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FDA Should Clarify that Tobacco Products for which FDA has not Received Adequate SE Reports by Established Deadlines Must be Removed from the Market

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FDA's Draft Guidance on Substantial Equivalence Reports: Manufacturer Requests for Extensions or to Change the Predicate Tobacco Product is a good step in the right direction. FDA correctly states that manufacturers have had more than enough time to prepare SE reports and amend pending SE reports to address any deficiencies within the time period granted in the deficiency letters. However, FDA should clarify the consequences to manufacturers whose SE reports for "provisional tobacco products" (those that were first marketed in the U.S. between February 15, 2007 and March 22, 2011, and for which SE reports were submitted no later than March 22, 2011, and that remain on the market until FDA issues a determination that they are not substantially equivalent and orders them off the market) are deficient.

Our reading of the Draft Guidance is that FDA's intention is to deny marketing approval to tobacco products for which inadequate SE reports have been submitted, and therefore neither "provisional tobacco products" nor "non-provisional tobacco products" may remain on the market. *However, while FDA clearly articulates this consequence for inadequate non-provisional reports and requests to change the predicate product, the consequence for inadequate SE reports for provisional tobacco products for which FDA does not grant an extension of time is ambiguous.*

To date, 3,513 tobacco products remain on the market for which provisional SE applications were submitted, but which FDA has neither approved nor denied. http://www.accessdata.fda.gov/FDATrack/track?program=ctp&id=CTP-OS-total-product-submissions-received&fy=all; http://tobacco.ucsf.edu/fda-removes-first-4-tobacco-products-market-3513-go. FDA should act quickly to determine whether these products are "substantially equivalent" to valid predicate products on the market and do not raise different questions of public health. FDA's Draft Guidance announces that CTP plans to grant extensions of time to respond to deficiency letters "in very limited instances." **FDA should state explicitly that provisional tobacco products must be immediately removed from the market if manufacturers did not**

address SE report deficiencies within the specified time period and FDA did not grant an extension of time.

On April 18, 2014, FDA announced the establishment of performance measures and timeframes for the review of certain tobacco products, including non-provisional or "regular" SE reports. http://www.fda.gov/TobaccoProducts/NewsEvents/ucm393894.htm?source=govdelivery&utm_medium=email&utm_source=govdelivery FDA established a timeframe to review and act on an original SE report within 90 days of FDA receipt, and to review and act on a SE report resubmission within 90 days of receipt. It noted that as of March 24, 2014, there was no longer a backlog of regular SE reports awaiting scientific review, and that as of April 4, 2014, FDA had concluded the review process for 232 of the 981 regular (non-provisional) reports that had been received before March 31, 2014. Since 87 days have passed since this announcement, presumably FDA has acted on many more non-provisional reports. **FDA should set similar timeframes for review of the 3,513 provisional tobacco products that remain on the market, and not allow manufacturers to delay the process with unnecessary requests for extensions of time or requests to change the predicate tobacco product.**