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FDA Deadline for Premarket Review Extended to September 2020

E-Cigarettes (https://countertobacco.org/category/e-cigarettes/), FDA (https://countertobacco.org/category/fda/), Product Availability (https://countertobacco.org/category/product-availability/)
April 29, 2020

Tobacco manufacturers now have an additional four months (https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-court-grants-fdas-request-extension-premarket-review-submission-deadline) to submit their e-cigarette and vaping products for premarket approval with the Food and Drug Administration (FDA). As part of a federal court-mandated order, tobacco manufacturers would have been required to file premarket applications to the FDA by May 12, 2020; now they will have until September 9, 2020.

The premarket approval process allows the FDA to weigh the risks and benefits of products on the health of the American public. Tobacco manufacturers are required to submit applications to sell any product that was not already on the market as of August 2016. If an application is not submitted or if the FDA determines that the product is not appropriate for protection of the public's health, the manufacturer cannot legally sell the product. However, up until the application deadline and throughout the 12 month review process, the products are allowed to stay on the market.

This is not the first time the deadline has been extended – read more about the timeline in "Extensions and an Epidemic: The FDA's Gatekeeping Authority for E-Cigarettes (https://www.publichealthlawcenter.org/sites/default/files/resources/FDA-Gatekeeping-Authority-ECigarettes-2019.pdf)" from the Public Health Law Center.

NEED GUIDANCE?