Summary of the Deeming Final Rule

FDA currently regulates cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco. The final rule, published on May, 10, 2016, extends FDA's "tobacco product" authorities to all other categories of tobacco products meeting the statutory definition of "tobacco product" in the Federal Food, Drug, and Cosmetic Act (FD&C Act), except accessories of such products. The final rule, among other things, also:

- Prohibits the sale of "covered tobacco products" to individuals under the age of 18;
- Prohibits vending machine sales of covered tobacco products (except in facilities that prohibit individuals under the age of 18 years from entering at any time);
- Requires the display of health warnings on covered tobacco products, cigarette tobacco, and roll-your-own tobacco (RYO tobacco) packages and advertisements;
- Requires the submission and approval of cigar warning plans for packaging and advertisements; and
- Results in the prohibition of free sample distribution of newly regulated tobacco products.

These newly regulated products include currently marketed products such as electronic cigarettes, cigars, pipe tobacco, and waterpipe (hookah) tobacco, as well as future tobacco products. These tobacco products are now required to comply with all provisions regarding "tobacco products" found in the FD&C Act ("automatic provisions") and FDA regulations. In addition, a subset of these products (referred to as "covered tobacco products"), are subject to certain additional restrictions. These automatic provisions and additional restrictions, as well as the timeframes for complying with these requirements, are discussed below.

Automatic Provisions

Newly deemed tobacco products automatically are required to comply with all provisions regarding "tobacco products" found in the FD&C Act and FDA regulations. These automatic provisions and FDA regulations require industry, which includes manufacturers and retailers, where applicable, that are Tribally owned and operated or within tribal jurisdictions, to take certain actions, such as:

- Ensure that tobacco products are not adulterated or misbranded.
- Provide FDA with ingredient listings for all tobacco products.
- Register manufacturing establishments and provide FDA with product listings for all tobacco products.
- Not introduce into interstate commerce modified risk tobacco products without an FDA order.
- Obtain premarket authorization for newly deemed products that meet the definition of "new tobacco product" via one of the pathways specified in the FD&C Act.

Additional Restrictions

The final rule establishes three additional restrictions with which "covered tobacco products" must comply: [1]

1. Requirement for a minimum age of purchase and verification of age via photographic identification.
2. Prohibition of vending machine sales, unless the vending machine is located in a facility where the retailer ensures that individuals under 18 years of age are prohibited from entering at any time.
3. Health warnings for product packages and advertisements:
    A. FDA is requiring that all "covered tobacco products" bear the following warning regarding the addictiveness of nicotine – "WARNING: This product contains nicotine. Nicotine is an addictive chemical." FDA is finalizing a self-certification option for manufacturers who certify that their product does not contain nicotine (and who have data to support that assertion). Such a product will be required to bear the statement, "This product is derived from tobacco."
    B. Tobacco products with packages too small to bear the warning and for which there is no carton or other outer container or wrapper that is large enough to carry the warning must carry the warning on a tag firmly and permanently affixed to the package.
    C. FDA also is finalizing six health warnings for cigars, five of which were included in the Federal Trade Commission consent agreements with the major cigar manufacturers signed in 2000. These warnings are:
        - WARNING: Cigar smoking can cause cancers of the mouth and throat, even if you do not inhale.
        - WARNING: Cigar smoking can cause lung cancer and heart disease.
        - WARNING: Cigars are not a safe alternative to cigarettes.
        - WARNING: Tobacco smoke increases the risk of lung cancer and heart disease, even in nonsmokers.
        - WARNING: Cigar use while pregnant can harm you and your baby.; or SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.
        - WARNING: This product contains nicotine. Nicotine is an addictive chemical.
    D. Requires the submission and approval of cigar warning plans for packaging and advertisements. Warning plans must be submitted for FDA review and approval by responsible manufacturers, distributors, importers, or retailers by 1 year after the date of publication of the final rule or 12 months before advertising or commercially marketing a product, whichever is later.

[1] FDA defines "covered tobacco product" as any tobacco product deemed to be subject to the Federal Food, Drug, and Cosmetic Act under § 1100.2 of this chapter, but excludes any component or part that is not made or derived from tobacco.

E. FDA is also finalizing a different labeling rule for premium cigars and other cigars that are sold individually and not in a product package. Health warnings for such cigars must be displayed on a sign posted at the point-of-sale in any retail establishment in accordance with specifications in the rule.

Effective and Compliance Dates

The deeming rule will be effective 90 days from the date of publication of the final rule for the part of the regulation that deems products to be subject to the FD&C Act, and for the age, ID, and vending machine restrictions.

