



February 16, 2017

CITMA Members:

I am writing regarding the recently announced [grandfathered tobacco products database](#) that is now available on CTP's website. We are aware that this database is causing substantial confusion in the marketplace and are working with FDA to clarify the significance of inclusion in this database in order to correct the current misunderstandings in the trade. In short, this database is substantially incomplete and stakeholders should not rely on it to conclusively determine the marketing status of any tobacco product.

The grandfathered products database includes only standalone grandfathered determinations, which are issued by FDA only if a company voluntarily chooses to submit a grandfathered determination request to FDA. Importantly, a grandfathered determination from FDA is not required to legally market a grandfathered product and numerous grandfathered products do not appear in FDA's database. Likewise, the database does not include grandfathered determinations made by FDA in the context of substantial equivalence (SE) applications. Moreover, a brand that appears in the database may not be legally marketed today if the product was modified after February 15, 2007 (e.g., the addition of FSC paper to a cigarette brand that was on the market in February 2007). Finally, the database may include only one brand name for a grandfathered product marketed under multiple brand names.

We have therefore requested that FDA issue an immediate statement to all stakeholders as follows:

- FDA's recently announced database for grandfathered tobacco products does not include all legally marketed grandfathered tobacco products.
 - It includes only products that were the subject of a voluntary grandfathered determination request submitted to FDA.
 - It does not include grandfathered determinations made by FDA in the context of SE applications.
 - It does not include grandfathered products for which a voluntary grandfathered determination request was not submitted to FDA.
 - It does not include grandfathered products that are physically identical to products included in the database but marketed under a different brand name.

- The fact that a product is not listed in the database does not mean it cannot be legally marketed as a grandfathered product or that premarket review is required.
- Likewise, the fact that a product is included in the database does not necessarily mean that the product is currently legally marketed without premarket review. As stated in FDA's grandfathered determination letters, the Agency does not review information concerning the composition, design, or ingredients of the product in order to make a grandfathered determination and the determination applies only to the product in the form it was marketed as of February 15, 2007.

We will continue to update you on our interactions with FDA with respect to this issue. In the meantime, please do not hesitate to contact me with any questions at 804-370-1443.

Sincerely,

Kevin Altman