



March 15, 2012

Request for FY 13 Budget Authority (BA) Appropriations for FDA

The Alliance for a Stronger FDA is requesting FY 13 budget authority (BA) appropriations (non-user fees) for the US Food and Drug Administration of \$2.656 billion. This is a \$150 million increase (6%) over the FY 12 level.

FDA is unique—in that it is the only federal agency that touches every American multiple times each day. We rely on FDA for the safety of the foods we eat and the safety and effectiveness of the drugs and devices we use. Even beyond that, the agency oversees over-the-counter medicines, cosmetics, dietary supplements and the food and medicines taken by food-producing animals and pets.

FDA's mission and responsibilities continue to grow and additional funding is required to handle them.

An obvious source of agency growth is new legislation. In FY 13, FDA will be implementing the Food Safety Modernization Act (FSMA) and the Biologics Price Competition and Innovation Act (BPCIA). It will also have to start implementing programs, initiatives and requirements that Congress passes this year as amendments to the user fee reauthorization legislation.

Additionally, **most new demands on the agency do not come through legislation.** Drug shortages, a new food pathogen, the need for bio-defense products, new sources of imports, and the advance of science....all place strains on the agency to do more and new things, often on tight timeframes. Meantime, consumers, patients, industry, NIH, Congress and international regulatory bodies are asking FDA at all levels for greater interactions, improved clarity, and clearer proactive guidance.

Chief among the growing demands are the resources needed to handle **globalization**. For example:

- Nearly 40% of the drugs and 50% of the devices Americans use are made overseas
- About 70% of seafood and 35% of fresh produce in the U.S. comes from foreign countries
- Imported products come from more than 300,000 foreign facilities located in 200 countries

Also important are the ways in which **science is growing more complex**; thus, requiring more time, manpower and knowledge than in the past to perform a comparable activity (review an application for approval; evaluate a clinical trial, perform a field inspection, etc.). For example, FDA is deeply involved in the emerging field of nanotechnology, which is used in some foods and cosmetics and is proposed for use in other FDA-regulated products, including medicines.

FDA also has an important and often resource-intensive role in **promoting innovation**. FDA plays a key role in the innovation eco-system working closely with companies during product development to bring safe and effective new products to market. A strong, science-based, and well-funded agency can promote predictability in the regulatory environment so that firms can invest in new innovations and drive economic growth.

The Alliance's 200 members are comprised of consumer, patient, professional and research groups, companies, trade associations, and individuals who support increased appropriated funding for FDA. More information about the Alliance can be found at www.StrengthenFDA.org.



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Updated 3-14-12

User fees are not included in this chart

Function Budget authority only (non-user fees)	FY 12 Final	Alliance FY 13 Request for BA Appropriations + \$150 million above FY 12 appropriated levels (6% increase)	
			Examples of Public Health Needs
Food	\$ 866 million	\$917 M + \$51 million	<ul style="list-style-type: none"> Prevention-based food safety system Risk-based inspection system (inc. imports) Other food safety/FSMA implementation
Human Drugs	\$ 478 million	\$506 M + \$28 million	<ul style="list-style-type: none"> Regulatory science initiatives "Maintenance of effort" for biosimilars
Biologics	\$ 212 million	\$224 M + \$12 million	<ul style="list-style-type: none"> Address drug shortages \$7.7 million for outfitting new bldg. Advancing medical countermeasures
Animal Drugs/Feed	\$ 138 million	\$146 M + \$ 8 million	<ul style="list-style-type: none"> Food safety/FSMA implementation Import safety
Devices & Radiological Health	\$ 323 million	\$342 M + \$19 million	<ul style="list-style-type: none"> Regulatory science initiatives Improve capabilities in diagnostics
Natl. Ctr. For Toxicological Res.	\$ 60 million	\$ 62 M + \$ 2 million	<ul style="list-style-type: none"> Regulatory science initiatives Food safety/FSMA implementation
HQ, Officer. of Comm. & Other	\$ 154 million	\$164 M + \$10 million	<ul style="list-style-type: none"> Commissioner's China Initiative Food safety/FSMA implementation Regulatory science initiatives
Rent & Facilities Cost	\$ 266 million	\$290 M + \$24 million	Consistent with President's request for rent; includes \$10 million for outfitting new bldg.
SUBTOTAL, Salaries & Expenses	\$ 2.497 billion	\$2.651 billion + \$154 million	
Building and Facilities Repair	\$ 9 million	\$ 5 M - \$ 4 million	Consistent with President's Request
All BA approps Total (no user fees)	\$ 2.506 billion	\$2.656 billion + \$ 150 million	6% INCREASE FOR FDA ABOVE FY 12 BA APPROPRIATED LEVELS

- Proposed funding includes monies needed for the Commissioner's three new program requests:
 - China Import Safety Initiative,
 - Advancing Medical Countermeasures, and
 - outfitting the new CBER/CDER laboratory building
- Chart does not include user fees.
- Some variation due to rounding.

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