



February 13, 2017

FDA Website Adds New Database on Grandfathered Tobacco Products

February 15, 2007 is an important date in the Family Smoking Prevention and Tobacco Control Act, the law that Congress passed to authorize the FDA to regulate tobacco products. That date is known as the “predicate date” or “grandfather date.” Every tobacco product that was on the market as of February 15, 2007 is grandfathered, which means that special applications do not need to be filed with the FDA to keep those products on the market.

If a tobacco product was not on the market as of February 15, 2007, there are two kinds of pre-market applications that a manufacturer needs to consider filing with the FDA to keep its products on the market. One kind of application is a Substantial Equivalency Application, called an SE, and the other is a Pre-Market Tobacco Application, or PMTA. A manufacturer can submit a SE application if a product introduced into the market after February 15, 2007 is very similar to, if not almost identical to, a product that was already on the market as of February 15, 2007. If there were no substantially similar products for a manufacturer to rely on as of February 15, 2007, then the manufacturer would need to file a PMTA application.

Last week, the FDA announced that it has included a page on the agency’s website to search a database to determine if a tobacco product is grandfathered. Clicking on the link below can access the database. To use the database, type in the tobacco product name, the name of the manufacturer, select the product category from the drop down list, and then click the search button. The search results will inform you if the product is grandfathered.

It is important for retailers and wholesalers to know whether a tobacco product is grandfathered because if a product is not grandfathered, then that can affect the length of time that the product can remain on the market depending on whether a manufacturer files a SE or PMTA application with the FDA. If a company needs to file a SE for a tobacco product and does not, then their product(s) can remain on the market until February 8, 2018. If a manufacturer needs to file a PMTA application and does not, then their product(s) can be on the market until August 8, 2018.

However, if a company does submit a SE application, the product(s) can remain on the market until February 8, 2019, which includes a twelve-month period for the FDA to review the application. Likewise, if a manufacturer does submit a PMTA application, then the product(s) can remain on the

market until August 8, 2019, which again includes the twelve-month FDA review period. Please note that there needs to be a separate SE or PMTA application filed with the FDA per product SKU.

Now, if SE or PMTA applications are still pending with the FDA at the end of the 12 month review period, and provided that the manufacturer has submitted all of the necessary information, the FDA will determine on a case by case basis whether to extend the time to review the application and allow the product to remain on the market or require the product to be removed from the market.

Link to FDA Grandfather Database: <http://www.accessdata.fda.gov/scripts/ctpGnd/>

Newly Introduced Congressional Tobacco Bills

United States House: House Bill 729 includes the following tax increases: (1) cigarettes by 94.64 cents per pack (from \$1.0066 per pack to \$1.953 per pack); (2) little cigars by \$47.32 per thousand (from \$50.33 per thousand to \$97.65 per thousand); (3) pipe tobacco by \$45.2489 per pound (from \$2.8311 per pound to \$48.08 per pound); (4) roll-your-own tobacco by \$23.30 per pound (from \$24.78 per pound to \$48.08 per pound); (5) snuff by \$24.53 per pound (from \$1.51 per pound to \$26.04 per pound); (6) chewing tobacco by \$9.8667 (from 50.33 cents per pound to \$10.42 per pound).

Newly Introduced State Tobacco Bills

The following bills were recently introduced in state legislatures:

Arkansas: Senate Bill 285 adds vapor products to the Clean Indoor Air Act.

Florida: House Bill 649 creates 4 separate surcharge taxes on a pack of cigarettes of \$2.00 per pack, \$.042 per cigarette, \$.339 per pack, and \$.0141 per cigarette, that would be in addition to what is already being taxed at the state and federal levels.

Kentucky: House Bill 263 increases tobacco taxes as follows: cigarette tax by \$1.00 per pack; snuff to \$.51 per unit (1.5 ounces); chewing tobacco to \$.51 per single unit of 4 ounces / \$1.07 per half-pound unit / \$1.73 per pound unit; other tobacco products (including e-cigarettes) taxed at 40% of wholesale.

Maryland: Senate Bill 624 (cross-filed with House Bill 354) prohibits the use of e-cigarettes in indoor areas open to the public, indoor places of employment and certain designated private areas (excludes vapor retail stores). Senate Bill 669 prohibits the sale of tobacco products to an individual under the age of 21.

New York Assembly Bill 4377 requires retailers of electronic cigarettes, not otherwise registered with the Department of Taxation and Finance to sell tobacco products, to register with the Department of Health. Assembly Bill 4722 prohibits the erection or maintenance of billboards advertising alcohol or tobacco products within a one-mile radius of schools or daycare centers.

Oklahoma: House Bill 1841 increases the tax on cigarettes by \$1.50 per pack. House Bill 1818 increases the legal age to purchase tobacco and vapor products from 18 to 21 years of age.

