

## FDA allows two new cigarettes to hit market

June 25 2013, by Steven Reinberg, Healthday Reporter



It's first such action since agency was given regulatory control over tobacco in 2009.

(HealthDay)—Using its newfound authority to regulate tobacco, the U.S. Food and Drug Administration has for the first time allowed two new cigarette brands to hit the market.

The agency also rejected requests to allow the marketing of four other new <u>tobacco products</u> it did not name.

The FDA first gained regulatory purview over tobacco products in 2009 under the Family Smoking Prevention and Tobacco Control Act.

Therefore, "new tobacco products under FDA's authority cannot come to market without FDA's review," FDA commissioner Dr. Margaret Hamburg explained during an afternoon news conference Tuesday.



The cigarettes the FDA allowed are both Lorillard Tobacco Co. products—Newport Non-Menthol Gold Box 100s and Newport Non-Menthol Gold Box.

Because these products are essentially "equivalent" to approved products already being marketed, they "do not raise new questions of public health" and can be sold to U.S. consumers, explained Mitchell Zeller, director of FDA's Center for Tobacco Products.

He stressed that allowing the sale of these cigarettes does *not* mean that they are safer or less harmful than <u>cigarettes</u> already on the market.

"An FDA product order is not a finding by the FDA that the product is considered safe or safer than its predicate product, or less harmful in general," he said. "In addition, the companies cannot say their products are 'FDA-approved.""

The agency rejected four new tobacco products because they determined that they were not similar enough to existing products already on the market.

"The applicant [also] did not adequately show that the new product did not raise new questions of public health," Zeller said at the news briefing.

By law, the FDA cannot release the names of the manufacturers of the rejected products or what types of products they were, he added.

**More information:** For more on tobacco regulation, visit the <u>U.S.</u> Food and <u>Drug Administration</u>.

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