

Virginia tobacco maker seeks new FDA designation

January 4 2011, By MICHAEL FELBERBAUM , AP Tobacco Writer

(AP) -- Tobacco maker Star Scientific Inc. says it has developed a moist smokeless tobacco with lower levels of cancer-causing chemicals than any other tobacco product now on the market.

The small Virginia company, which sells tobacco lozenges that dissolve in the mouth, said Tuesday it plans to soon ask the [Food and Drug Administration](#) for approval to sell the new item as safer than any competing product.

Star Scientific hopes its products will be the first the federal agency allows to be marketed as less harmful than other forms of tobacco.

Star Scientific says the "modified-risk" label that the FDA is developing belongs on the new Stonewall Moist-BDL because it contains 90 percent to 99 percent less tobacco-specific carcinogens than other smokeless tobacco products.

The federal Centers for Disease Control says that, because smokeless tobacco contains 28 cancer-causing agents, it is not a safe substitute for [smoking cigarettes](#). But a 2007 report from the United Kingdom's Royal College of Physicians suggests that some smokeless tobacco products are less harmful than cigarettes.

Curtis Wright, senior vice president and clinical director for Star Scientific's subsidiary Rock Creek Pharmaceuticals, said the new product could "substantially" reduce the amount of carcinogens that

moist tobacco users encounter.

The FDA is still considering similar applications from Star for two of its dissolvable tobacco products. Star has sold dissolvable tobacco under the Ariva and Stonewall brands since 2001.

The applications highlight a philosophical debate over how best to control tobacco. Some health advocates and officials say there's no safe way to use tobacco. Others say smokeless tobacco, electronic cigarettes and other products with lower levels of carcinogens than traditional tobacco products can improve public health by reducing the number of people who smoke.

Cigarette sales have been falling for years due to tax increases, health concerns, smoking bans and social stigma. Bigger tobacco companies are watching the FDA response to Star's applications for clues about what products they'll be able to sell to replace the revenue from cigarettes.

The FDA won the authority in 2009 to evaluate tobacco products and approve some as safer than others. But it may take the agency another year to iron out its guidelines for such products, and approvals would come only after guidelines are set.

About one in five Americans smoke, down from one out of four in 1995, according to the Centers for Disease Control and Prevention. About 3 percent of American adults use smokeless [tobacco](#); the segment has grown about 7 percent in recent years.

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