NATO

Summary of FDA Deeming Regulations

May 12, 2016

1. Background on the Deeming Regulations

A. The Family Smoking Prevention and Tobacco Control Act

When Congress passed the Family Smoking Prevention and Tobacco Control Act ("TCA") in 2009, the U.S. Food and Drug Administration ("FDA") initially regulated cigarettes, roll your own tobacco, and smokeless tobacco products. However, the TCA also authorized the FDA to "deem" other products that met the definition of "tobacco products" to be subject to federal tobacco regulations. The term "tobacco product" means "any product made or derived from tobacco that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product)."

Upon "deeming" a product to be subject to the FDA's tobacco regulations, the FDA may adopt "restrictions on the sale and distribution of a tobacco product," including age-related access restrictions and advertising and promotion restrictions. The main basis on which new regulations can be adopted is the FDA's standard that the restrictions are appropriate for the protection of the public health.

B. New Tobacco Products Regulated

All cigars (premium and domestic), pipe tobacco, e-cigarettes, e-hookah, e-cigars, vape pens, advanced refillable personal vaporizers, electronic pipes, hookah tobacco, dissolvable tobacco products, and nicotine gels are deemed "tobacco products" and now subject to regulation by the FDA.

C. Components and Parts Regulated

The definition of "tobacco product" includes components and parts (the objects intended or reasonably expected to be used with or for the consumption of a tobacco product that are not accessories). "Component or Part" means "any software or assembly of materials intended or reasonably expected: 1) to alter or affect the tobacco product's performance, composition, constituents or characteristics; or 2) to be used with or for the human consumption of a tobacco product." A non-exhaustive list of examples of components and parts used with electronic nicotine delivery systems (ENDS) (including e- cigarettes): e-

liquids; tanks; batteries (with or without variable voltage); cartomizers (atomizer plus replaceable fluid-filled cartridge); digital display/lights to adjust settings; tank systems; flavors; vials that contain e-liquids; and programmable software.

D. Accessories Not Regulated

The FDA does not regulate accessories because accessories do not contain tobacco, are not derived from tobacco, and do not affect or alter the performance, composition, constituents or characteristics of a tobacco product. Examples of accessories include ashtrays, spittoons, hookah tongs, cigar clips, cigar cutters, stands and pipe pouches, humidors or refrigerators that solely control the moisture and/or temperature of a stored product, conventional matches, and lighters that solely provide an external heat source to initiate but not maintain combustion of a tobacco product.

E. Effective Date of the Deeming Regulations

The deeming regulations go into effect 90 days after the publication of the regulations in the Federal Register. This means that the actual effective date is August 8, 2016. The FDA has established other compliance periods and dates for particular regulations that are explained in this memo.

2. General Deeming Regulations

A. Minimum Age to Purchase

Under the deeming regulations, retailers are prohibited from selling the deemed tobacco products (through any medium, including the Internet) to individuals under 18 years of age.

[Note: State and local lawmakers have the authority to adopt a higher minimum age to purchase tobacco products. The FDA does not have the authority to raise the federal legal age; that authority rests with Congress].

B. Manufacturer Requirements

Just like manufacturers of cigarettes, roll your own, and smokeless tobacco products, the manufacturers of the newly deemed tobacco products must comply with the following FDA regulations:

1. Submission of ingredient lists for each deemed tobacco product and reporting of harmful or potentially harmful constituents (HPHCs).

2. Registration of tobacco product manufacturing establishments and a list of all tobacco products manufactured.

3. Prohibition against the sale and distribution of products with modified risk descriptors (e.g., "light," "low," and "mild" descriptors) and claims unless the FDA issues an order authorizing the marketing of a modified risk product.

4. Premarket review requirements for products introduced in the marketplace after the predicate date (grandfather date) of February 15, 2007.

C. No Free Samples

The deeming regulations prohibit manufacturers, wholesalers and retailers from giving out free samples of the deemed tobacco products. The FDA believes that prohibiting free samples is a minor restriction on distribution, because tobacco product manufacturers, distributors, and retailers are still able to inform consumers about their products.