Provision	**Effective Date**
Minimum age of sale and age verification	90 days from the date of publication of the final rule
Prohibition of vending machine sales	90 days from the date of publication of the final rule
Health Warning Requirements	24 months after publication of the final rule, with an additional 30 days for manufacturers to sell existing merchandise manufactured before 24 months.
Warning Plan Submission	1 year after the date of publication of the final rule

Among other automatic provisions in the FD&C Act that will be effective 90 days after publication, newly-regulated tobacco products will be subject to premarket authorization requirements, unless they are eligible for grandfather status (were on the market as of February 15, 2007). However, the FDA does not intend to enforce the requirements of premarket review against manufacturers whose newly deemed tobacco products are on the market as of the effective date if they submit applications seeking marketing authorization within specific timeframes set forth below. As a result of this policy, the FDA expects such products currently on the market will continue to be available for up to 3 years while manufacturers seek authorization under the staggered compliance periods.

We are including compliance dates for certain automatic provisions that would require labeling changes or information submissions to the Agency to give regulated industry time to comply with such provisions, including:

Provision	
Ingredient reporting	Effective date plus 6 months or 90 days prior to marketing
Submission of health information	Effective date plus 6 months
Premarket tobacco product applications (PMTA), Substantial equivalence (SE) submissions, Exemption from SE – for newly deemed tobacco products that are on the market as of the effective date of the final rule but were not on the market as of February 15, 2007	Initial compliance periods for manufactures to submit (and for FDA to receive): • SE Exemption Request - 12 months • SE applications - 18 months • PMTA applications - 24 months Unless the FDA has issued an order denying or refusing to accept the submission, manufacturers who submit

	applications by these deadlines will be subject to a continued compliance period for 12 months. FDA does not intend to initiate enforcement action for products remaining on the market without the following FDA authorization after the effective date of the rule as follows: • SE Exemption Request - 24 months • SE applications - 30 months • PMTA applications - 36 months
Not introduce into interstate commerce modified risk tobacco products, including a product whose label, labeling, or advertising claims presents a lower risk of tobacco-related disease or is less harmful, the product or its smoke contains a reduced level/presents a reduced exposure to a substance, or the product or its smoke does not contain/is free of a substance, without an FDA order	Effective date (90 days from the date of publication of the rule)
Not introduce modified risk tobacco products with label, labeling, or advertising that uses descriptors low, light, mild and similar descriptors that are not based on scientific evidence and reviewed and authorized by FDA	Effective date plus 12 months to stop manufacturing; Effective date plus 13 months to stop distribution
Reporting of Harmful and Potentially Harmful Constituents	Effective date plus 3 years or 90 days before delivery for introduction into interstate commerce (products entering the market after the effective date)
Establishment registration and product listing submissions	Date will be specified in a new guidance

Guidances and Rules Accompanying the Deeming Final Rule

The following documents are available on FDA's website at: http://www.fda.gov/TobaccoProducts/GuidanceComplianceRegulatoryInformation/ucm281147.htm.

- Electronic Nicotine Delivery System (ENDS) Pre Market Tobacco Application draft guidance
- Tobacco Product Master File (TPMF) guidance
- Small Entity Compliance Guidance

In addition, FDA is issuing an updated final rule regarding user fees for cigars and pipe tobacco and a small entity compliance guidance to accompany the final rule.

Small-Scale Tobacco Manufacturer

For purposes of the FDA compliance policy set forth below, a "small-scale tobacco product manufacturer" is 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. 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 for small-scale tobacco product manufacturers includes:

- SE extension request – For the first 30 months following the effective date of the deeming rule, extensions will be available 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 6 months of the submission date that otherwise would apply (see chart above).

- 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) and 904(c) of the FD&C Act within 12 months of the effective date of the deeming rule.

Small-scale tobacco product manufacturers will also benefit from additional assistance, including:

- Assistance with Marketing Applications – As with manufacturers in general, small-scale tobacco manufacturers will receive additional assistance with their marketing applications including the designation of a Regulatory Health Project Manager, access to an appeals process in the event that FDA denies their marketing applications and assistance from CTP's Office of Compliance and Enforcement (OCE) staff with identifying the types of documents that may be used to establish that their products were on the market on February 15, 2007.

- Assistance in Navigating Other Regulatory Requirements – CTP's OCE staff will continue to assist small-scale tobacco product manufacturers in submitting rotational warning plans for FDA approval. CTP also has an extension system to assist small businesses in navigating the regulatory requirements of FDA. For example, the Center has a Call Center that triages all calls received from regulated industry. The Center's Office of Small Business responds to hundreds of calls, emails, and correspondences from small businesses every year to assist them in answering their specific questions on how to comply with the law.