SWEDISH MATCH

September 25, 2014

Division of Dockets Management (HFA-305),
Food and Drug Administration, 5630 Fishers Lane, rm. 1061,
Rockville, MD 20852.
http://www.regulations.gov

Document Number: 2014-N-0987

On behalf of Swedish Match AB and Swedish Match North America I am responding to the Federal Register Notice of July 14, 2014, Document Number 2014-N-0987, requesting comments on the proposed quantitative testing, specifically formative pretests, designed to enhance the FDA Center for Tobacco Product's risk communication efforts.

Swedish Match has a tradition of product stewardship that includes a commitment to effectively communicate with the public. For example, one of the elements of our GothiaTek product standard is to provide information to consumers and the general public. In addition, we recently submitted a Modified Risk Tobacco Product (MRTP) application that includes a premarket consumer perception study. The application also cites scientific evidence relating to consumer knowledge, attitudes and beliefs regarding Swedish snus.

We fully understand the challenges in communicating about the relative risks of tobacco and nicotine products. We believe it is in the best interest of the public health and the tobacco enterprise that FDA CTP be viewed as the most credible source in the field of tobacco risk communication. FDA has a well-deserved reputation as a highly credible scientific evidence based agency and it is critical that it has the tools necessary to effectively communicate science to the public. It is particularly important that CTP has the flexibility to act quickly to collect evidence that allows for effective communication in the ever changing nicotine product environment. There is often a critical need for short turn around studies to address emerging public concerns and questions about tobacco products and it is imperative that CTP has the tools and authority to respond in timely fashion.

We support CTP's proposal to conduct formative pretests to ensure that health communication messages are received, understood and accepted by the intended audiences. It is reassuring that CTP seeks to ensure its risk communication budget is wisely and effectively utilized. Swedish Match recently devoted considerable resources to determining premarket consumer perceptions of a label change proposed in our recent MRTP application. Similar to what CTP

proposes, we decided to conduct cognitive testing of the study protocol prior to the actual survey to ensure the study provided the most useful evidence possible.

As a regulated party, we appreciate FDA's commitment to risk communication and particularly the role of the Risk Communication Advisory Committee (RCAC). I have been impressed by the work of the RCAC and particularly value the 2011 publication *Communicating Risk and Benefits: An Evidence-Based User's Guide*. I believe in general that CTP's risk communication efforts could benefit from utilizing the expertise of the RCAC and I encourage CTP to involve the RCAC in the proposed formative pretest initiative and the other elements cited in the Federal Register notice.

In summary, Swedish Match believes the proposed information collection is necessary and will have practical utility. In addition, CTP's projection of the burden of the proposed collection effort seems reasonable. We believe the evidence collection effort could be enhanced by seeking input from the FDA Risk Communication Advisory Committee.

Sincerely,

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