



August 25, 2015

Division of Dockets Management (HFA-305)
U.S. Food and Drug Administration
5630 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2014-N-1051, Reopening of Comment Period for Modified Risk Tobacco Product Applications: Applications for 10 Products Submitted by Swedish Match North American, Inc.

The undersigned organizations submit these comments in response to the Food and Drug Administration's (FDA) reopening of the comment period in this Docket to receive comments on amendments made to the originally-filed modified risk tobacco product applications filed by Swedish Match North American, Inc.¹ We incorporate by reference the comments we filed in this Docket on November 25, 2014 ("November, 2014 Comments").

The Swedish Match amendments do not appear to alter the substance or merits of Swedish Match's requested changes in the statutory health warnings currently required for their Swedish snus products, nor do they change the products for which the revised warnings are sought. Rather, the amendments appear to consist of the provision of additional information by Swedish Match to FDA in response to a series of FDA requests.

However, FDA has redacted such substantial portions of its own inquiries to Swedish Match, as well as even larger portions of the Swedish Match responses, that it is impossible to assess the significance of the additional information provided by the company since the filing of the original modified risk application. The redaction of huge portions of the Swedish Match submission raises important questions about whether FDA has provided a meaningful opportunity for public comment on the proposed Swedish Match amendments. For example, the continued redaction of information about the levels of harmful and potentially harmful constituents in Swedish snus is difficult to justify, particularly since such information has been

¹ 80 Fed. Reg. 45661 (July 31, 2015).

made public in articles published by scientists employed by Swedish Match, as we pointed out in our November, 2014 Comments.

As discussed below, the publicly-available information in the Swedish Match amendments does not cure the serious deficiencies in the original Swedish Match application. Nor do they alter the conclusions of the Tobacco Products Scientific Advisory Committee (TPSAC), which find an insufficient scientific basis for the Swedish Match application.

Deficiencies in the Original Swedish Match Application

Nothing in the Swedish Match amendments made publicly available casts doubt on the analysis and conclusions in our November, 2014 Comments, which indicated serious deficiencies in the original Swedish Match application. We summarize those conclusions here.

1. The Swedish Match application is legally defective because the modified risk provisions of Section 911 of the Food, Drug and Cosmetic Act, as amended by the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act or TCA) cannot be used to adjust the text of the statutory smokeless warning labels. The authority to revise the statutory health warnings is granted FDA by Section 205 of the TCA, which provides for an entirely distinct regulatory process, and is governed by entirely distinct, statutory standard, than the modified risk provisions of Section 911. Because the Swedish Match application, as amended, seeks only to revise the statutory health warnings by invoking Section 911, FDA lacks the legal authority to grant the application, in whole or in part, and the agency is vulnerable to a successful legal challenge by anyone who opposes this action should it seek to alter any of the statutory warnings as requested in the application.
2. The proposal by Swedish Match to transform a warning label into a government-sponsored statement of reduced risk creates a special risk of adverse population-wide effects, including increased initiation of tobacco use by youth and former users. In addition, Swedish Match has not proposed a modified risk claim that it would carefully target to existing smokers, nor has it proposed limitations or conditions that would minimize the risk that non-users of tobacco products, particularly young people, will be exposed to the reduced risk message, which may persuade them that use of the products involves negligible health risks. Rather, the proposed reduced risk message will be in the form of a warning label that would appear generally on packages and advertising of the products, with broad exposure to, and no protection against marketing to, non-users of tobacco, particularly young people.
3. Even if the Swedish Match application were considered a request to adjust the statutory smokeless warnings under Section 205, the requested adjustments would not

meet the standard under Section 205 that the changes “would promote greater public understanding of the risks associated with the use of smokeless tobacco products” because (1) the changes requested by Swedish Match eliminate all warnings of specific disease risks except nicotine addiction, when in fact there is substantial evidence that Swedish snus increases the risk of heart disease and stroke, esophageal and pancreatic cancer and adverse pregnancy outcomes, and (2) the proposed language “this product presents substantially lower risks to health than cigarettes” is itself misleading because it fails to inform consumers that the health benefits of snus depend on switching completely from cigarettes to snus.

4. Although studies by independent researchers indicate that Swedish snus poses a substantially lower disease risk to individual users than other smokeless tobacco, the extensive redactions of data by FDA in the Swedish Match documents make it impossible to confirm from the company’s submission that its Swedish snus, as sold and used in the U.S., poses the same or no greater risk as the products sold in Sweden.
5. Swedish Match’s reliance on the so-called “Swedish experience” with snus is misplaced and offers little assurance that it would be replicated in the United States. The Swedish market for tobacco products is radically different than the U.S. market. In Sweden, Swedish Match snus products have long been the dominant smokeless tobacco product. In the U.S., in contrast, they enjoy little popularity or market presence, facing significant competition from other smokeless products. Moreover, in Sweden, snus is marketed in an environment where no tobacco advertising is permitted; in the U.S., tobacco companies spend over \$8 billion annually to market cigarettes through advertising, promotion and price discounting and millions more to market smokeless tobacco products that do not meet the same standards of Swedish Snus. Given this pervasive marketing activity, it is far less likely that cigarette smokers will switch to snus in U.S. than in Sweden, even with the change in warning labels proposed for Swedish snus.
6. Evidence of consumer use of smokeless tobacco in the U.S. suggests it is unlikely that the proposed change in warning labels would lead U.S. consumers to switch from cigarettes to Swedish snus. Longitudinal studies show no strong evidence that U.S. cigarette smokers switch to smokeless products. Instead, the research shows that smokeless tobacco may be a gateway to smoking, particularly among youth. The evidence also suggests that smokers in the U.S. often use smokeless in conjunction with smoking, particularly in places where smoking is prohibited, rather than switching entirely. Thus, smokeless tobacco is often used to maintain cigarette addiction among those who may otherwise have quit smoking. The issue of dual use

is pivotal because it is clear that there is no reduction of risk from use of Swedish snus unless smokers switch completely from cigarettes to snus.

