FDA ISSUES TOBACCO "DEEMING RULE"

E-Cigarettes, Cigars and Other Tobacco Products Now Subject to Regulation

Summary

In 2009, President Obama signed the Family Smoking Prevention and Tobacco Control Act, which called for regulation of cigarettes, roll-your-own tobacco, and smokeless tobacco. In May 2016, the U.S. Food and Drug Administration (FDA) issued a new rule that expands the regulations' coverage to include other nicotine and tobacco products. This so-called "deeming rule" is effective August 8, 2016.

In addition to cigarettes, roll-your-own tobacco, and smokeless tobacco, the FDA will regulate the following "newly deemed tobacco products":

- E-cigarettes, vape pens, and other electronic nicotine delivery systems (ENDS);
- All cigars, including premium cigars;
- Waterpipe (hookah) tobacco;
- Pipe tobacco;
- Nicotine gels;
- Dissolvable tobacco products;
- Novel and future tobacco products; and
- Components and parts of newly deemed tobacco products.[1]

Accessories of the newly deemed products, such as screwdrivers and lanyards used with e-cigarettes, hookah glow balls, foil pokers, tongs, and bags will not be subject to the new regulations.

Requirements for selling tobacco products largely remain the same—they just apply to more products. For instance, under the new rule, convenience store owners will be prohibited from selling the newly deemed tobacco products to minors, giving out free samples, or selling these products from vending machines (unless minors are never admitted in the retail facility).

There are some changes, however, with respect to product packaging and advertisements, which may impact retailers. Beginning in May 2018,[2] retailers may not offer, sell, distribute or

[1] Examples of components and parts of newly deemed products include: waterpipes (hookahs), hookah tobacco flavor enhancers, hose cooling attachments, water filtration base additives, flavored hookah charcoals, atomizers, flavors (with or without nicotine), e-liquid solvents, tanks, batteries, coils, cartomizers, digital display/lights to adjust settings, clearomisers, and ENDS programmable software.

[2] More specifically, retailers may not offer, sell, distribute, or import products without proper packaging starting on May 10, 2018, unless the safe harbor applies. Advertisements must bear

import covered products, including cigarettes, cigars, and roll-your-own tobacco, with non-compliant packaging, nor may they display any ads that do not contain a proper warning (i.e., without an approved nicotine addictiveness, tobacco, or cigar warning, whichever is applicable to the product). Notably, the rule contains a safe harbor for retailers with respect to the new packaging requirements: a retailer of covered products will not violate these provisions if (1) the packaging contains a health warning; (2) the product was supplied by a properly-licensed manufacturer, importer or distributor; and (3) the packaging is not altered by the retailer in any way that is material to these requirements. There also is a special rule for *cigars* sold individually without packaging, which is discussed below.

The rule in its entirety is available at http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm394909.htm.

In addition, the FDA has issued several guidance documents for retailers, which are available at http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm388395.htm.

Retailers are encouraged to review the guidance relevant to the products sold and advertised in their stores.

Specific Retailer Compliance Requirements

1) **Prohibition on underage sales.** Retailers must never sell "covered tobacco products," including e-cigarettes, cigars, hookah tobacco, pipe tobacco, nicotine gels, dissolvable tobacco, and components or parts of these items that are made from tobacco, to customers younger than 18. Components and parts that are not made from tobacco, such as waterpipes and other devices sold without tobacco or nicotine, will not be subject to this restriction.

2) **Age verification.** Store clerks must always check photo identification for any customer who may potentially be younger than 27.

3) **Prohibition on free samples.** Retailers must not give out free samples of any tobacco products, including e-cigarettes, vape pens, other ENDS, cigars, hookah tobacco, pipe tobacco, nicotine gels, dissolvable tobacco, or components or parts of these items. This prohibition applies even to those components or parts that are not made from tobacco.

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an addictiveness, tobacco, or cigar warning, whichever is applicable, by May 10, 2018. Manufacturers may not manufacture products with non-compliant packaging beginning on May 10, 2018, and may not distribute such products beginning June 11, 2018, regardless of the date of manufacture.

4) **Restrictions on vending machines.** Consistent with current law, retailers may not sell cigarettes, cigarette tobacco, roll-your-own tobacco, or smokeless tobacco from vending machines, unless the store is an adult-only facility. The rule extends the vending machine restriction to newly-deemed products (i.e., like cigarettes, vendors may not sell these products from vending machines, except in adult-only establishments).

5) **No New Restrictions on Self-service displays.** Current law prohibits selling cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco from self-service displays, unless the store is an adult-only facility. The new rule does *not* extend restrictions on self-service displays to newly-deemed products at this time. So, self-service displays may be used for newly-deemed tobacco products. The rule states, however, that the FDA will continue to monitor the issue of self-service displays with respect to the newly-deemed products and will issue a new proposed rule on this narrow subject if the FDA deems it in the interest of protecting public health.

6) **Health/Addictiveness warnings on tobacco product packages.** As discussed above, retailers must ensure that packages of cigarettes, roll-your-own tobacco, smokeless tobacco, cigars, and other covered tobacco products have proper health warnings, and retailers must not alter the warnings/packaging in any material way if they wish to take advantage of the rule's safe harbor. Although it is primarily the manufacturers' responsibility to properly label tobacco products, retailers may still be held liable if they sell these products without health/addictiveness warnings or if they alter the warnings.

