FDA Regulatory and Compliance Monthly Recap

FEBRUARY 2015

KEY FINDINGS

FY 2016 budget request reflects FDA's broadening scope of activities

The regulator's requested budget of $4.9 billion for the upcoming fiscal year represents a 9% increase from the enacted FY 2015 budget, with $147.7 million allocated for initiatives associated with what it calls "key areas," including improving the safety and quality of medical products, implementing a new food safety system and modernizing the FDA, as well as $277.2 million allocated for user fees.

The budget reflects the agency's expanded scope of activities – which has grown both as the number of imported food and medical products continues to increase, and through significant legislation like the Patient Protection and Affordable Care Act, the Food Safety Modernization Act, the FDA Safety and Innovation Act and the Drug Quality and Security Act.

Commissioner Margaret A. Hamburg said that the FDA is looking to expand on a number of fronts amid an "increasingly complex and scientifically demanding" regulatory landscape, and thus needs the appropriate resources. She noted in a letter posted on the FDA blog that the products her agency oversees account for more than 20 cents of every dollar that American consumers spend. Despite the regulator's vast mandate, however, Hamburg said that American taxpayers actually only contribute roughly $8 each, per year, to the budget.

In her letter, Hamburg wrote that the request includes a nearly $148 million increase in budget authority to concentrate on a number of areas, including several relating to medical product safety, such as:

- Addressing the growing threat of antibiotic resistance ($14.8 million increase);

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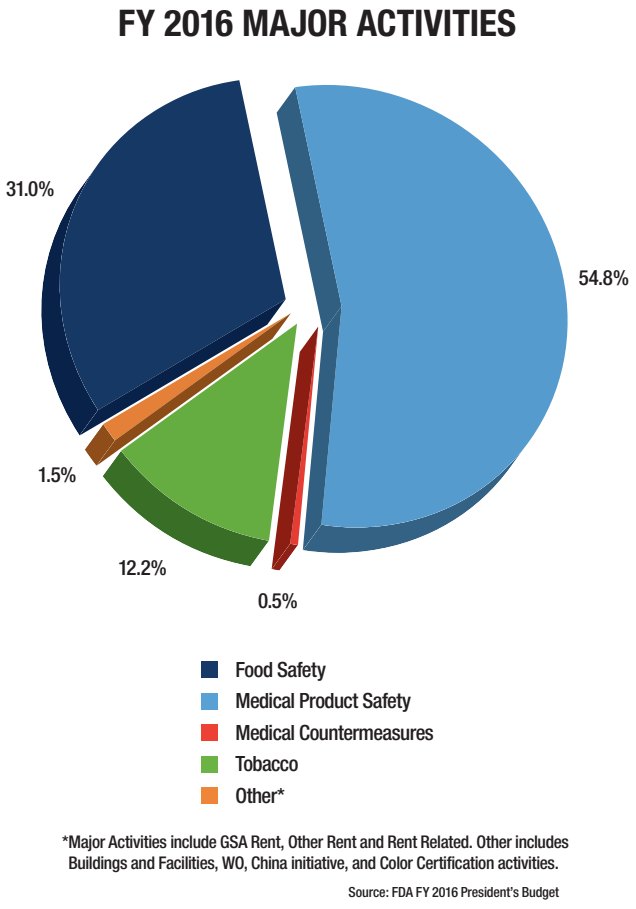
- Encouraging the development and appropriate use of reliable molecular and genetic diagnostics – precision medicine tools – to "personalize" the diagnosis, treatment and prevention of disease ($9.7 million increase);
- Implementing FDASIA requirements to improve medical product review and inspections ($5 million increase); and
- Addressing the safety of compounded drugs ($0.7 million increase).

The budget request also includes an anticipated 15% increase in user fee collections, with $277.2 million allocated to this revenue source.

According to the FDA's budget request, the agency estimates that medical product safety will account for 54.8% of its major activities in FY 2016, while food safety will make up 31%, tobacco 12.2%, medical countermeasures 0.5% and "other" 1.5%.



FDA eases regulation of mobile apps and medical device data systems due to the low risk they pose to users, puts out two guidance documents

The FDA's Center for Devices and Radiological Health (CDRH) is taking a risk based approach to medical device data systems (MDDS) and medical apps, again announcing that it will use its enforcement discretion for low-risk digital health products.

The regulator finalized guidance on MDDS, and updated the medical apps guidance to bring it in line with the former. In an FDA blog post, Bakul Patel, Associate Director for Digital Health in the CDRH, and Jeffrey Shuren, Director of the CDRH, wrote that the FDA is "narrowly tailoring" its regulatory approach to the degree of risk to patients. He also noted that by issuing these documents, CDRH is attempting to distinguish products that will be regulated under a low risk classification from products for which CDRH does not intend to enforce compliance with medical devices regulations.

Accordingly, the FDA won't regulate MDDS, medical image storage devices and medical image communication devices because the risk they pose to users is so low.

Clarifying which devices are outside its intended scope of regulatory enforcement, the FDA's guidance document describes a MDDS as a "hardware or software product that transfers, stores, converts formats and displays medical device data." However, devices that control or alter the functions or parameters or any connected medical devices are not covered by this guidance. Further, medical image storage and medical image communication devices are defined as "a device that provides electronic storage and retrieval functions for medical images."