7. The Swedish Match consumer perception survey offers no assurance that the proposed reduced risk message is more likely to lead smokers to quit smoking than to lead to increased dual use that will simply perpetuate their smoking and their risk of disease. Indeed, the survey failed to test whether consumers would understand from its proposed reduced risk message that the health benefits of snus depend on quitting cigarettes.

TPSAC Consideration of Swedish Match Application

Nothing in the Swedish Match amendments made publicly available casts doubt upon the conclusions of the Tobacco Products Scientific Advisory Committee that should be fatal to the Swedish Match application. These conclusions were reflected in the votes of TPSAC members at the conclusion of its April 9-10 meeting to consider the Swedish Match modified risk application. These conclusions are summarized here.

There was no consensus on TPSAC supporting a scientific basis for Swedish Match's proposal to omit the current statutory warnings on the risks of oral cancer, gum disease or tooth loss. Instead, TPSAC unanimously found that the science does not support the removal of the gum disease and tooth loss warnings and was sharply divided on the risks of oral cancer. On these issues of individual risk, TPSAC voted as follows:

1. Does the evidence support that these snus products do not pose risks of gum disease to individual users of these products? **TPSAC answered "no" by a vote of 8-0.**
2. Does the evidence support that these snus products do not pose risks of tooth loss to individual users of these products? **TPSAC answered "no" by a vote of 8-0.**
3. Does the evidence support that these snus products do not pose risks of oral cancer to individual users of these products? **On this issue, TPSAC divided 3 votes "no," 3 votes "yes," and 2 abstentions.**

In addition, on issues of the overall health risks from Swedish snus, there also was no TPSAC consensus supporting the scientific basis for the Swedish Match application. The key votes were as follows:

1. Does the evidence support the statement that health risks to individual users from using these snus products exclusively are "substantially lower" than the health risks from smoking cigarettes? **On this issue of relative risks, TPSAC was evenly divided, with 4 members voting "yes" and 4 voting "no".**

2. Does the evidence support that the proposed warning statement adequately communicates the potential health risks to individual users of these snus products? **TPSAC answered “no” by a vote of 8-0.**

It is particularly significant that TPSAC voted unanimously that the proposed warnings do not adequately communicate the potential health risks of Swedish snus.

TPSAC also reached conclusions on the relevance of epidemiological evidence from Sweden. The key votes on these issues were as follows:

1. Does the Committee believe that the epidemiological data from Sweden concerning tobacco use behavior provide relevant information on the likelihood that current tobacco users in the U.S. will switch to the use of these snus products? **TPSAC voted 6 votes “no,” 1 vote “yes,” and 1 abstention.**
2. Does the Committee believe that the epidemiological data from Sweden concerning tobacco use behavior provide relevant information on the likelihood that non-users of tobacco in the U.S. will initiate the use of these snus products? **TPSAC answered “no” by a vote of 5 votes “no” with 3 abstentions.**

Thus, on the two key issues bearing on the population-wide effect of the proposed warning changes, TPSAC found the “Swedish experience” unhelpful in predicting those effects in the U.S. In addition, **TPSAC voted 7-1 that the Swedish Match application did not include sufficient information on the behavioral aspects of these snus products among the U.S. population.**

Finally, TPSAC addressed the impact on consumers of Swedish Match’s proposal to convey modified risk information in a warning label:

From the perspective of enabling consumers to understand the modified risk information in the context of total health, does the Committee believe it is appropriate to include modified risk information within the context of the required warning label as opposed to in a statement separate from, and in addition to, the warning label? **TPSAC answered with 6 votes “no,” with 1 abstention.**

Thus, TPSAC concluded that including a modified risk message as part of a warning label, as proposed by Swedish Match, would not enable consumers to understand that message.

In summary, TPSAC found that the scientific evidence (1) does not support the deletion of health warnings on Swedish snus products, as sought by Swedish Match; (2) does not indicate that the proposed warning statements adequately communicate the health risks of Swedish snus to individual users; (3) does not support the relevance of the Swedish experience, either in assessing the likelihood of U.S. smokers switching from cigarettes to Swedish snus or in assessing the likelihood that non-users of tobacco in the U.S. will initiate the use of Swedish

snus; (4) as provided by Swedish Match, does not provide sufficient evidence on the behavioral aspects of the use of Swedish snus in the U.S.; and (5) does not support the appropriateness of including modified risk messaging in warning labels.

The amendments to the Swedish Match application throw no doubt on the validity of these TPSAC conclusions, which should be fatal to the application.

Respectfully submitted,

Campaign for Tobacco-Free Kids

Tobacco Control Legal Consortium