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FDA panel opposes dropping warnings from tobacco pouch (Update)

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Government advisers recommended against a proposal by Swedish Match to market its smokeless tobacco pouches as less harmful than cigarettes and other tobacco products.

The company has asked the Food and Drug Administration for permission to remove or revise several warning labels on the pouches, called snus. It's the first request the FDA has considered publicly since it gained authority to regulate tobacco products in 2009.

But a panel of FDA advisers said overwhelmingly Friday that company data do not support relaxing warning labels on snus.

The eight-member panel voted unanimously that the company's application does not show that snus lack the same risks of gum diseases and tooth loss as other smokeless tobacco products. Swedish Match has asked the FDA to drop those warnings from its U.S. offerings, including brands such as Longhorn, Timber Wolf and General snus.

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. Swedish Match holds about 9 percent of the U.S. market, which is dominated by Richmond, Virginia-based Altria Group Inc., parent company of Phillip Morris.

Stockholm-based Swedish Match also wants the FDA to certify new

language that its snus have "substantially lower risks to health than cigarettes." The company points to studies showing that snus are not associated with lung cancer, lung disease and other ailments tied to cigarettes.

But panelists said the company's warning language oversimplifies the issue, since some snus users also smoke, exposing themselves to negative effects from both products. Panelists voted unanimously that the company's revised language did not adequately describe the health risks of snus, including pregnancy complications such as early delivery and stillbirth.

"I did not think the warning was clear, it did not adequately convey the health risks that are relevant," said Dr. Philip Huang, committee chair and an official with the health department of Travis County, Texas.

The FDA is not required to follow the advice of the panel, which is composed of experts specializing in tobacco control, public health and cancer care.

Anti-tobacco advocates said the FDA panel made the right call and that Swedish Match missed the mark in its presentation.

"The only health benefits of snus come if smokers take up the product and give up smoking and Swedish Match never addressed that issue," said Matthew Myers, president of the Campaign for Tobacco-Free Kids.

A day earlier Swedish Match representatives presented findings suggesting that Swedish uptake of snus has helped reduce diseases linked to cigarettes there.

But panelists pointed to key differences between the U.S. and Sweden, including Sweden's ban on tobacco advertising and a population that is

less diverse racially, economically and culturally than the U.S.

The advisory panel meeting 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 have been given the OK yet. Agency officials have previously noted that some tobacco products could pose less of a health risk to users than smoking.