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May 2017: Web Statement

Web Statement – May 3, 2017

The U.S. Food and Drug Administration is announcing information about the outstanding compliance deadlines related to the May 2016 final rule that extended the agency's authority to additional tobacco products, including e-cigarettes, cigars, hookah tobacco and pipe tobacco, among others.

In lawsuits regarding the final rule, the FDA has stated that it will defer enforcement of all future compliance deadlines under the rule for electronic nicotine delivery systems (ENDS) such as e-cigarettes, cigars, and pipe tobacco for three months. In light of this, the FDA also intends to defer enforcement of all future compliance deadlines for all categories of newly regulated products for three months and plans to issue guidance describing its position in the near future.

This concerns deadlines set for May 10, 2017, or later, including those for manufacturer submission of cigar warning label plans, registration and listing, ingredient listing, health documents, substantial equivalence exemption requests, substantial equivalence applications, premarket tobacco product applications (PMTAs), and harmful and potentially harmful constituent (HPHC) reports.

This does not apply to provisions of the final rule where compliance deadlines already have passed, such as mandatory age and photo-ID checks to prevent illegal sales to minors.

This extension will allow new leadership at the FDA and the Department of Health and Human Services additional time to more fully consider issues raised by the final rule that are now the subject of multiple lawsuits in federal court.

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