The Alliance for a Stronger FDA thanks the Subcommittee for its continuing support of the U.S. Food and Drug Administration (FDA).

As you consider FY 19 appropriations, we urge the Subcommittee to recognize the multiple opportunities for FDA to be a more effective protector of the public health, as well as a fairer and more efficient regulator. We are at a point where additional investment in FDA will result in substantial added value to the American public.

To accomplish this, we respectfully request that the FDA’s budget authority (BA) budget increase to at least $3.364 billion. This should include the President’s request for $432 million in additional spending, primarily on medical products programs and at least $50 million more than the FY 18 appropriated levels for food safety programs. This total would also include appropriating $70 million for the already-paid-for funding of the 21st Century Cures legislation.
The Alliance is a 150-member coalition of all FDA’s stakeholders—consumers, patients, health professionals, trade groups and industry. Our sole purpose is to advocate for increased appropriated resources for the FDA, an agency that oversees 100% of drugs, vaccines, medical devices, and personal care products and 75% of our nation’s food supply. Altogether, the products and industries regulated by FDA account for about 20% of all consumer spending in the United States, approximately $2.4 trillion.

We are very encouraged by the proposed $400 million increase for new medical product initiatives at CDER, CBER and CDRH and the proposed $18 million increase for medical product programs at the Center for Veterinary Medicine. Collectively, these represent cutting-edge opportunities to make the agency more efficient and more effective. We urge the Subcommittee to fund the President’s request.

Some of the highlights:

**Improved manufacturing technology can produce substantial return-on-investment.**

Good Manufacturing Practices (GMP) and Quality Systems Regulations (QSR) create valuable standards but can be inflexible and greatly add to the risks for a company trying to manufacture based on alternative approaches. As opportunities for innovation in manufacturing increase—both in drugs and devices--FDA wants to work with companies to create guidances, regulations and systems that enable change. The result is expected to be improved efficiencies, lower costs and the movement of more manufacturing back to the US.
**Building the outsourcing market to diminish shortages.** Outsourcing facilities can provide important medicines not otherwise commercially available. However, the requirements of the Act are rigorous and the industry needs help to meet their statutory obligations, protect consumers, and decrease drug product shortages.

**Using Real-World Evidence (RWE) to enhance regulatory decision-making.** RWE is still in its early stages, but has the potential to improve patient health, support pre-market evaluation and post-market safety, and make the FDA regulatory process (drugs and devices) more efficient. The agency needs funding to develop and expand data sources and analytical tools to collect and evaluate real-world evidence.

**Digital Health framework is outmoded:** FDA has been working with stakeholders to develop a risk-based model that allows digital health products to move to market more efficiently. Two benefits of an improved regulatory framework would involve better access to post-market data and the opportunity to focus more on the cybersecurity issues inherent in digital health.

**Rare Diseases present special challenges.** Despite the obvious success in development of therapies to treat rare diseases, there are a number of methodological challenges that need significant additional work. Notably, there are unresolved questions about the design of small clinical trials and the potential to simplify drug development for rare diseases through increased availability of natural histories.
**Modernize Generic Drug Development.** A new review platform is needed that will significantly modernize generic drug review from a text-based to a data-based assessment with structured submissions and FDA assessments. This more automated system will improve clarity for generic sponsors, making initial reviews more efficient, decreasing the risk of refuse-to-file letters, increasing the rate of first-cycle approvals, and greatly increasing overall efficiency.

The Alliance also urges the Subcommittee to add $50 million to the FY 18 enacted levels for existing food safety programs.

Since enactment of FSMA in 2011, FDA has worked collaboratively with the states, as well as consumer, public health, and food industry stakeholders to:

- advance implementation centered around seven foundational rules, and
- assure that imported and domestic foods are held to the same safety standards and domestic producers not placed at a competitive disadvantage.

The FDA will need increased funding in FY 19 to expand the scope of its successful state partnership program. Additionally, import safety remains a particularly high priority, as is the creation of the tools and the provision of training needed by regulated stakeholders to comply with the new federal standards.