FDA should require that all communications from tobacco manufacturers regarding MRTPs be done in a way that narrowly target smokers

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The individual and population health goal of any MRTP is to reduce risks to smokers of higher risk products. At the same time, it is important to minimize risks of increasing initiation and relapse and reducing cessation or increasing dual use. Any MRTP application or possible MRTP order must minimize the risk of undesired impacts (e.g., increasing initiation, increasing relapse among non-using former users). Therefore, ***any reduced-risk claim that obtains an MRTP order should be permitted to be delivered only to the users of the higher-risk tobacco products (the only persons who could possibly benefit from using the reduced-risk product) and be required to be delivered in such a way as to minimize any exposure to the reduced risk claim among youth or adult non-tobacco-using populations (who might be prompted to start using) or even among current users of the reduced-risk product (who might be prompted to keep using instead of quitting) is minimized.***

This standard likely means that the MRTP claim obtaining an order should be delivered only through direct communications (e.g., email, regular mail) to pre-verified adult smokers.

In addition, any reduced risk claim permitted by an FDA order should be required to be delivered with accompanying government messages about the need to switch entirely and completely to possibly obtain any harm-reduction benefit, that quitting all tobacco use is the most effective and powerful way to reduce harms and risks.

In this case, Swedish Match is not even asking for an order allowing it to make a reduced-risk claim to any consumers but is asking FDA to change the government's warning labels that are required by law to be on the packages of the subject products.

Putting aside the fundamental question as to whether the MRTP process can be used to request changes to the use or content of government warning labels, the text changes to the warning label requested by Swedish Match would be only on the alleged reduced-risk products, meaning that the primary audience receiving the proposed reduce-risk text would be those already using the product (who would likely respond to the message by being less likely to try to quit or reduce consumption) and the claim would not be effectively delivered directly to smokers (those who would be the most likely to benefit from switching to the reduced-risk product). Moreover, if the warning label text change were featured in Swedish Match ads, it would be seen by youth, those at risk of relapse, and all the other sub-populations that would not benefit from seeing it.

For these reasons, the Swedish Match MRTP application should be denied.

In addition, to ensure that future MRTP applications do not suffer from this problem, FDA should issue a Guidance making these points. FDA has authority to place such restrictions and requirements on the delivery of MRTP claims through Sec. 911(h)(4).