SWEDISH MATCH

June 23, 2010

Center for Tobacco Products
Food and Drug Administration
9200 Corporate Boulevard
Rockville, MD 20850 U.S.A.
TPSAC@fda.hhs.gov

Dear Sirs,

Re: Impact of Dissolvable Tobacco Products on Public Health

This submission is made to the Center for Tobacco Products (CTP), US Food and Drug Administration (FDA) on behalf of Swedish Match AB in response to the notice for comments to the Tobacco Products Scientific Advisory Committee (TPSAC) regarding discussions concerning the impact of dissolvable tobacco products on public health. We understand that during its July 15-16, 2010 public meeting the TPSAC will hear and discuss a presentation on dissolvable tobacco products in order to prepare for developing a report to be submitted to the Secretary of Health and Human Services. In addition, FDA has established a public docket to provide an opportunity for interested parties to share information, research, and ideas on how use of dissolvable products may impact public health, including such use among children. The relevant Federal Register Notice (March 22, 2010) presents a list of areas of research concerning patterns of use of dissolvable products and the relationship to smoking.

Swedish Match does not manufacture dissolvable tobacco products; however we are interested in the impact of tobacco products on public health in general, and in particular the areas of research listed in the March 22, 2100 Federal Register Notice. Some of the research areas presented is fundamental to the field of harm reduction, including impact on cessation, dual use, and initiation of use. Our comments will focus on those three key areas of research.

We will also comment on the vital role advisory committees play in the FDA regulatory science process. In March of 2010 Swedish Match submitted comments regarding ways in which transparency can be increased between FDA and regulated industry (Docket No. FDA-2009-N-0247). We stated our belief that the FDA advisory committee process is particularly valuable to ensuring transparency. However, to ensure maximum transparency and effectiveness it is important that advisory bodies – and regulated industry – are given as much advance notice as possible to provide and assess information. Therefore, we are pleased to note that FDA is taking time during the July 15-16 TPSAC agenda to collect information and ideas that will be used later when the Committee focuses on dissolvable tobacco products. We hope this is representative of future TPSAC operations, and that a similar process will be employed to prepare for discussions on potential modified risk tobacco products.

Patterns of Use and Relationship with Smoking

The FDA has requested comments on eight areas of research regarding dissolvable tobacco products. The research areas all relate to patterns of use and relationship with smoking; which is of great interest to Swedish Match. However, some of the information areas listed are very specific to dissolvable products and therefore we won't be offering comments. The areas that do warrant comment relate to cessation, dual use, and initiation of use.

Our consulting firm, ENVIRON International Consulting, is in the process of preparing a report reviewing the scientific literature on patterns of use of Swedish snus and US

smokeless tobacco products and the relationship with smoking. The report will be completed within the next few months and it will serve as the basis of comprehensive comments to be submitted to the Public Docket prior to the September 20 deadline. The ENVIRON report will not address dissolvable products but will examine areas of research of interest to the TPSAC.

The patterns of use report will complement the recently issued (April 2010) ENVIRON report *Review of the Scientific Literature on Snus,* which was submitted to FDA pursuant to Section 904 of the Tobacco Control Act. The report provides a comprehensive review of the relevant published chemistry, epidemiology, and toxicology studies available for Swedish snus, including literature identified through systematic ongoing searches of Medline and several additional databases in Dialog® through December 31, 2009. The ENVIRON review summarizes studies of the potential health risks associated with the use of Swedish snus. The review includes sections on the chemical properties, the manufacturing process, biomarkers of exposure, and epidemiological and toxicological studies.

The ENVIRON patterns of use report will examine geographic, temporal and demographic variation in snus use in Sweden, and the same in the US for smokeless tobacco products. US smokeless tobacco products (STPs) differ from traditional Swedish snus, and therefore it is necessary to separately examine patterns of use in the two countries. Swedish snus is a specific type of moist snuff, whereas US STPs are variable in manufacture and form, and include chewing tobacco, and moist and dry snuff. In addition, the culture and history of tobacco use in the two countries is very different.