The FDA has decided that allowing prospective adult buyers to smell or handle a cigar is not considered the distribution of a "free sample" as long as the cigar is not actually consumed in the retail store and the prospective buyer does not leave the store with a free tobacco product (in whole or in part). According to the FDA, affording adult consumers the opportunity to handle a tobacco product will give them the ability to feel the resistance of the cigar's structure, and allow them to clearly see the color of the product, which is an indication of the fermentation period for the tobacco. It also will allow users to capture the aroma of the cigar and the cigar box (if the cigar is sold in a box). However, if the prospective buyer lights and draws or puffs on the cigar to keep the cigar lit, or otherwise uses the free cigar or leaves the retail establishment with a free cigar, this would constitute a "free sample" in violation of the deeming regulations.

The FDA also believes that in most circumstances, other retail stores, including stores that sell e-cigarettes and vapor products, can similarly allow customers to touch, hold, and smell their products so long as a customer is not allowed to leave the store with a free tobacco product.

D. New Nicotine Health Warning

The FDA is requiring a new health warning on the packaging and on advertisements for cigarette tobacco/roll your own tobacco and all of the newly deemed tobacco products (cigars, pipe tobacco, e-cigarettes, vapor products, hookah tobacco, dissolvables, and nicotine gels). The new warning reads as follows:

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

This warning will be required to appear on at least 30 percent of the two principal display panels of a product's package and at least 20 percent of the area of any advertisement of the tobacco product. The FDA is defining "principal display panels" of a product package as the panels of a package that are most likely to be displayed, presented, shown or examined by the consumer. The health warning statement must be printed in at least 12-point font size in order to be clear and legible. The effective date for this new health warning is 24 months after the date of publication, or May 10, 2018. This means that after the effective date, a distributor or retailer may not sell, offer to sell, distribute, or import for sale or distribution within the United States any of these tobacco products the package of which does not include this new health warning.

However, this requirement will not apply to any roll your own tobacco or deemed tobacco products that were manufactured prior to the effective date of May 10, 2018. Distributors and retailers can sell through the tobacco products that were manufactured before the May 10, 2018 effective date.

E. Cigar Health Warnings

In the initial draft of the deeming regulations, the FDA proposed to require four of the five warnings already included on most cigar packages and in most cigar advertisements as a result of settlement agreements between the Federal Trade Commission and the seven largest U.S. cigar manufacturers. The deeming regulations add two more health warnings so that the full list of six health warnings for cigars is as follows:

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

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, as an optional alternative statement: SURGEON GENERAL WARNING: Tobacco Use Increases the Risk of Infertility, Stillbirth and Low Birth Weight.)

The cigar health warnings are required to appear on at least 30 percent of each of the two principal display panels of the cigar package and on at least 20 percent of the area of the print advertisements and other advertisements with a visual component (website ads, etc.). The font used for warnings on packaging and advertisements must be at least 12-point font size.

For advertisements of cigars, the warnings must be rotated quarterly in alternating sequence in each advertisement for each brand of cigar in accordance with a warning plan submitted to, and approved by, the FDA. Manufacturers, distributors and importers must submit a warning plan for cigar health warnings by May 10, 2017, which is one year after the date of publication of the final deeming regulations. Retailers that create their own cigar advertisements must also draft and submit a cigar health warning plan to the FDA by May 10, 2017.

The same warning statement requirements will apply to cigars sold individually and not in product packages. However, instead of being required to place warnings directly on the cigars sold individually, retailers will be required to post signage at the point of sale listing the six warnings on a sign that measures at a minimum 8.5 inches x 11 inches. The deeming regulations require that the sign be placed on or within 3 inches of each cash

register where payment is made and that the sign be unobstructed and easily read by each consumer making a purchase. Since all six health warnings will appear on the sign placed in retail stores, there is no quarterly rotation requirement for the six warnings nor is a retailer required to submit a health warning plan to the FDA.

These advertising health warning requirements will take effect on May 10, 2018, which is 24 months after the date that the deeming regulations are published in the Federal Register.

Advertisements which are subject to displaying a cigar health warning include promotional materials (point-of-sale or non-point-of-sale), billboards, posters, placards, published journals, newspapers, magazines, other periodicals, catalogues, leaflets, brochures, direct mail, shelf-talkers, display racks, websites, Internet web pages, television, electronic mail (e-mail) correspondence, and also include advertisements communicated via mobile telephone, smartphone, social media websites, applications, or other programs that allow for the sharing of audio, video, or photography files, video and audio promotions.