Oregon: Senate Bill 180 and House Bill 2062 impose a new tax on e-liquid that is sold separately from an inhalant delivery system or sold in a disposable cartridge at the rate of 95% of the wholesale price. Both SB180 and HB2062 would also impose an excise tax on vapor products at the rate of 70% of the wholesale price of an inhalant delivery system that is sold containing e-liquid that does not require additional components for use. Senate Bill 235 would prohibit the retail sale of vapor products without a license. Senate Bill 754 increases the legal age to purchase tobacco and vapor products from 18 years of age to 21 years of age.

Pennsylvania: House Bill 403 repeals the local option cigarette tax authority of school districts of the first class.

Rhode Island: Senate Bill 206 modifies the definition of “little cigars” to 4.5 pounds per 1,000, and requires “little cigars” to be in packs of 20 or more and taxes “little cigars” in the same manner as cigarettes. Senate Bill 232 prohibits the sale of electronic nicotine-delivery systems without having a license to sell cigarettes and/or tobacco products.

Tennessee: Senate Bill 303 (same as House Bill 122) allows local governments, airports, and utility districts to regulate the use and possession of tobacco products in all public places, places of employment, and parks within the entity's jurisdiction as long as the regulations are more stringent than those in effect under state law. House Bill 1364 and Senate Bill 876 increase the cigarette tax from 3.1 cents per cigarette to 8.45 cents per cigarette and the OTP rate from 6.6% to 17.0%.

Utah: House Bill 325, which increases the penalties on retailers selling tobacco to underage persons, was introduced on February 8, 2017.

Washington: House Bill 1919 would allow a person holding a tobacco products retailer’s license to apply for a special endorsement as a cigar lounge or retail tobacconist shop. House Bill 1946 would exempt pipe tobacco from the prohibition on shipping or transporting tobacco products ordered or purchased by mail or through the internet.

West Virginia: Senate Bill 37 would increase the legal age to purchase tobacco and vapor products from 18 to 21.

Action on Previously Introduced State Tobacco Bills

The following bills that were previously introduced had action recently:

Arizona: House Bill 2335, which increases the age for purchase, use and possession of tobacco products (including e-cigarettes) to 21 and extends the smoking ban to include e-cigarettes, passed the House Health Committee on February 2.

Hawaii: House Bill 246, which imposes a new excise tax of 70% of the wholesale price on e-cigarettes and related products, effective January 1, 2018, was amended and passed the House

Committee on Consumer Protection and Commerce on February 6, 2017. Senate Bill 871, which changes the excise tax on large cigars (currently 50% of the wholesale price) to the lesser of 50% of the wholesale price or 50 cents, passed Senate Ways and Means Committee on February 7, 2017.

Kentucky: House Bill 125, which allows a minor to sell tobacco products on behalf of an employer, was posted in committee on February 8, 2017.

Nebraska: Legislative Bill 190, which limits the excise tax on cigars to 50 cents per cigar, was indefinitely postponed on February 7, 2017.

New Hampshire: House Bill 112, which requires child-resistant packaging for electronic cigarette cartridges, failed to pass the House on February 9, 2017. House Bill 242, which amends the definition of e-cigarette to mean any electronic smoking device that may or may not include nicotine and defines e-cigarettes as a tobacco product for purposes of sale and licensing, passed the House on February 9, 2017. Senate Bill 207, which changes the tax rate on chewing tobacco from 65.03% of wholesale to \$1.55 per ounce, is scheduled to be heard in the Senate Ways & Means Committee on February 15, 2017.

New Mexico: House Bill 282, which increases the state cigarette tax by \$1.50 per pack, increases the tax on other tobacco products an additional 51% of the purchase price, and also includes “electronic cigarettes” in the definition of “tobacco products” with the sole purpose of imposing a new tax on electronic cigarettes at rate of 76% of the purchase price, was considered in the House Revenue and Taxation Committee on February 10, 2017.

North Dakota: House Bill 1312, which increases the purchase age for tobacco products and vapor products from 18 years of age to 19 years of age, failed to pass the House on February 3, 2017.

Virginia: House Bill 1925, which grants all counties the authority to tax cigarettes, was left in committee February 7, 2017.

Washington: House Bill 1054, which increases the legal age to purchase tobacco products and vapor products from 18 years of age from 21 years of age, received a “Do Pass as Substituted” recommendation from the House Health Care and Wellness on February 3, 2017 and was referred to the House Finance Committee on February 7, 2017.

Wyoming: House Bill 151, which would increase the state cigarette tax by 30 cents per pack (from \$.60 per pack to \$.90 per pack), was referred to the Senate Revenue Committee on February 6th.