   There are two exceptions to this requirement. First, if the product package is too small to display a warning statement, retailers must ensure that the carton, outer container, wrapper, or tag contains a warning. Second, with respect to cigars that are sold individually and not in a product package, retailers must display warning statements on an unobstructed sign posted within three inches of each cash register. Details about warning signs for individual cigar sales are available at http://www.fda.gov/tobaccoproducts/labeling/productsingredientscomponents/ucm482562.htm#regs.

7) **Health/Addictiveness warnings on tobacco product advertisements.** Retailers must ensure advertisements for cigarettes, roll-your-own tobacco, smokeless tobacco, cigars and other covered tobacco products contain health/addictiveness warnings, and they must not alter those warnings. Advertisements include print advertisements and other advertisements with a visual component, such as advertisements on signs, shelf-talkers, retailers' webpages, and in email correspondence.

8) **Regulation of modified risk tobacco products.** Convenience store owners cannot sell any tobacco products that purport to have a low risk of tobacco-related disease—including those labeled "light," "low," or "mild"—unless those products have a modified

risk tobacco product order in effect. It is the manufacturers' responsibility to obtain modified risk tobacco product orders, but retailers will be held liable if they sell those products without the proper product orders in place.

9) **Licensed/Permitted manufacturer, importer, or distributor.** Retailers must ensure tobacco products are supplied by tobacco product manufacturers, importers, or distributors who have obtained all required state, local, or Alcohol and Tobacco Tax and Trade Bureau-issued licenses and permits.

10) **Additional regulations applicable to manufacturers.** Convenience store owners should understand that if a retail establishment manufactures, assembles, labels, or relabels tobacco products, then it is considered a "tobacco product manufacturer" for purposes of the deeming rule and must comply with additional regulations. Establishments, such as vape shops, that mix and/or prepare e-liquids or assemble vaporizers are considered tobacco product manufacturers. Similarly, establishments that obtain cigars from a manufacturer, remove them from the original packaging, and repackage or relabel them are also considered tobacco product manufacturers.

Some of the additional regulations with which manufacturers must comply include:

- Registering with the FDA;
- Submitting lists of products and ingredients to the FDA;
- Submitting pre-market tobacco product applications to the FDA for review and authorization; and
- Submitting a warning plan to the FDA to cover the display requirements on cigar packaging.

More information about the regulations for tobacco product manufacturers is available at http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm499351.htm and http://www.fda.gov/TobaccoProducts/Labeling/RulesRegulationsGuidance/ucm499344.htm.

Enforcement Timeline

The deeming rule will take effect on August 8, 2016, but the FDA will not begin enforcing all of the rule's provisions at that time. Below is a timeline outlining when the FDA will begin enforcing various parts of the deeming rule.

Regulated Activity	Enforcement Date
Prohibition on underage sales	August 2016
Age verification (by checking photo identification)	August 2016
Prohibition on free samples	August 2016

Self-service machine restrictions	August 2016
Regulation of modified risk tobacco products except those labeled "light," "low," or "mild"	August 2016
Regulation of modified risk tobacco products labeled "light," "low," or "mild"	September 2017
Health/Addictiveness warnings on packages	May 2018
Health/Addictiveness warnings on advertisements	May 2018

Source: Final rule deeming tobacco products subject to the Federal Food, Drug, and Cosmetic Act – 81 FR 28973

Penalties

The FDA has stated that it will issue updated guidance on civil penalties as they apply to the new rule's requirements. For now, however, the current enforcement mechanisms and penalties in place for violations concerning cigarettes, roll-your-own tobacco, and smokeless tobacco have not changed and will also apply to the newly deemed products. This means that if the FDA finds a retailer has violated the new deeming rule, it may issue a warning letter, a civil penalty, or, in some circumstances, a no sale order.

The penalty schedule provided in the original Family Smoking Prevention and Tobacco Control Act (which the deeming rule has not changed) is below. Notably, this schedule represents maximum possible penalties; the FDA has authority to reduce a penalty's severity.

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
Serious violations relating to minimum age requirements	No Sale Order	No Sale Order

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

The new deeming rule also has not changed the process retailers should follow if they receive notice of a violation. As with cigarettes, roll-your-own tobacco, and smokeless tobacco,

if a retailer receives a warning letter with respect to any of the newly deemed tobacco products, he or she should submit a response to the FDA in accordance with any instructions in the warning letter. In addition, if there is any basis on which to contest the allegations, NACS recommends that retailers request a hearing.

If the FDA attempts to penalize a retailer for more than one violation discovered in the course of a single inspection, that is a violation of the Family Smoking Prevention and Tobacco Control Act. NACS successfully pursued a test case in which an administrative law judge ("ALJ") agreed that only one violation could result from one inspection. The case also established that the FDA cannot count a violation for which it did not give the retailer the opportunity to contest the result in writing or through a hearing. This has been the case in the past when FDA issued warning letters (and it did not allow retailers to contest them). If either of these types of penalty situations arises, retailers should contest them. At this time, the ALJ's decision is on appeal, so it is subject to change.

If a retailer is served with an administrative complaint that includes a civil penalty or no sale order, he or she may: (a) pay the penalty immediately, (b) enter into a settlement agreement, or (c) contest the allegations. The retailer should take action within 30 days of receiving the complaint. Further guidance is available at http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm232109.htm.