3. Predicate Date (Grandfather Date)

The FDA has concluded that the agency lacks the authority to change the predicate date or grandfather date for the newly deemed tobacco products. The original predicate date or grandfather date is February 15, 2007. Based on this predicate date, any tobacco product that was on the market as of February 15, 2007 is "grandfathered" and not required to have a Substantial Equivalency application (SE) or Pre-Market Tobacco Application (PMTA) filed with the FDA to remain on the market.

A manufacturer can submit a SE application if a product introduced to the market after February 15, 2007 is substantially similar to a product that was already on the market on or before February 15, 2007. A substantially similar product is known by the FDA as a "predicate product". If there were no substantially similar predicate products for a manufacturer to rely on, then the manufacturer would need to file a PMTA with the FDA.

4. Substantial Equivalency or Pre-Market Tobacco Application Requirements

A. Application Deadlines

A manufacturer will have 18 months after August 8, 2016 to submit a SE application for all deemed tobacco products that are not substantially similar to a predicate product that was on the market as of February 15, 2007 and 24 months after August 8, 2016 to submit a PMTA for tobacco products that were introduced to the market after February 15, 2007.

B. Hours to Complete an Application

The FDA estimates that the time burden to compile a PMTA application would on average be 1,713 hours. This average represents a wide range of hours that will be required for these applications under different circumstances, with some requiring more hours (e.g., as many as 5,000 hours for early applications that involve complex products and for which

the company has no experience conducting studies or preparing analysis of public health impacts). The FDA estimates that a PMTA application will cost $330,000.00. The FDA also believes that compiling an SE application will take considerably less time and money than compiling a PMTA application for an e-cigarette product.

The FDA reported in the deeming regulations that it has determined that some e-cigarettes and other electronic nicotine delivery systems (ENDS) were manufactured in 2006 and commercially marketed in the United States in early 2007. In particular, the FDA has identified an ENDS product that may have been on the market on February 15, 2007. This product may possibly be able to serve as a valid predicate product for purposes of a manufacturer filing a SE application rather than the more time intensive and expensive PMTA application.

C. SE and PMTA Application Compliance Periods

If a manufacturer timely files a SE application within 18 months after the effective date of the deeming regulations, the FDA will add on another 12 month compliance period for the manufacturer's product to remain on the market while the SE application is being reviewed by the agency. Likewise, if a manufacturer timely files a PMTA application within 24 months after the effective date of the deeming regulations, the FDA will add on another 12 month compliance period for the manufacturer's product to remain on the market while the PMTA application is being reviewed by the agency.

At the end of the 30 month application and compliance review time period for SE applications and 36 month application and compliance review time period for PMTA applications, if the applicant has provided the needed information and FDA's review of a pending application has made substantial progress toward completion, the FDA may consider, on a case-by-case basis, whether to defer enforcement of the SE or PMTA authorization requirements for a reasonable time period.

D. Cigars and SE vs. PMTA Applications

Generally, the FDA expects that cigars with blending changes (other than blending changes to address the natural variation of tobacco), will be able to use the SE application process rather than the PMTA process so long as the blending change does not significantly raise levels of harmful or potentially harmful constituents in the product. If a cigar product is unable to utilize the SE application process because no substantially similar cigar was on the market as of February 15, 2007, then the TCA requires the manufacturer to compile and submit a PMTA application, including such an application for limited edition cigars or seasonal blend cigars.

E. What This Means

Based on the fact that the predicate date/grandfather date has not been changed, and that a significant majority of cigars, pipe tobacco, e-cigarettes, hookah tobacco and other deemed tobacco products were introduced in the market after February 15, 2007, manufacturers will be required to file SE or PMTA applications for a substantial number of deemed tobacco products. The number of SE and PMTA applications will be so high

because the FDA believes that a separate SE or PMTA application will likely be necessary for each product SKU. However, the time involved preparing SE and PMTA applications plus the cost of doing so may be too expensive for some manufacturers, possibly resulting in various deemed tobacco products no longer being manufactured and removed from the marketplace.

