FDA: Agency must review tobacco products

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(AP) -- The Food and Drug Administration says it must review tobacco products that were introduced or changed over the last four years in order for companies to keep selling them.

The agency on Wednesday issued guidance to the tobacco industry outlining how to apply for review.

Tobacco makers have until March 22 to prove that the cigarettes or other tobacco products are "substantially equivalent" to ones commercially available before Feb. 15, 2007. That means the ingredients and design are similar and do not raise different public health concerns.

The FDA said it may deny an application if the product poses an increased health risk to users or causes nonusers to start using tobacco.

Companies planning to introduce new products after the March deadline must get approval from the FDA in the form of a market order before they can be sold.

Officials say the requirements are part of a 2009 law giving the FDA the ability to regulate tobacco. They are meant to ensure that new tobacco products are evaluated by the FDA before they are allowed to enter the marketplace.

"Up till now tobacco products had been the only mass-consumed products for which users do not know what they're consuming," Dr. Lawrence Deyton, director of the FDA's Center for Tobacco Products,

said in a conference call. "No longer will changes to products consumed by millions of Americans be made without anyone knowing."

Still, Deyton warned that "no known existing tobacco product is safe," and FDA approval for a company to sell the product does not make it safe.

"These products will not be safer, but we are required by this law to not allow even more dangerous products to cause further harm to those Americans who use tobacco products," he said.

The agency estimates that, under its definition, about 230 new products are introduced every year - a number it expects will continue going forward, according to its submissions in the Federal Register. But, the FDA said, additional regulation may lead tobacco makers to slow that number in the future.

The FDA won the authority in 2009 to regulate tobacco products, including the ability to ban certain products, regulate marketing, reduce nicotine in tobacco products and block labels such "low tar" and "light." Tobacco companies also will be required to cover their cartons with large, graphic warnings.

About 46 million, or one in five Americans, smoke and about 3 percent of American adults use smokeless tobacco, according to the Centers for Disease Control and Prevention. Tobacco use in the U.S. also is responsible for about 443,000 deaths per year.