FDA questions evidence for lower-risk tobacco product

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Credit: Vera Kratochvil/public domain

U.S. health regulators have questions about the data submitted by tobacco maker Swedish Match in its bid to become the first company to market a smokeless tobacco product as less harmful than cigarettes.

Food and Drug Administration scientists say they have "concerns" about how the company studied its snus tobacco product and its proposal to modify cancer warning language on the packaging.

Snus are teabag-like pouches or loose tobacco that users stick between their cheek and gum to absorb nicotine. They are popular in Scandinavian countries and are part of a growing smokeless tobacco market in the U.S.

The FDA has scheduled a two-day meeting to review Swedish Match's data intended to show that snus do not carry the same risks of mouth cancer, gum disease and tooth loss as other tobacco products.

In an application filed in June, Swedish Match, whose North American headquarters is in Richmond, Virginia, proposed a new warning emphasizing that snus are less risky than smoking: "No tobacco product is safe but this product presents substantially lower risks to health than cigarettes."

But in a scientific review posted Tuesday, FDA staff question whether that language "adequately reflects the health risks of using snus."

Swedish Match also wants FDA clearance to remove a warning about mouth cancer from its product. But agency staffers note that the studies submitted by the company may have underestimated cases of mouth cancer as users quit using snus.

Among other changes, Swedish Match wants the FDA to permit dropping another warning that smokeless tobacco products can cause gum disease and tooth loss. But regulators note a number of shortcomings with the company studies of that issue, including small populations that were often made up of adolescents and young adults. Additionally regulators say the company "does not provide an argument as to why it is biologically plausible that effects of snus on gum disease and tooth loss would be significantly different from other smokeless tobacco products."

The agency will ask an advisory panel to weigh in on these and other issues. The FDA is not required to follow the advice of the group, which is composed of outside experts specializing in tobacco control, public health and cancer care.

The advisory panel's review and FDA's ultimate action on the application are being closely watched by both the public health community and tobacco companies, which are looking for new products to sell as they face declining cigarette demand due to tax increases, health concerns, smoking bans and social stigma.

Under a 2009 law, the FDA was given authority to evaluate tobacco products for their health risks and approve ones that could be marketed as safer than others. The agency has received 17 applications for such products, according to an agency spokeswoman, but none has been given the OK yet. Ten are currently pending review. Agency officials have previously noted that some tobacco products could pose less of a health risk to users than smoking.