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FDA to require substantial equivalence reviews for new tobacco products
Certain products introduced or changed in the United States since Feb. 15, 2007 to be reviewed

The U.S. Food and Drug Administration announced today that certain tobacco products introduced or changed after Feb. 15, 2007 must be reviewed by the agency. In FDA guidance published today, the agency outlines a pathway for marketing a product whereby the company marketing the product must prove that it is "substantially equivalent" to products commercially available on Feb. 15, 2007.

"Substantially equivalent" means the products must be the same in terms of ingredients, design, composition, heating source and other characteristics to an existing, single predicate product or have different characteristics, but not raise different questions of public health.

"This specific part of the law is meant to ensure that new tobacco products are evaluated by the FDA before they are cleared to enter the marketplace. The law requires FDA to carefully examine the impact those products may have on the public health," said Lawrence R. Deyton, M.S.P.H., M.D., director of the agency's Center for Tobacco Products. "Products that are equivalent to those which were on the market on February 15, 2007, may be cleared to go to market; those that are not may be prohibited from the market, or withdrawn if they are already available, if the changes raise different questions of public health."

"This piece of the Tobacco Control Act protects the health of all Americans," said Health and Human Services Secretary Kathleen Sebelius. "It does this by setting a clear deadline for tobacco companies to provide important product information to the FDA so the agency can then begin evaluating tobacco products for any potential new risks to public health."

The Family Smoking Prevention and Tobacco Control Act, which became law June 22, 2009, granted the FDA regulatory authority over tobacco products. Generally, the law allows the FDA to deny applications for new products if marketing the product poses a harm to public health. FDA may deny applications for substantial equivalence if the marketing of the modified product would raise different questions of public health. An example would be a product that poses an increased health risk to users of the product or to nonusers by causing more of them to start smoking.

In general, in order to continue to market these products, manufacturers of tobacco products that were introduced or changed after Feb. 15, 2007, which include cigarettes, roll-your-own tobacco and all smokeless products must apply for equivalency by Mar. 22, 2011. Manufacturers intending to introduce new products into the market after that date must submit an application for the new product and obtain a marketing order from the FDA before introducing the product to market.

"No known existing tobacco product is safe, and a market order issued by the FDA for these products should never be interpreted as such" said Deyton. "One of the FDA's missions required by this new law is to ensure new products do not pose an increased threat to the American public. 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."

FDA also intends to issue guidance on materials the agency believes would show that a tobacco product was on the market on Feb. 15, 2007, as well as hold a Webinar Series in order to provide more assistance to manufacturers.

Information on the Webinar Series (available soon) and application process details and answers to questions can be found here[1].

The FDA welcomes public comment on this issue. Go to www.regulations.gov[2] and insert docket number FDA-2010-N-0646 into the "search" box and follow the prompts.

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