LETTER FROM THE COMMISSIONER

I am pleased to present the FY 2020 Food and Drug Administration (FDA) Budget. FDA holds critical responsibility for ensuring the safety, effectiveness, and security of human and animal drugs, biological products, and medical devices; ensuring the safety of our nation's food supply, cosmetics, and radiation-emitting products; and regulating tobacco products.

Our mission impacts the life of every American, every day. Our FY 2019 accomplishments illustrate our dedication to protecting and promoting the health of the public we serve. Select, notable accomplishments include:

- Taking New Actions to Combat the Opioid Crisis – FDA began implementing the Opioid Policy Work Plan by accomplishing a broad array of scientific advances and regulatory actions. This work includes encouraging more appropriate prescribing to decrease exposure to opioids and prevent new addiction, as well as our initiatives to advance innovations in both novel pain therapies and better treatments to help those with opioid use disorder. For example, in 2018, FDA took steps to address concerns regarding intentionally misusing and abusing high doses of loperamide (Imodium), an anti-diarrhea medicine. FDA also took new steps to expand the use of safe and effective, FDA approved treatments for opioid use disorder, and the agency approved Lucemyra (lofexidine hydrochloride), the first non-opioid treatment for the mitigation of withdrawal symptoms associated with abrupt discontinuation of opioids. Our efforts to combat this public health emergency also extend to stopping the spread of illicit opioids and further securing all aspects of the supply chain for legitimate medications, including opioids. FDA focused new efforts on interdiction work to stop the flow of illegal controlled substances, including increased support of the Port of Entry (Imports) program, resulting in 91 arrests that led to 73 convictions. FDA also took new steps to expand its efforts to stop illegal opioid sales online, including efforts to limit the misuse and abuse of legally marketed opioid drugs by issuing warning letters to the marketers and distributers of 12 fraudulent opioid cessation products and to 17 online networks illegally marketing unapproved opioids. Additionally, FDA issued 21 abuse complaints to website registrars and registries for sites offering for sale opioids, as well as cancer and antiviral drugs. Furthermore, FDA solicited stakeholder and patient insights on approaches that address the crisis aggressively and protect patient needs.

- Fostering Drug Competition – FDA implemented the Drug Competition Action Plan to promote robust generic drug entry as a way to foster competition and lower drug prices. We focused new efforts on expanding competition to complex drugs that are no longer protected by patents or other exclusivities, and we approved the first generic version of the epinephrine auto-injector, which treats life-threatening allergic reactions. Our approval gives patients access to a lower-cost option and helps to protect against potential drug shortages. We approved seven biosimilars in 2018, a record for the number of biosimilar approvals in a single calendar year, and also released the Biosimilar Action Plan to continue to enhance competition for biologics and streamline the development of biosimilars.

- Advancing Food Safety and Nutrition – FDA launched its Nutrition Innovation Strategy to leverage nutrition as a tool to reduce the burden of chronic disease, and we took steps to empower consumers with nutrition information by supporting retail food establishments in meeting menu labeling

requirements. We also furthered implementation of the FDA Food Safety Modernization Act (FSMA) that builds proactive safety approaches into the production of human and animal foods.

- Developing a Comprehensive Plan for Tobacco and Nicotine Regulation – FDA took new action to reduce the morbidity and mortality associated with tobacco use, seeking input on potential public health benefits of limiting nicotine in cigarettes to minimally or non-addictive levels, and advancing new steps to warn youth about the risks of electronic cigarettes and limit the access and appeal of e-cigarette products to children. We also took the largest coordinated enforcement effort in FDA's history and issued more than 1,300 warning letters and fines to retailers who illegally sold e-cigarette products to minors during a nationwide, undercover blitz of brick-and-mortar and online stores.

The FY 2020 Budget will allow FDA to continue to deliver high-impact results that help Americans every day. FDA is requesting a total of $6.1 billion; an increase of $643.1 million compared to the FY 2019 Annualized Continuing Resolution (12 percent increase). FDA will invest in initiatives focused on the most urgent priorities, including efforts to:

- Reduce the Burdens of Addiction Crises that are Threatening American Families by reducing harms from opioids and reducing youth tobacco use;

- Foster Competition and Innovation by supporting production of quality compounded drugs, expanding FDA's capacity to review human food and animal feed ingredients, and continuing to implement the 21st Century Cures Act;

- Empower Consumers and Patients by continuing to support patient-focused medical product development, support medical innovation, provide consumers with information about healthy choices using the most up to date science, and modernize regulation and oversight of dietary supplements;

- Strengthen Science and Efficient Risk-Based Decision Making by advancing food safety, transforming medical device safety, ensuring the safety of the blood supply, and investing in FDA's capacity to facilitate the development and availability of medical countermeasures to respond to chemical, biological, radiological, and nuclear threats and emerging infectious diseases as well as FDA laboratory safety activities.

New scientific advances give us more opportunities to reduce the burden of disease and advance the public health. FDA's FY 2020 budget request enables the agency to ensure that we will be well positioned to leverage these scientific opportunities to secure the safety and well-being of Americans.

Scott Gottlieb, M.D.
Commissioner of Food and Drugs