The patterns of use report will further the current understanding of the use of these types of tobacco products by consumers and the relationship of the products to smoking. The report will provide us with useful information in the short term; and long term could contribute to our approach to postmarketing surveillance, which is mandated under Section 911 of the Tobacco Control for any product approved as a modified risk product

to "determine the impact of the order issuance on consumer perception, behavior, and health…".

The patterns of use report is still being drafted but key chapters will examine the relationship of snus and US smokeless products to smoking. The chapters will include an analysis of the scientific literature relating to dual use, transition between products, and gateway theory. Dual tobacco use -- defined as the use of both smokeless tobacco products and cigarettes-- is a fundamental issue for the characterization of modified risk products and has been widely studied in Sweden. Some literature exists in the US, most of it quite recent, likely reflecting the increased interest in harm reduction. The report will make several points about dual use, including the core fact that there are many smokeless tobacco users in both Sweden and the US who have smoked at some point in their lifetime, and understanding the temporality of use is an important component of tobacco harm reduction. Secondly, there is conclusive evidence of switching from smoking to snus use at both the population and individual levels in Sweden. Furthermore, switching from cigarettes to snus is much more common than switching from snus to cigarettes in Sweden. In addition, there is evidence that smokeless tobacco is used by individuals as a smoking cessation aid in both Sweden and the US. The ENVIRON report will elaborate on, and document these conclusions to be included in the Swedish Match submittal to the dissolvable tobacco products public docket.

The Federal Register Notice listing the areas of dissolvable products research of interest to FDA and the TPSAC includes the impact on initiation of use of tobacco products. Related to initiation of use is the concern that smokeless products serve as a gateway to cigarette smoking. The ENVIRON patterns of use report examines the literature addressing this complex theory and cites studies that suggest that smokeless product use is only a gateway if the temporal sequence is established and the relationship is causal. The report will address theories of causation that contend the gateway theory is applicable only if someone who would have not started smoking if they did not have the option of using smokeless products begins to use these products and later initiates smoking. Certainly some people who would not have smoked are likely to use smokeless

products. However, it is unlikely that people who made the conscious choice to not smoke (possibly due to concerns about health) later switch from a low risk product to a high risk product if they are accurately informed about the health risks.

TPSAC and Transparency

Section 907(f) of the Tobacco Control Act charges the TPSAC with providing to FDA a report on dissolvable tobacco products impact on public health. This is one of several tasks the statute assigns to the TPSAC, including addressing menthol cigarettes, tobacco constituents and modified risk products. These statutory provisions include a date by which the TPSAC and CTP are to complete the tasks. Understandably, CTP and the TPSAC are focused on addressing the tasks with the most pressing deadlines. So, for example, the agendas for the first two TPSAC meetings have focused on menthol cigarettes, which is the first deadline facing the Committee.

We understand the necessity of first addressing time sensitive tasks; however, it is essential the TPSAC also be forward thinking and allot time on agendas to consider information needs related to upcoming tasks. This is seemingly the approach used for the July 15-16, 2010 TPSAC meeting. Although the bulk of the agenda addresses menthol issues, there is an opportunity to inform the TPSAC of issues and information needs related to dissolvable products. Ideally, industry resources will be tapped in developing an effective briefing to the TPSAC. We trust the same approach will be used for modified risk products, and the TPSAC will soon include this topic on its program agenda.

At the appropriate time, Swedish Match will submit to FDA an application for a product to be characterized as modified risk. We assume companies that make potential modified risk products will be asked to provide information to the TPSAC and answer specific questions. We look forward to such a request, for several reasons: we want to assist the TPSAC in its work; we want to demonstrate our commitment to being engaged in the regulatory science process; and we want to demonstrate that Swedish Match has an

abundance of information, due to its historical commitment to researching the health effects associated with its products. However, in order to most effectively respond to the projected TPSAC request, it would be useful to have advance warning and ideally begin working with CTP staff as soon as possible.

Yours sincerely,

Lars E. Rutqvist, M.D., Ph.D.
Senior Vice President for Scientific Affairs
Swedish Match AB – Smokefree Division
Stockholm
SWEDEN

e-mail: lars-erik.rutqvist@swedishmatch.com
tel: +46 (0)768 788 498