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Rob Smith
rob.smith@capalphadc.com
(202) 548-0057

FDA Risk for Tobacco, Food and Beverages Expert Call Takeaways

- Last week we hosted a call on FDA tobacco, food and beverage risks with Stuart Pape, former agency counsel and head of the FDA practice at Squire Patton Boggs.
- Please see below for our topline takeaways on FDA action regarding menthol, e-cigarettes, tobacco branding, nutrition labels, GMOs and energy drinks.
- A replay of the call is available on request, and we're always happy to chat if you have additional questions.
- For New York area clients, we are meeting with investors for 1-on-1's on June 16 and have times available if you would like to explore these topics in more depth. Please reply for availability.

Menthol: FDA is very unlikely to propose a ban due to lack of scientific evidence, challenges with clearing the regulatory review process and law enforcement concerns regarding black market creation. Stuart does not necessarily discount the possibility FDA will propose a step-down since this option was mentioned in the agency's Notice of Proposed Rulemaking last summer but notes it would face similar challenges as a full ban.

On timing, pending menthol regulations were not listed on the Administration's spring unified regulatory agenda published last month (update will be published this fall), so we will not see a menthol proposal from FDA until at least the end of 2014, if at all. [Like us](#), Stuart doubts FDA could finalize a menthol rule by the end of the Obama Administration.

E-Cigarettes: FDA proposed "deeming" regulations are benign and unsurprising but leave open questions about future product innovation. Look for the agency to attempt to finalize the proposal in the next 12 to 18 months. FDA has nothing in the works on flavoring or marketing or it would have proposed such provisions in the April rule.

Misbranded Tobacco: Concerns regarding misbranded tobacco (branding cigarette tobacco as pipe to take advantage of lower tax rate) FDA raised in the deeming reg will do not mean it will crack down more aggressively on the

practice. The agency already has the authority to go after retailers who misbrand but hasn't.

FDA Nutrition Labeling Proposal: Biggest concern is for foods traditionally thought of as "healthy." For example, yogurts would have to label "added sugar." And serving size changes would cause many low sodium and similar products to run afoul of FDA labeling rules. Again, [like us](#), Stuart doubts FDA can finalize the proposal before Obama leaves office.

GMO Labeling: Stuart thinks there is very little chance state action on mandatory GMO labeling will prompt FDA to issue regulations. An industry-backed bill to require FDA to issue guidance to preempt state labeling laws is likely to continue to languish, leaving GMOs as a state issue for now.

Energy Drinks: Some in Congress may continue to make noise on the issue, but FDA does not appear to be contemplating taking action that would require manufacturers to reduce caffeine or other ingredient levels. If anything, we may see voluntary guidelines regarding caffeine content disclosure, consistent with our long-held [views](#).

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