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Contacts: Steven Grossman 1-301-539-9660
Ladd Wiley 202-549-3595

The President's FY 18 Budget Request Sustains FDA's Funding Needs; Raises Concerns With Further Increases in Industry Fees

Silver Spring, MD---The Alliance for a Stronger FDA, which unites consumers, patient groups and industry in advocating for Food and Drug Administration (FDA) funding, said today that the agency's ability to carry out its essential mission is threatened by the funding approach proposed in the President's FY 18 Budget Proposal.

The proposal would provide the FDA with \$ 5.1 billion in total funding, a higher level than in FY 17. The higher funding level, the Alliance said, reflects the Administration's view that FDA's programs need to be sustained and grow.

At the same time, the President's budget proposes to change the source of the funding by substantially increasing the amount raised through fees charged to the medical products industries, and reducing the amount that comes from taxpayers. User fees are already paying for nearly half of FDA's activities that the agency characterizes as supporting drugs, biologics, medical devices, and veterinary medicine.

"The Alliance believes, and the President would appear to agree, that FDA's responsibilities—safe and effective medical products and safe foods—are essential governmental functions," said Troy Zimmerman, Alliance President and Vice President for Government Relations at the National Kidney Foundation.

He added: "However, we are gravely disappointed that the budget proposal reduces the amount of FDA funding that comes from taxpayers. The agency provides public health and consumer protections that are essential to the American public, who expect that the agency is ensuring their safety in the routine, everyday uses of countless food and medical products."

Under the President's Request, the agency would see an \$871 million cut in the agency's taxpayer-funded budget authority (BA) appropriation and the replacement of those dollars with a proposed doubling of industry user fees.

"We are especially concerned because the Congress has made clear that these additional user fees will not be adopted," Zimmerman said. "Thus, the Administration has not proposed a viable pathway for the agency to avoid a 31% cut in FDA's BA appropriation."

"Although we appreciate that the President wants to increase the total amount of funding for the FDA, we do not think it is appropriate or feasible to lessen taxpayer financing of the agency's programs," said Ladd Wiley, Executive Director of the Alliance. "The primary beneficiary of the FDA's work is the American people and they should have the central role in funding the agency."

He added: “The President’s proposal is not realistic because Congress has already told the Administration that no additional user fee programs would be considered. In addition, user fees have always been intended to supplement the agency’s appropriation, never to replace it.”

FDA not only has ultimate responsibility for ensuring the safety for millions of products that represent about 20% of American consumer spending, but also has a rapidly expanding role in food and drug safety and innovative medical product development. To ensure that the agency can secure and retain the highly trained workforce required to carry out this mandate, more than 80% of the FDA’s budget is dedicated to its personnel needs.

“We are concerned that should the FDA, as a consequence of this proposed budget shift, become significantly underfunded, the agency will have to choose among important public health priorities,” said Kristin Stephenson, Alliance Vice President and Vice President of Policy and Advocacy at the Muscular Dystrophy Association. She added: “Beyond the needed investment in FDA’s core functions, sufficient funding is necessary to spur innovation and provide critical oversight initiatives for drugs, biologics, and food.”

The Alliance for a Stronger FDA is a multi-stakeholder advocacy group that unites patient groups, consumer advocates, biomedical research advocates, health professionals and industry to work to increase FDA’s budget authority appropriations. The Alliance is known for its detailed analysis of the FDA budget and has included a chart (below) that compares the administration’s current budget request to prior year funding. More information about the Alliance can be found at www.StrengthenFDA.org.

Initial ANALYSIS of the President’s Budget Request

(FY 17 and FY 18 budget documents are inconsistent, so all numbers are estimates)

	FY 17 Omnibus Approp. Bill¹	FY 18 President’s Budget Request	Annotation
BA---Total	\$ 2.759 billion	\$ 1.888 billion	Decrease \$.871 billion; 31% decrease
Food	\$ 1.318 billion	\$ 1.209 billion	8% decrease
BA---Med. Products	\$ 1.353billion ²	\$.648 billion ²	52% decrease
Uncharacterized	~\$.088 billion	~\$.031 billion	
User Fees	\$ 1.895 billion	\$ 3.226 billion	Increase \$1.331 billion
PDUFA, GDUFA, BsUFA, MDUFA	\$ 1.226 billion	\$2.404 billion	Congress Reauth. Leg.(+\$.371 billion) Pres. Req (adds another \$.804 billion)
Tobacco	\$.635 billion	\$.672 billion	By law (+ \$.037 million)
Animal user fees	\$.034 billion	\$.088 billion	Animal user fees (+\$.054 billion)
Misc. other fees	[\$.058 billion]	\$.058 billion	Non-Add in FY 17; Included in FY 18
Proposed User Fee	-----	\$.004 billion	Export certification—change in statute
Buildings & Facilities	\$.009 billion	\$.009 billion	
FDA BA/UF TOTAL	\$ 4.664 billion	\$ 5.116 billion	9% Increase; Potentially a Massive Cut

¹ President’s Request uses different numbers because its base year is the Continuing Resolution that ended April 28, 2017. This table uses the final FY 17 Omnibus Appropriations bill (Pages 28 and 29), with supplementary information from the FY 18 Major Activities Table in the President’s Request.

² Includes Cures Funding: \$.020 billion in FY 17 and \$.060 billion in Cures funding