FDA denies bid to drop some warnings from tobacco pouches (Update)

December 14 2016, by Matthew Perrone

This Oct. 14, 2015, file photo shows the Food and Drug Administration campus in Silver Spring, Md. The FDA announced Monday, Dec. 12, 2016, that it denied the request by Swedish Match to remove several health warnings from its smokeless tobacco pouches, though regulators left open the possibility for other labeling changes it seeks. It's the first decision of its kind handed down by the agency since it gained authority to review the relative risks of tobacco products in 2009. (AP Photo/Andrew Harnik, File)

U.S. health officials have rejected an attempt by a Swedish company to
remove several health warnings from its smokeless tobacco pouches, though regulators left open the possibility for other labeling changes it seeks.

The Food and Drug Administration announced Wednesday that it denied the request by Swedish Match to remove warnings about gum disease and tooth loss from its chewable pouches, called snus. It's the first decision of its kind handed down by the agency since it gained authority to review the relative risks of tobacco products in 2009.

The agency said scientific evidence shows that snus are linked to gum disease and tooth loss, similar to other smokeless tobacco products.

Despite rejecting one of the company's requests, FDA regulators said they are still considering two other proposals, including one to remove a warning related to mouth cancer. The head of the FDA's tobacco center encouraged Swedish Match to resubmit its application.

"The door is absolutely open and we've tried to show the steps they would need to take to come back to us," said Mitch Zeller, director of the FDA Center for Tobacco Products, in an interview.

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., where Swedish Match competes with snus from Altria Group., the parent company of Philip Morris.

The agency delayed making a decision on two other labeling changes that would allow Swedish Match to market its pouches as less harmful than similar products. The agency requested additional information from the company about its request to remove a warning about mouth cancer and to add a new claim that snus have "substantially lower risks to health
than cigarettes." Currently snus and other smokeless tobacco products must state on their labeling that they are "not a safe alternative to cigarettes."

In its release Wednesday, the FDA suggested it could support those changes if the company updated its request with additional data and evidence.

Swedish Match said in a statement that the FDA's guidance is "encouraging" and "will be critical" in helping the company obtain an updated label. The company is headquartered in Stockholm with U.S. operations in Richmond, Virginia.

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. Wednesday's announcement marked the FDA's first completion of such a request. Swedish Match submitted its application in June 2014.

"While this took us a while it shows that the system works," said Zeller.

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