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F.D.A. Orders 4 Bidi Cigarette Brands Removed From Shelves

By CATHERINE SAINT LOUIS February 21, 2014

The Food and Drug Administration on Friday ordered four tobacco products removed from the market, the first time the agency has done so since being given the legal authority in 2009.

"It's a big deal," said Matthew L. Myers, the president of the Campaign for Tobacco-Free Kids, an advocacy group. "This is first time the F.D.A. has ever ordered a product to be removed from the market for broad public health concerns."

"It's also significant that they did so because the manufacturer was unable or unwilling to provide sufficient evidence that the product didn't raise new or different concerns for public health," he added.

Since June 2013, the F.D.A. has <u>rejected 13 new tobacco products</u> because agency scientists believed they posed health risks above and beyond comparable products already on the market.

Agency officials said that four cigarette brands made by Jash International <u>may no longer be domestically sold, distributed or imported</u>. They are Sutra Bidis Red, Sutra Bidis Menthol, Sutra Bidis Red Cone and Sutra Bidis Menthol Cone. In 30 days, the F.D.A. will begin seizing any goods that remain on shelves.

The unconventional cigarettes are bidis — thin, hand-rolled cigarettes stuffed with tobacco, wrapped in leaves from a tendu tree and sometimes tied with a colorful string. Popular in India, bidis are not widely smoked here, but their novelty appeals to some adolescents.

In 2012, the Centers for Disease Control and Prevention reported that <u>1.7 percent of middle school students and 2</u> percent of high school students were bidi smokers.

Mitchell Zeller, director of the Center for Tobacco Products at the F.D.A., called today's action "historic" and said, "It shows the role and the power of regulation."

David B. Abrams, executive director of the Schroeder Institute for Tobacco Research and Policy Studies at Legacy, a nonprofit group in Washington, said the ruling was significant for two reasons.

"We don't want any tobacco products out there that we don't know what their ingredients are," he said. "But also because we don't want anything out there that's inexpensive, and therefore easier for kids to get a hold of."

The F.D.A. action comes on the heels of the latest surgeon general's report, published last month, which noted that modern cigarettes <u>have increased the risk of the most common type of lung cancer</u>, because of changes in design and composition since the 1950s.

The report also noted that levels of some carcinogens in cigarette smoke have increased as manufacturing processes have changed.

"Some additives and flavorings at low levels enhance appeal, taste and addictiveness, but when they burn they are carcinogens," said Dr. Abrams, a professor at Johns Hopkins Bloomberg School of Public Health.

Today's action is an attempt to stop undocumented ingredient changes, Dr. Abrams said. "The F.D.A. is saying, 'You can't do this. We want to know down to the nanogram what little things you're putting in cigarettes.'"

The Sutra brands were removed not because of their flavorings, but because of the company's failure to provide ingredient information. Still, the removal of two menthol brands raises a larger question: whether menthol in cigarettes should be banned. "It's long overdue," Dr. Abrams said.

Kenneth E. Warner, a professor of public health at the University of Michigan, said that it was "very encouraging" to see the F.D.A. exerting its authority, but that today's action was mostly a "symbolic victory."

Bidi cigarettes are not widely used in United States, he said, and Jash International is "an easy target, because it's not a major tobacco company."

The F.D.A. cannot ban nicotine, but it does have the authority to lower nicotine to nonaddicting levels.

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