THE PATHWAY TO A ROBUST MARKET FOR COMPLEX DRUG-DEVICE GENERIC COMBINATION PRODUCTS

JUNE 2017

FDA prioritizes the review of generic drug applications that reference a branded drug with less than three approved generic drugs and releases the guidance: "Comparative Analyses and Related Comparative Use Human Factors Studies for a Drug-Device Combination Product Submitted in an ANDA".

OCTOBER 2017

FDA announces the Drug Competition Action Plan to help reduce drug prices and improve consumer access to generic drugs, and three additional draft guidances aimed at providing clarity around the submission of Abbreviated New Drug Applications (ANDAs).

DECEMBER 2017

FDA sets a new record by approving 1,027 new generic drugs in 2017, 214 more than their previous record of 813 set in 2016. Of these, 80 were "first generic" drugs – the first generic alternatives to a brand-name product.

The Office of Generic Drugs (OGD) issues 178 new product-specific guidances for generic drug development in 2017.

JANUARY 2018

FDA Commissioner Scott Gottlieb, MD, provides an update on the FDA's ongoing efforts to increase access to complex generic drugs in response to the GAO report "Generic Drugs: FDA Should Make Public Its Plans to Issue and Revise Guidance on Nonbiological Complex Drugs."

FDA releases draft guidance "Good ANDA Submission Practices Guidance for Industry."

APRIL 2018

FDA releases annual report, Drug Safety Priorities 2017, which explains how CDER's Clinical Safety Surveillance staff monitors generic drug use in the marketplace to flag early safety concerns and is addressing post-marketing safety concerns related to complex generic drug-device combination products.

OCTOBER 2018

More than 20 FDA representatives will speak at DIA's *Complex Drug-Device Generic Combination Products Meeting*, October 9-10 in Silver Spring, MD.

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