this administrative process, the FDA would file a complaint that identifies the specific statutory or regulatory violations alleged to have been committed by the retailer as the basis for the CMP, NTSO or both.

