Tuesday, December 15, 2015 11:42 AM

CALL TO ACTION

Update 12/11/15: The FDA has reopened the comment period for this proposed rule. The new deadline is Wednesday, December 30th, 2015. Please follow the instructions in the post below to submit your comment.

The FDA is requesting comments on a proposed rule about "Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding 'Intended Uses.'"

By way of background, FDA considers nicotine-containing products to either be pharmaceuticals (regulated as a drug, device, or combination product) or tobacco products. Pharmaceuticals are subject to a lengthy and expensive approvals process, and any e-cigarette products treated as pharmaceuticals would be immediately removed from the market as unapproved drugs/devices. Regulation as a tobacco product is problematic as well[1], but regardless, it is imperative that if e-cigarettes are to be marketed as tobacco products, manufacturers[2] be permitted to make reasonable claims in their marketing and not be hamstrung by FDA's over-zealous regulation. Prohibiting manufacturers from providing honest and helpful information is bad for consumers and bad for public health.

CASAA

FDA COMMENTS