Validation and Verification of Analytical Testing Methods Used for Tobacco Products: Guidance for Industry
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FDA's draft guidance for industry on "Validation and Verification of Analytical Testing Methods used for Tobacco Products" provides information and recommendations related to the validation and verification of analytical test methods, including analytical testing of tobacco product constituents, ingredients, and additives, as well as stability testing of tobacco products. Companies must establish through FDA's premarket review process that any product they wish to bring to market is appropriate for the protection of the public health. Therefore, the quality and reliability of their analytical test methods is crucially important. Because the draft guidance's recommendations will be used by the industry to produce data that will be used to support their regulatory submissions for finished tobacco products, the guidance is significant.

We appreciate the opportunity to review the draft guidance and believe it is overall straightforward, comprehensive, and appropriate.

However, we found one error that may be an inadvertent typo on page 18, Section A, "Total Error Acceptance Ranges" where the guidance states: "For example, nicotine in burley tobacco leaf is generally between 4 to 12 micrograms per gram of tobacco." It appears that the units chosen are incorrect as this range is too low. Nicotine in tobacco is generally in the "***milligrams*** per gram range," not micrograms. For example, the concentration of nicotine in the tobacco filler of the 1R6F Reference Cigarette is listed as 18.0 *milligrams* per gram.[1] We think that the units should be changed from "micrograms" to "milligrams."

[1] Certificate of Analysis 1R6F Certified Reference Cigarette. Certificate Number: 2017-002CCTRP, University of Kentucky Center for Tobacco Reference Products.