U.S. FOOD & DRUG ADMINISTRATION

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Re: Docket Nos. FDA-2011-P-0512, FDA-2013-P-1079, FDA-2015-N-2002, FDA-2016-N-1149

Dear Mr. Kalb, Ms. Klasmeier, Mr. Guerra, Mr. Griffin, Ms. Combs, Mr. Hallward-Driemeier, Ms. McPhee, Mr. Stansel, Mr. Murphy, and Mr. Florence:

I am writing to inform you that the Food and Drug Administration (FDA or we) has not yet resolved the issues raised in your petition for reconsideration and stay of action received on February 8, 2017 (petition). The petition requests that the FDA reconsider its final rule entitled "Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices or Combination Products; Amendments to Regulations Regarding 'Intended Uses'" (Final Rule), which was published in the Federal Register on January 9, 2017 (82 FR 2193). The petition also requests that FDA indefinitely stay the Final Rule.

FDA has been unable to reach a decision on your petition because it raises complex issues requiring further review and analysis by Agency officials. On March 20, 2017, FDA published a notice in the Federal Register (82 FR 14319) that delayed the effective date of the rule until March 19, 2018 and that asked for comments on particular issues raised by the petition to help in our further consideration of the petition. On May 18, 2017, we extended the date for comments until July 18, 2017, in response to requests from stakeholders (82 FR 22741), and FDA is still in the process of reviewing and analyzing the comments we have received. This interim response is provided in accordance with FDA regulations on citizen petitions (21 CFR 10.30(e)(2)). We will respond to your petition as soon as we have reached a decision on your request.

Sincerely,

Leslie Kux
Associate Commissioner for Policy

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