5. Regulation of Premium Cigars

As originally proposed, the deeming regulations included two options, with Option 1 regulating premium cigars and Option 2 not regulating premium cigars. The FDA concluded that deeming all cigars, both premium and domestic, more completely protects the public health and therefore adopted Option 1 in the final deeming regulations. The FDA's decision was based on three factors, including: (1) all cigars pose health risks, (2) the available evidence does not provide a basis for FDA to conclude that the patterns of premium cigar use sufficiently reduce the health risks to warrant exclusion, and (3) premium cigars are used by youth and young adults.

Moreover, the FDA intends to enforce the SE or PMTA application requirements for cigar products that have tobacco-blending changes (including those cigars that have seasonal blends and those cigars that are boutique blends) that are intended to alter the chemical or perception properties of a new cigar (e.g., nicotine level, pH, smoothness, harshness).

6. Tobacco Product Manufacturer Status for Retailers

A. Definition of Tobacco Product Manufacturer

The definition of "tobacco product manufacturer" under the TCA includes "any person, including any repacker or relabeler, who manufactures, fabricates, assembles, processes, or labels a tobacco product." Additionally, the Food, Drug & Cosmetic Act defines "manufacturing, preparation, compounding, or processing" to include "repackaging, or otherwise changing the container, wrapper or labeling of any tobacco product package from the original place of manufacture to the person who makes the final delivery or sale to the ultimate consumer or user."

B. Retailer Regulated as a Manufacturer

The TCA authorizes the FDA to regulate the manufacture of all newly deemed tobacco products, including those products manufactured at the retail level. This means that tobacco retailers that blend pipe tobacco or retailers that mix e-liquids for e-cigarettes or vapor devices will meet the definition of a "tobacco product manufacturer" and be regulated by the FDA as a manufacturer.

As of August 8, 2016, persons who own or operate a domestic establishment engaged in the manufacture, preparation, compounding, or processing of tobacco products will need to comply with the manufacturer requirements listed under Section 2(B) above.

C. Manufacturer Registration and Product Listing Filling Requirements for Pipe Tobacco and Vapor Product Retailers

Tobacco retailers that blend different pipe tobaccos together by repackaging bulk pipe tobacco meet the definition of a "tobacco product manufacturer" under the TCA. Similarly, vape retailers are considered "tobacco product manufacturers" if the retailers mix or prepare e-liquids or aerosol apparatus are modified for direct sale to consumers.

These retailers will be required to register with FDA and submit product listings to the agency as of August 8, 2016.

NATO' s comments about the proposed deeming regulations submitted to the FDA expressed a serious concern that retailers who blend pipe tobacco would be subject to all of the requirements for manufacturers of tobacco products, such as establishment site disclosure, product ingredient listings, SE or PMTA applications, etc. The NATO comments requested that retailers blending up to 5,000 pounds of pipe tobacco per year be exempt from the requirements of manufacturers under the TCA.

However, in the deeming regulations, the FDA replied that all entities that meet the definition of "tobacco product manufacturer" in the TCA, including retail establishments that blend pipe tobacco or mix vapor e-liquids, are subject to and must comply with all applicable statutory and regulatory requirements for tobacco product manufacturers.

If retail stores are mixing or preparing pipe tobacco blends or nicotine e-liquids, then they will have to report to the FDA each pipe tobacco blend and e-liquid combination that they sell. The retailer will be responsible, as a regulated manufacturer, to determine how many and which products they plan to manufacture. For shops that prepare an expansive number of custom blends or mixes, with many gradations of flavor, nicotine strength or other characteristics, the FDA would require the retailer to identify, list, and report ingredients for a large number of distinct products.

However, the FDA also states in the deeming regulations that it expects such retailers will elect to narrow the list of flavor combinations they sell (with more limited distinctions in strength and flavor, etc.), since such a narrowing will allow them to continue providing custom products and a variety of options while simplifying their reporting. The FDA also expects that most vape shops will stop mixing e-liquids to avoid being "manufacturers" under the TCA.

D. Manufacturer Tobacco Health Document Submissions for Pipe Tobacco and Vapor Product Retailers

Section 904(a)(4) of the Food, Drug & Cosmetic Act requires each tobacco product manufacturer or importer to submit all documents that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives. The FDA intends to allow small-scale tobacco manufacturers (like pipe tobacco retailers and vapor product retailers) to submit ingredient listings within 12 months of August 8, 2016, and is granting small-scale tobacco product manufacturers an additional six-month compliance period for

the tobacco health document submission requirements.