Alongside the MDDS document, the FDA also issued a medical apps guidance, saying it will only apply its regulatory authority to a subsection of mobile apps,

and aiming to clarify this subsection. While certain apps meet the definition of a medical device, many pose a low risk to users, and therefore the FDA will "exercise enforcement discretion over these devices."

The subset of apps to which the FDA will apply its regulatory oversight includes only apps that are medical devices and whose functionalities could pose a risk to a user's safety if they malfunction – thus mobile medical apps. Further, the regulator will take into consideration risks posed by mobile medical apps when determining the appropriate regulatory oversight for such products.

The FDA provided a list of medical apps that it does intend to regulate, including those that connect to a medical device in order to control that device or for use in active monitoring or analysis of medical device data; those that transform a mobile platform into a regulated medical device using attachments, display screens or sensors, or by having similar functionalities as regulated medical devices; and those that perform patient-specific analysis or provide patient-specific diagnosis or treatment recommendations.

The FDA also provided examples of mobile apps for which it will exercise discretion, including those that provide supplemental care, by coaching or prompting, to help patients manage their health; those intended to help patients document or communicate potential medical conditions to care providers; and those performing simple calculations regularly used in clinical practices, such as body mass index.

The guidance also clarifies that entities which exclusively distribute medical apps, including owners and operators of app stores, don't qualify as medical device manufacturers.

FDA advises pharma companies to simplify consumer print ads, hopes new approach will resonate better with patients

The FDA is recommending that drug companies aim for comprehension with their consumer-directed print ads by limiting the risk information, more fully integrating it via text and visual cues, and by using more consumer-friendly language.

According to the guidance document, an FDA survey showed that consumers currently don't read the brief summary in direct-to-consumer (DTC) print drug ads, with the majority of people describing it as difficult to read. It's worth noting that for DTC print ads, manufacturers use a format for prescription drugs that contains the entire risk-related section of the package insert (PI) in order to satisfy the regulator's previous requirements – this is known as the traditional approach.

Not only is the PI - whose target audience is healthcare providers - often comprised of lengthy lists of all possible adverse events, it's also written in technical medical terminology that doesn't resonate with all consumers. For these reasons, the FDA believes the traditional approach isn't ideal for these types of ads, and is proposing alternative methods.

The guidance calls for a brief summary focused on the most vital risk information instead of one that includes the entire list of risks. Further, the information should be presented in a way that lends itself to consumer understanding, thus helping patients "make informed decisions about the medication being promoted."

The agency is strongly recommending that companies use consumer-friendly language in all consumer-directed print material. The language in the consumer brief summary should be designed for comprehension by a broad target audience with varying literacy skill levels.

The guidance also states that the information should be "presented in a readable format," recommending that drugmakers carry over elements from the ad creative, such as logos and branded colors, use easily readable font sizes and style, and avoid plain block paragraphs, instead opting for the use of spacing and indentations.

Draft documents on drug compounding and repackaging issued by the FDA help entities comply with public health provisions

The regulator published five draft documents as part of a larger series of policy documents concerning the FDA's oversight of drugs produced by state-licensed pharmacies, federal facilities and outsourcing facilities.

With these documents, the FDA covered:

- Outsourcing facility registration, providing information about the regulatory impact of registering with the regulator as an outsourcing facility after confusion was expressed about whether entities that take part in a variety of activities should register. The FDA recommends not registering if a facility doesn't intend to compound all drugs at the facility in accordance with section 503B of the FD&C Act.
- Drug repackaging, explaining how it will address repackaging by state-licensed pharmacies, federal facilities or outsourcing facilities, and describing when it won't take action for violations when such entities repackage drug products.
- Mixing, diluting and repackaging biological products, describing when it won't take action for violations of certain Public Health Service Act and FD&C Act sections when state-licensed pharmacies, federal facilities or outsourcing facilities mix, dilute or repackage specific biological products without an approved biological license application, or when prescription sets of allergenic extracts are prepared without one. Because there are instances where biological products need to be handled in ways that aren't covered in approved labeling for the product, the FDA put out this guidance to explain when it won't take action.
- Outsourcing facility adverse event reporting, explaining adverse event reporting for outsourcing facilities. The document requires the reporting of all serious, unexpected adverse drug experiences related to the use of a compounded product, but recommends the broader reporting of all serious adverse drug experiences associated with a product.
- Draft Memorandum of Understanding with the states, describing the responsibilities of a participating state in probing and responding to complaints about compounded human drug products distributed outside the state, and in dealing with the interstate distribution of "inordinate amounts" of compounded human drug products.

For more information on any of these FDA regulatory and compliance updates, please contact Scott S. Liebman at sliebman@loeb.com.

Loeb & Loeb LLP's FDA Regulatory and Compliance Practice

Loeb & Loeb's FDA Regulatory and Compliance Practice comprises an interdisciplinary team of regulatory, corporate, patent and litigation attorneys who advise clients on the full spectrum of legal and business issues related to the distribution and commercialization, including marketing and promotion, of FDA-regulated products. Focusing on the health and life sciences industries, including pharmaceuticals, biologics, medical devices, wellness products, dietary supplements and organics, the practice counsels clients on regulatory issues, compliance-related matters and risk management strategies; advises on laws and regulations related to product advertising and labeling; counsels on FDA exclusivity policies and related Hatch-Waxman issues; and provides representation in licensing transactions and regulatory enforcement actions.

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