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FDA EXTENDS REGULATORY AUTHORITY OVER ALL TOBACCO PRODUCTS, INCLUDING E-CIGARETTES, CIGARS AND HOOKAHS

The U.S. Food and Drug Administration ("FDA") today issued historic final rules that extend the statutory definition of "tobacco products" to e-cigarettes, pipe tobacco, dissolvables, cigars, and "novel and future products." The new rules go into effect on August 8, 2016, and warrant immediate attention by these billion dollar industries.

By deeming that e-cigarettes, pipe tobacco, dissolvables, cigars, and "novel and future products" meet the statutory definition of a "tobacco product," impacted industries are now subject to the same regulatory regime as cigarettes, roll your own tobacco, and smokeless tobacco. Whether your product is currently on the market or in product development, manufacturers of the foregoing products will be subject to, at minimum, the following regulatory guidelines:

- Every manufacturer, importer and retailer of these products must follow applicable provisions related to tobacco products under the Federal Food, Drug and Cosmetic Act ("FDCA") and all FDA regulations;
- Enforcement actions by FDA, including adulteration and misbranding charges;
- Registration and listing requirements with FDA;
- Reporting ingredients to FDA, including Harmful and Potentially Harmful Constituents ("HPHCs");
- Requiring premarket review and authorization of new tobacco products;
- Health warning placement on all product label and labeling;
- Removal of modified risk tobacco claims, such as "light," "low," "mild," unless authorized;
- Banning of flavors; and

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- Significant restrictions on youth access to these products.

As Armstrong Teasdale's Agriculture, Food & Health ("AFH") practice group predicted just a few months ago, FDA's radical expansion will now require all affected industries to incur significant new costs to bring new products to market and keep existing ones on the market. These new expenses include researching, testing, corresponding, challenging, and navigating a complex FDA regulatory framework, while trying to stay competitive. Some analysts predict the premarket review and authorization process could cost some industry actors between $2 million and $10 million dollars.