

Final deeming regulation at a glance

The U.S. Food and Drug Administration (FDA) “deeming” regulation was released May 6, 2016 and published May 10, 2016. These are some of the highlights of what’s in, and isn’t in, the regulation.

WHAT’S IN THE RULES

- Includes all tobacco products, including premium cigars, except for accessories.
- Establishes a federal minimum age of sale of 18 years old for all tobacco products.
- Bans vending machine sales except in facilities where only those over 18 are allowed. (Does not ban Internet sales or require face-to-face sales for newly deemed products.)
- Bans free samples of newly covered tobacco products.
- Vape shops that mix or otherwise assemble e-liquid/product are treated as manufacturers and subject to the requirements and restrictions for manufacturers.
- On effective date, modified risk tobacco product (MRTP) provisions will apply. Prohibits unapproved modified risk claims, and provides a clear pathway to make such claims.
- Requires submission to FDA of ingredients and health documents for all tobacco products

Effective date for the rule is August 8, 2016.

WARNING LABELS

- Requires new addictiveness warning labels for all tobacco products:

"WARNING: This product contains nicotine. Nicotine is an addictive chemical."

Must be placed on the main panel of product. If the panel is too small warning must be on the carton or otherwise permanently attached to the package. Warning also required in advertising.

- Requires rotating warning labels for cigars:

- (i) WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
- (ii) WARNING: Cigar smoking can cause lung cancer and heart disease.
- (iii) WARNING: Cigars are not a safe alternative to cigarettes.
- (iv) WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
- (v) (A) WARNING: Cigar use while pregnant can harm you and your baby; or (B) SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.
- (vi) WARNING: This product contains nicotine. Nicotine is an addictive chemical.

- For cigars sold singly, warnings must appear on an 8x11 inch sign located within 3 inches of each cash register. Warnings also required in advertising.
- Effective date of warnings is May 10, 2018.

WHAT'S NOT IN THE RULES

- DOES NOT: change statutory grandfather date of February 15, 2007, which means products introduced after that date must meet the public health standard and receive marketing authorization from the FDA.
- DOES NOT: Address flavors. FDA says a Notice of Proposed Rule Making to ban flavors from cigars is forthcoming; there are no specific plans on flavored hookah tobacco.
- DOES NOT: Address childproof packaging. A Notice of Proposed Rule Making may be forthcoming.
- DOES NOT: Extend other provisions of 1996 rule to products other than cigarettes/smokeless (minimum package size; tobacco branding of non-tobacco products or non-tobacco branding of tobacco products; ban on event sponsorships).

SPECIFICS OF PREMARKET TOBACCO AND SUBSTANTIAL EQUIVALENCE APPLICATIONS

While not in the language of the rule, FDA outlined its compliance policy for non-grandfathered products (on the market *after* February 15, 2007). FDA has instituted a scaled compliance policy, with no FDA enforcement for 24, 30 or 36 months as follows:

- 12 months to submit an SE *exemption* (for products nearly identical to products on the market as of grandfather date). If application submitted on time, then additional 12 months to be on market before FDA takes action. 24 months total for a product to be on market.
- 18 months to submit SE *application* (for products substantially like products on the market as of the grandfather date). If application submitted on time, then additional 12 months to be on market before FDA takes action. 30 months total for a product to be on market.
- 24 months to submit a PMTA (new product application). If application submitted on time, then additional 12 months to be on market before FDA takes action. 36 months total for a product to be on market.