What’s New In The FDA’s 2015 Budget?

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A few days ago, President Obama released his Fiscal Year 2015 Budget Message to Congress, which included a high-level summary of his proposed funding for the FDA. Then the White House is out with the full budget, complete with all of the nitty gritty details.

Although these budgetary times are difficult, the FDA received some good financial news. The president is requesting a $4.7 billion budget for FDA, an 8.1 percent increase over the 2014 budget that Congress passed earlier this year.

For ease in discussing a budget of such scope, we typically group budgetary line items into a few large categories. This year our categories are medical product safety (which also includes our premarket review activities) and food safety (which also includes cosmetics).

Most of the $61 million increase for medical product safety comes from increases that were written into the statute when Congress authorized each of the five-year user fee programs.

One new line item in the budget is $25 million to strengthen oversight of the pharmacy compounding industry. In 2012 there was a fungal meningitis outbreak that killed 64 people and infected over 750 others in 20 states. This outbreak was shown to be the result of compounded drugs – the combination of two or more drugs to create a custom medication – that were created in unsafe conditions. To better protect the American people, FDA stepped up activities within available resources and Congress passed the Drug Quality and Security Act, giving us new responsibilities and authorities, but without commensurate resources. The President’s proposed 2015 budget doesn’t provide FDA with a $25 million increase

to cover the agency's pharmacy compounding activities. The money is coming from trims "on the margin" to other portions of our medical product programs.

The food safety portion of the budget includes $263 million in increased funding — including $253 million to implement the landmark Food Safety Modernization Act or FSMA. That 2011 law provided FDA with the authorities and mandates to build a modern domestic and imported food safety system designed to prevent rather than react to food-borne illness. Every year, contaminated food sickens about 48 million Americans and kills about 3,000.

FDA estimated in 2012 that it would need $400 million to $450 million to implement FSMA. Since then, the agency has received $78 million and issued proposed rules for all seven of the foundational provisions of FSMA.

Most of the $253 million proposed for FY 2015 would come from new user fees for imported foods, imposed on the industry. It's worth noting that with current resources, we will still be able to issue the rules, but we won't be able to effectively implement them and improve food safety without new resources to retrain inspectors, provide guidance and technical assistance to industry, partner with state agencies and build the modern import safety system Congress mandated.

The budget contains one final broad category of note, promoting the development of products that can be used to prevent or protect the public from bioterrorism. These medical countermeasures promote readiness against deliberate and naturally occurring public health threats. The FY 2015 budget includes $25 million for this initiative, the same as in FY 2014.

The FDA delivers significant results that help Americans every day in many different ways. FDA's drug approval system continues to lead the world in both quality and speed. The agency approved 27 drugs that are entirely new to medicine in 2013, including advances in the treatment of rare forms of cancer and a virtual cure for Hepatitis C. The FDA approved a new flu vaccine, and a bird flu vaccine to be reserved in case of an outbreak. In addition to new drug approvals, the FDA has reduced the time it takes to review new medical devices. And the agency is promoting greater safety of cosmetic products. Finally, the FDA has made progress in carrying out new tobacco control legislation.

Americans rely on the FDA to keep their food and medical products safe and effective. The Fiscal Year 2015 budget contains the blueprint for how the FDA plans to accomplish this mission. We invite you to follow this link to peruse the details of the FDA budget [1] of greatest interest to you.

This blog originally appeared at the FDA Voice blog. You can find it by clicking here [2].

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