Submission to FDA on the MRTP application of Swedish Match
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Please accept this contribution to the FDA consultation on the Modified Risk Tobacco Product application made by Swedish Match for its snus products. [Swedish Match North America MRTP Applications]. In our view, the available scientific literature supports the regulatory conclusions drawn in the application.

We write as experts in the field of nicotine science and public health policy. We wish to make the following observations relevant to FDA's examination of this application:

1. Disease risk associated with use of modern Swedish-style snus is very low or negligible relative to that generated by use of cigarettes and is not exceptional compared to other risks routinely accepted in society. The evidence base provides unequivocal support for the contention that snus is a reduced risk product within the definition a Modified Risk Tobacco Product.

2. The experience of Sweden and Norway suggests significant and continuing population public health benefits have been achieved as a result of use of snus as an alternative to smoking or use of snus to quit smoking. In the country (Sweden) where snus use has been widespread and increasing among men, it is now clear that mortality attributable to tobacco among men is lower than in any other EU Member State and that the use of snus has been an important contributor to this situation It is no longer

appropriate to discuss the risks of snus use without reflecting the benefits of switching from smoking to snus or using snus instead of ever starting smoking, and this applies equally to the growing market for snus in the United States.

3. Misleading warnings may cause actual harm to health and contribute to unnecessary disease and death. If smokers are convinced that snus is more risky than it is, it is possible that some will be deterred from switching, or will be more indifferent to the choices they make between different tobacco products. If there is an undeclared aim to use warnings, known to be misleading, to deter smokeless tobacco use rather than to provide accurate risk information, this would be unethical and inappropriate regulation.

4. The current generic warning: "*WARNING: This product is not a safe alternative to smoking"* is too ambiguous to be useful in helping users make decisions about tobacco use. It could refer to any level of risk between 'almost as dangerous as smoking' and 'almost as safe as not smoking'. It is unlikely that consumers will guess correctly the appropriate realistic point in this range, and the warning is in effect meaningless and likely to be misleading for most people seeing it.

5. As the FDA recognises a continuum of risk in the products that deliver recreational nicotine, it is important not to deny this insight in warnings the public. It is appropriate therefore to replace the generic warning: "*WARNING: This product is not a safe alternative to smoking"* with the more subtle, complete and informative message "*WARNING*: *No tobacco product is safe, but this product presents substantially lower risks to health than cigarettes"*. Equally, it would be inappropriate not to do this, given the relative risks of snus use and smoking.

6. The risks of unintended consequences arising from the revised generic warning are slight: it is impossible to interpret this as implying no risk, and 'substantially lower' could easily still imply far greater risk than there actually is. The new warning is unlikely to mislead dual users, who will still see warnings of high risks on the cigarettes they consume. It would be unreasonable to deny the users of snus accurate warnings because of hypothetical and unlikely confusion of risks in dual users.

7. It is implicitly misleading to warn of specific risks that are negligible, especially if the undeclared purpose of this is to manipulate behaviour by creating a sense of revulsion rather than accurately communicate risk. The specific warnings: "*WARNING: This product can cause mouth cancer*"and "*WARNING: This product can cause gum disease and tooth loss"* are no longer justified.

8. It is premature to remove health warnings entirely and it remains justified to retain a warning about the addictiveness of snus: *WARNING: Smokeless tobacco is addictive* as there is no dispute that nicotine delivered through snus may form dependence.

9. FDA should address the anomaly that will arise if the new warnings can be used on

the applicant's products, but cannot be generalised to physically and functionally similar products, such as other products complying with the Gothiatek standard. In that situation, continued use of the existing warnings may be overtly misleading and not serving public health. However, we recognise that the MRTP process requires a tobacco company to have the incentives to make an application in the first place, and those incentives may include exclusive use of the reduced risk claim. We invite FDA to consider if the process for applying and approving MRTP applications creates the right incentives to maximise the public health benefit of reduced risk products.

10. The MRTP regime is flexible enough to take account of new evidence and to adjust warnings if necessary. This implicitly, and correctly, recognises an element of uncertainty but acknowledges that regulators have to make determinations based on the available evidence and their judgement, taking account of the reality that the case for retaining the *status quo* does not have a convincing evidence base.

We hope FDA Center for Tobacco Products and the Tobacco Products Scientific Advisory Committee will take these views into account.

Yours faithfully,

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