GRAY | ROBINSON
ATTORNEYS AT LAW

FDA's Deeming Rule Extends the Agency's Authority over Tobacco Products

By, Anna M. Wiand

On May 05, 2016, the U.S. Food and Drug Administration (FDA) finalized the long awaited and slightly contentious rule: "Deeming Tobacco Products To Be Subject to the Federal Food, Drug, and Cosmetic Act" (the "Deeming Rule"). The Deeming Rule extends the FDA's authority to regulate tobacco products to include electronic nicotine delivery systems (such as e-cigarettes and vape pens), all cigars, hookah (waterpipe) tobacco, pipe tobacco, and nicotine gels.

The Tobacco Control Act, enacted on June 22, 2009, amended the Federal Food, Drug and Cosmetic Act (FD&C Act), providing FDA with the authority to regulate tobacco products.[1] With the Tobacco Control Act's passage, FDA immediately obtained regulatory authority over cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco. Other types of tobacco products, such as cigars and pipe tobacco, were not subject immediately to FDA's regulatory authority.

Section 901(b) of the FD&C Act (21 U.S.C. 387a(b)), however, grants FDA authority to deem the other types of tobacco products subject to FD&C Act. In addition to the provisions in the FD&C Act, and implementing regulations that apply automatically to the newly "deemed" products, FDA may require restrictions on the sale and distribution of a tobacco product if FDA determines such restrictions are appropriate for the protection of public health.[2]

Pursuant to these authorities, FDA published a proposed rule on April 25, 2014, seeking to deem all products that meet the statutory definition of tobacco product set forth in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) subject to FDA's regulatory authority. The rule also proposed additional provisions requiring warning statements and other restrictions on the sale and distribution of tobacco products, but exempted accessories from additional regulation.[3] After review and consideration of comments on the proposed rule, FDA published the Deeming Rule.

Tobacco Control Act Requirements

Under the Deeming Rule, the newly regulated products now will be subject to the FD&C Act and related regulations, including:

- Registering manufacturing establishments and providing product listings to the FDA;
- Reporting ingredients, and harmful and potentially harmful constituents;
- Requiring premarket review and authorization of new tobacco products by the FDA;
- Placing health warnings on product packages and advertisements; and
- Not selling modified risk tobacco products (including those described as "light," "low," or "mild") unless authorized by the FDA.

---

[1] Family Smoking Prevention and Tobacco Control Act ("Tobacco Control Act"), Pub. L. 111– 31, 123 Stat. 1776 (2009).

[2] Section 906(d) of the FD&C Act (21 U.S.C. 387f(d)).

[3] 79 FR 12342.

In addition, there are several provisions aimed at restricting youth access to tobacco products, including:

- Not allowing products to be sold to persons under the age of 18 years (both in-person and online);
- Requiring age verification by photo ID;
- Not allowing the selling of tobacco products in vending machines (unless in an adult-only facility); and
- Not allowing the distribution of free samples.

The Final Rule goes in to effect on August 8, 2016. One substantial hurdle for manufacturers and importers of the newly deemed products is compliance with the premarket authorization requirements. The FD&C Act provides three pathways for obtaining premarket authorization: substantial equivalence (SE) exemptions; SE reports; and premarket tobacco applications (PMTAs).

Tobacco products that were on the market as of February 15, 2007, are grandfathered and do not require premarket authorization. However, the Agency provides an avenue for manufacturers to demonstrate grandfather status and receive an Agency determination on their product status. An Agency determination may be used by manufacturers in premarket authorization filings for other related tobacco products.

For newly deemed tobacco products that were on the market as of the effective date of the Deeming Rule, but that were not on the market as of February 15, 2007 (i.e., are not grandfathered), FDA is providing two compliance periods: one for submission and FDA receipt of applications; and one for obtaining premarket authorization. During these compliance periods, FDA does not intend to take enforcement action for products remaining on the market without authorization, as set forth below.

Compliance Timeframes

The compliance periods for submission and FDA receipt of applications for newly deemed tobacco products under the three premarket pathways are as follows:

- SE Exemption Requests – 12 months from the effective date of the Deeming Rule;
- SE Reports – 18 months from the effective date of the Deeming Rule; and
- PMTAs – 24 months from the effective date of the Deeming Rule.

New products for which no application has been submitted within 24 months of the effective date of the Deeming Rule will no longer be subject to this compliance policy, and will be subject to enforcement.

Unless FDA has issued an order denying or refusing to accept the submission, newly deemed tobacco products for which timely premarket submissions have been submitted will be subject to a continued compliance period for 12 months after the initial compliance period described above. For such products, FDA does not intend to initiate enforcement for failure to have premarket authorization during the continued compliance periods, which are as follows:

- SE Exemption Requests – 24 months from the effective date of the Deeming Rule (12 months after the compliance period for submission of such requests);
- SE Reports– 30 months from the effective date of the Deeming Rule (12 months after the compliance period for submission of such reports); and
- PMTAs – 36 months from the effective date of the Deeming Rule (12 months after the compliance period for submission of such applications).

Once the continued compliance period ends, new tobacco products on the market without authorization will be subject to enforcement, even if the review of the respective submission has not been completed. FDA has stated that it will act as expeditiously as possible with respect to all new applications, but will ensure that statutory standards are met. Further, if the applicant has provided the needed information and review of a pending marketing application has made substantial progress toward completion at the conclusion of the continued compliance period, FDA may consider, on a case-by-case basis, whether to defer enforcement of the premarket authorization requirements for a reasonable time period.

Small Businesses

Recognizing the difficultly that small businesses might face in meeting these filing requirements, the FDA is including targeted relief to "small-scale tobacco product manufacturers." For purposes of such relief, FDA considers a "small-scale tobacco product manufacturer" to be a manufacturer of any regulated tobacco product that employs 150 or fewer full-time equivalent employees and has annual total revenues of $5,000,000 or less. FDA considers a manufacturer to include each entity that it controls, is controlled by, or is under common control with the small-scale tobacco product manufacturer. To help make FDA's individual enforcement decisions more efficient, a manufacturer may voluntarily submit information regarding employment and revenues.

The additional time to comply afforded to the small-scale tobacco product manufacturers includes:

- SE Extension Request – For the first 30 months following the effective date of the Deeming Rule, FDA presently intends to grant extensions on a case-by-case basis, for SE applicants that need additional time to respond to SE deficiency letters.
- Tobacco Health Document Submission – FDA presently intends not to bring enforcement action against small-scale tobacco product manufacturers who submit the required information within 12 months of the effective date of the Deeming Rule.
- Ingredient Listing Submission – FDA presently intends not to bring enforcement action against those small-scale tobacco product manufacturers who submit the information required in section 904(a)(1) of the FD&C Act within 12 months of the effective date of the Deeming Rule.

Regardless of the size of the operation, however, the Deeming Rule creates substantial new requirements for businesses manufacturing, importing, and selling the newly covered tobacco products. Therefore, early adoption and application is highly recommended.

For more information regarding the FDA's Deeming Rule, or for assistance in complying with the Rule's new filing requirements, please contact Anna Wiand with GrayRobinson's Regulated Products Group at 813-382-5132 or anna.wiand@gray-robinson.com.

Anna M. Wiand
GrayRobinson, P.A.
401 East Jackson Street
Suite 2700
Tampa, Florida 33602
P 813-273-5000
F 813-273-5145