

SUMMARY

H.R. _____, Food and Drug Administration Amendments Act of 2007

Title I. Prescription Drug User Fee Amendments of 2007

Title I reauthorizes the prescription drug user fee program through fiscal year (FY) 2012. Changes to the prescription drug user fee program fall into three major categories: enhancements to ensure sound financial footing for the human drug review program, enhancements for premarket review of human drug applications, and enhancements to modernize and transform the postmarket safety system.

Title I includes the Administration's request for an increase in the total annual user fees collected to \$392.8 million for FY2008, an \$87.4 million increase over the current base. The increases in fees take into account inflation and increased resources needed to conduct certain activities, known as a workload adjustment. Title I also expands the amount and scope of fees devoted to postmarket safety. This title contains an additional \$225 million in user fees that will be collected over five years. These additional funds are intended to be used for drug safety activities and are intended to supplement and not supplant any other drug safety resources. There will be a dollar-for-dollar decrease in user fees collected for these additional drug safety activities for every dollar appropriated for the same purpose.

Title I establishes a new program to assess, collect, and use fees for the voluntary review of prescription drug direct-to-consumer (DTC) television advertisements. This title also requires the Food and Drug Administration (FDA) to consult with other stakeholders such as consumer and patient advocates during the negotiations for PDUFA V.

Title II. Medical Device User Fee Amendments of 2007

Title II reauthorizes medical device user fees through FY2012. Changes to the medical device program fall into two major categories: enhancements to ensure sound financial footing for the device review program, and enhancements to the process for pre-market review of device applications. Medical device companies will pay 31 percent more in fees in 2008 and 8.5 percent more in each subsequent fiscal year through 2012. This will ensure fee increases over the next five years to cover anticipated costs related to rent, security, and statutorily mandated payroll and benefit increases.

In an effort to add stability to this fee program, Title II includes 2 new types of fees, which are intended to generate about 50 percent of the total fee revenue. The new fees are an annual establishment registration fee and an annual fee for filing periodic reports, for devices approved under a pre-market approval application to FDA at least annually that provides a variety of information, including manufacturing and design changes, and new studies involving their products. This title authorizes \$7.1 million in appropriations for additional post-market

safety activities. Title II also includes provisions to streamline the third-party inspection program.

Title II requires FDA to consult with other stakeholders such as consumer and patient advocates during the negotiations for MDUFMA III.

Title III. Pediatric Medical Device Safety and Improvement Act of 2007

Title III provides incentives to device manufactures to create medical devices specifically designed to meet the needs of pediatric patients. It also gives FDA the authority to review these devices in a manner distinct from devices in general, and to require post-market studies to ensure the continued safety and effectiveness of pediatric devices.

Title III modifies the existing humanitarian device exemption (HDE) for medical devices to allow manufacturers of HDE-approved devices specifically designed to meet a pediatric need to make a profit from the sale of such devices. This HDE modification will sunset in 2012. The HDE provisions in Title III only apply to devices that are used in 4,000 or fewer individuals.

Title III authorizes FDA to establish a mechanism to track the number and types of devices approved specifically for children or for conditions that occur in children. Title III also grants explicit authority to FDA's Pediatric Advisory Committee to monitor the use of pediatric devices and to make recommendations for improving their availability and safety.

Title IV. Pediatric Research Equity Act of 2007

Title IV reauthorizes FDA's authority to require a manufacturer of a drug or biologic who submits an application to market a new active ingredient, new indication, new dosage form, new dosing regimen, or new route of administration to also submit a pediatric assessment.

Title IV grants the Secretary of the Department of Health and Human Services (HHS) authority to require pediatric tests in appropriate circumstances through 2012. Provisions of current law that allow a deferral of pediatric tests for new products are strengthened. The standard for requiring tests for drugs currently being marketed is also strengthened. Requirements with respect to labeling drugs are strengthened to ensure that they reflect in a timely way the results of studies.

Title V. Best Pharmaceuticals for Children Act of 2007

Title V reauthorizes for five years FDA's authority to grant an additional six months marketing exclusivity to a manufacturer of a drug in return for FDA-requested pediatric use studies and reports. Title V also includes provisions to encourage pediatric research for products that are off-patent or for products whose manufacturer declines to conduct FDA-related studies.

Title V increases to 180 days the time limit that the Secretary has for deciding whether or not to grant exclusivity. This title also strengthens labeling requirements to ensure that labels reflect study results in a timely and consistent fashion.

