Exhibit 1. FDA Actions to Promote Competition and Transparency

ISSUE	ANNOUNCEMENT	DATE ANNOUNCED	ACTION TAKEN AS OF MARCH 31, 2018
Sole Source Markets	FDA will maintain a public list of drugs without competition	June 2017	The list of off-patent, off-exclusivity branded drugs without approved generics was published in June 2017 and updated in December 2017. FDA will continue to update the list periodically.[9] This was also a requirement in the FDA Reauthorization Act of 2017 (FDARA).[10]
Abbreviated New Drug Application (ANDA) Process	FDA will institute expedited and priority reviews for abbreviated new drug applications (ANDAs) or generic drug applications where there is a lack of competition	June 2017	FDA began expediting these reviews in June 2017. In November 2017, FDA expanded this policy by creating a new category of applications eligible for priority review. FDA will prioritize applications likely to be ready for approval upon or shortly after the expiration of the 180-day exclusivity period that is awarded to a first-to-file ANDA.[11]
	FDA intends to improve the application process for manufacturers to apply for generic drug approval. Will publish guidances for requesting meetings with FDA, including before a manufacturer prepares and submits an ANDA up through the entire process, and for enhanced communication between manufacturers and FDA[12]	October 2017	Draft guidances not yet final
	FDA will improve submission and review of generic drug applications by publishing draft guidance highlighting best practices for manufacturers in submitting an ANDA and guidance on how FDA staff assess ANDAs[13]	January 2018	Draft guidance not yet final
	FDA intends to increase overall efficiency of generic drug reviews by increasing productivity, conducting reviews in a timely manner, and keeping costs low to file a generic application[14]	January 2018	No action to date
	FDA will publicize plans to increase access to complex generic drugs by releasing "sameness" requirements for ANDAs and guidance on drug–device combination products[15]	January 2018	No action to date
Risk Evaluation and Mitigation Strategies (REMS)	FDA will eliminate misuse in REMS by publishing draft guidance to streamline the submission and review process for shared system REMS[16]	November 2017	Draft guidance not yet final
Anticompetitive Behaviors	FDA will work with other agencies to identify anti-competitive practices	November 2017	In the 2018 strategic plan, FDA announced plans to establish an interagency working group to explore areas where FDA can more closely collaborate with FTC.[17] No further action to date.
	FDA will identify and address manufacturers' behaviors that delay generic drug competition[18]	January 2018	No action to date
Citizens Petitions	FDA will evaluate use of Citizens Petitions in blocking generic drug entry[19]	January 2018	No action to date
Biosimilars	FDA stated it will introduce its new Biosimilar Innovation Plan to facilitate approval and adoption of biosimilars[20]	January 2018	No action to date
	FDA is educating providers on biosimilars	October 2017	Campaign has been implemented. FDA will conduct additional research with health care professionals to learn more about the types of information providers need to properly communicate with their patients about biosimilars.[21]
Orphan Drugs	FDA is addressing loopholes within the Orphan Drug Modernization Action Plan. This includes publishing draft guidance that states it will no longer grant orphan drug designation to drugs for pediatric subpopulations of common diseases unless the use of the drug in that subpopulation meets the regulatory criteria for an orphan subset or unless the disease in the pediatric subpopulation is considered a different disease from the disease in the adult population.[22]	June 2017	Draft guidance not yet final
	FDA is making orphan designation requests more efficient	February 2018	FDA started a pilot project of a new electronic fillable form to make submission requests easier to submit and review[23]
	FDA is incorporating patient experience into regulatory discussions on orphan drugs	February 2018	FDA entered into a memorandum of understanding with the National Organization of Rare Diseases[24]
Compounding	FDA will restrict compounding of drugs that are essentially copies of FDA-approved drugs	January 2018	Two guidances explaining the agency's policies on the "essentially a copy" provisions of sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act are final[25]

Source: Henry Waxman et al., *What Commissioner Gottlieb's FDA Is Doing to Lower Prescription Drug Prices and Steps Congress Can Take to Help* (The Commonwealth Fund, April 2018).