E. Retailers That Mix E-Liquids Have Options for SE or PMTA Applications During Initial Compliance Period

If a retailer currently mixes e-liquids and continues to do so as of August 8, 2016, the retailer has two options under the deeming regulations regarding the continued sale of mixed e-liquids.

First, the retailer can continue to sell the same e-liquids that it mixes as of August 8, 2016 for up to an additional 24 months without submitting either a SE or a PMTA application. The FDA announced in the deeming regulations that the agency does not intend to enforce the SE or PMTA application requirements for this 24-month period to provide more time for retailers to compile and submit the appropriate applications. However, the retailer must stop selling the e-liquids at the end of the 24-month compliance period if no SE or PMTA applications are filed for e-liquids mixed by the retailer or be subject to FDA enforcement actions.

Second, if the retailer prepares and submits SE and/or PMTA applications during the 24-month period following August 8, 2016 for e-liquids that it mixes, the retailer can sell e-liquids that it mixes during the 24-month period plus another 12-month period while the FDA reviews the applications. At the end of this 36-month period, and even if the retailer has SE and/or PMTA applications pending with the FDA, the continued sale of e-liquids covered by a SE or PMTA application are subject to enforcement action by the FDA.

Note: The decision of a retailer to file or not file SE or PMTA applications for mixed e-liquids does not relieve the retailer from complying with the other manufacturer registration and product listing requirements.

F. Retailers That Blend Pipe Tobacco Likely Have Same Options as Retailers that Mix E-Liquids

While the deeming regulations are very specific as to the options available to a retailer that mixes e-liquids as explained above in Section 6(E), there is no similar explanation of options for retailers that blend pipe tobacco. However, since the FDA states in other sections of the deeming regulations that both pipe tobacco blending and e-liquid mixing retailers would be considered manufacturers under the TCA, then retailers that blend pipe tobacco should be provided equal treatment and afforded the same two options explained in Section 6(E) above.

7. FDA Does Not Respond to Concerns About SE and/or PMTA Applications

Despite numerous comments submitted to the FDA by industry members, the FDA did not respond directly concerns that requiring SE and/or PMTA applications will be too time consuming and expensive for some manufacturers to compile, forcing products off the market and possibly some industry businesses to cease operating. Rather, the FDA responses referenced the TCA that provides manufacturers the option of filing SE and PMTA applications to seek approval to keep tobacco products on the market.

The FDA also took the position that the deeming regulations are not banning any tobacco product, but rather the agency is extending its authority to regulate such products under the TCA.

8. Future Tobacco Product Regulations (Self-Service, Product Standards and Flavor Bans)

According to the FDA, the final deeming regulations differ from most public health regulations in that they are enabling regulations. In addition to directly applying the substantive requirements of the TCA and its implementing regulations to newly deemed tobacco products, the deeming regulations enable the FDA to issue further regulations related to tobacco products that are appropriate for the protection of the public health. The FDA states that asserting its authority over these tobacco products will enable the agency to propose further regulatory action in the future as appropriate, and those actions will have their own costs and benefits.

FDA also has the authority under Section 907 of the Food, Drug & Cosmetic Act to establish product standards for deemed products, including requirements with respect to packaging and to limit, restrict or ban ingredients or constituents in tobacco products or tobacco smoke. Although the deeming regulations do not ban self-service displays of the deemed tobacco products, the FDA will continue to monitor this issue and, if it determines that it is appropriate for the protection of public health to extend the self-service display prohibition to newly deemed tobacco products, the agency will issue a new proposed rule to do so.

In response to industry comments, the FDA clarified that it is not banning flavored tobacco products with this final deeming rule. However, to address concerns with the growing flavored cigar market and its impact on youth and young adult initiation with tobacco products, the FDA states in the deeming regulation that it intends in the future to issue a proposed product standard that, if finalized, would eliminate characterizing flavors in all cigars including cigarillos and little cigars.

9. Severable Regulations

The FDA states that the new deeming regulations are intended to be severable, which means that if the courts strike down one regulation, the other regulations remain in force. In the event any court or other lawful authority were to temporarily or permanently invalidate, restrain, enjoin, or suspend any provision of this final rule, the FDA would conclude that the remaining parts continue to be valid.