Title VI. Reagan-Udall Foundation

Title VI creates the Reagan-Udall Foundation for the Food and Drug Administration. The purpose of the Foundation is to establish a private-public partnership to advance FDA's Critical Path Initiative to modernize medical product development, accelerate innovation, and enhance product safety. Title VI sets forth the duties of the Foundation to include identifying unmet needs in the sciences of developing, manufacturing, and evaluating the safety and effectiveness of diagnostics, devices, biologics, and drugs. Other duties include establishing goals and priorities to meet the identified unmet needs, and awarding grants to advance the goals and priorities identified.

Title VII. Conflicts of Interest

Title VII requires all individuals under consideration for appointment to serve on an advisory committee to disclose to the Secretary all financial interests that would be affected by the advisory committee's actions. The Secretary shall determine the aggregate percentage of waivers provided in fiscal year 2007. The Secretary will then be required to decrease the number of waivers by 5 percent for each of fiscal years 2008 through 2012. Disclosure of waivers must be made public 15 or more days prior to the meeting of the advisory committee and must be posted on the Internet.

Title VII enhances FDA's outreach activities for identifying non-conflicted experts to participate on advisory committees and directs the Secretary to review guidance on conflict of interest waiver determinations with respect to advisory committees at least once every five years and update this guidance as necessary.

Title VIII. Clinical Trial Databases

Title VIII expands the existing publicly available clinical trials registry data bank in three phases. First, except for preliminary studies, all clinical trials on drugs, biologics, and devices would be required to provide trial registry information. Second, trials for approved products would be required to post basic results to the data bank. Third, the Secretary shall expand the database further by rulemaking to consider the inclusion of other data elements as well as trials of unapproved products. Title VIII also provides for civil monetary penalties for noncompliance.

Title IX. Enhanced Authorities Regarding Postmarket Safety of Drugs

Title IX strengthens FDA's post-market drug safety authority and provides greater FDA transparency. Specifically, Title IX provides FDA with the authority to require labeling changes under appropriate circumstances and provides FDA with the authority to impose civil monetary penalties for certain violations of the Federal Food, Drug, and Cosmetic Act with respect to drugs. Title IX provides FDA with a process to pre-review television pharmaceutical advertisements. Specifically, this title strengthens FDA's ability to monitor and remedy false and misleading television advertising and provides an administrative procedure and CMPs for violations.

Title IX provides FDA with enhanced tools to ensure post-market drug safety through a “Risk Evaluation and Mitigation Strategy” (REMS) process. This title grants the Secretary the authority to require a REMS for drugs and biologics, if the Secretary determines it is necessary to ensure that the benefits of a drug or biologic outweigh its risks. Title IX also directs the Secretary to establish an active post-market drug surveillance infrastructure.

Title IX requires the Secretary to issue guidance for the conduct of clinical trials with respect to antibiotic drugs. This title prohibits food to which drugs or biological products have been added and includes provisions to increase security of the drug supply. Title IX improves the citizen petition process and makes post-market drug safety information transparent and more accessible to the public. This title also requires the Secretary to make action packages publicly available and creates a database of approved generic drugs.

Title X. Food Safety

Title X requires the Secretary to establish processing and ingredient standards with respect to pet food, animal waste, and ingredient definitions. The Secretary is also required to update standards for pet food labeling that include nutritional and ingredient information. Title X requires the Secretary to establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food.

Title X provides improved communication requirements during an ongoing recall of human or pet food including posting information regarding recalled products on FDA’s website in a consolidated, searchable form that is easily accessed and understood by the public. This title requires the Secretary to work with States in undertaking activities that assist in improving the safety of fresh and processed produce.

Title X requires the Secretary to establish an Adulterated Food Registry to which instances of reportable adulterated food may be submitted by FDA and requires the Secretary to issue an alert in certain instances. This title also requires the Secretary to immediately notify the Secretary of Homeland Security if the Secretary suspects such food may have been deliberately adulterated.

Title XI. Other Provisions

Title XI requires the Secretary to establish and make publicly available, clear written policies to govern the timely clearance of articles written by FDA employees. Title XI provides an incentive, through a priority review voucher, to develop new drug, biologic, and device products to treat neglected or tropical diseases.

Title XI provides reporting and study requirements for FDA regarding labeling information for tanning beds and genetic test safety and quality. This title also contains provisions regarding exclusivity for enantiomers.