FDA Report to PharmPAC
February 8, 2007
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News

- FDA is negotiating the renewal of the Prescription Drug User Fee Act (PDUFA). PDUFA is the law that allows FDA to fund a portion of the review of drugs and other agency priorities through fees paid by the companies that submit new drug applications and biologic license applications. The proposed recommendations for the next reauthorization of this program, PDUFA IV (FY 2008 to 2012), include an expansion and modernization of FDA's drug safety system, additional resources for information technology, and enactment of user fees to increase our capacity to review direct-to-consumer TV ads. The proposed recommendations will provide FDA with increased resources necessary to contribute to the evaluation of the safety and effectiveness of new medicines in a comprehensive and efficient manner. http://www.fda.gov/ope/pdufa/report2005/default.htm
- FDA Corrects 'Misperceptions' Regarding Newer Contraceptives: To correct recent news reports implying that newer generation hormonal contraceptives are less effective than those approved decades ago, FDA has issued a statement saying the newer products are "highly effective in preventing pregnancy." FDA said the news reports prompted "misperceptions" about the effectiveness of current contraceptive products.
  http://www.fda.gov/bbs/topics/NEWS/2007/NEW01550.html

Resources

- Drug Shortages: To obtain information on FDA drug shortages please visit FDA's web-page as follows: http://www.fda.gov/cder/drug/shortages/default.htm. You can also receive email notification of drug products added to the Current Drug Shortages, Discontinued Products and Resolved Drug Shortages lists, by visiting the NIH Listserv and completing the Drug-Shortages Listserv Form. The FDA website is linked to the ASHP drug shortage website and FDA partners with ASHP on drug shortage issues. For questions, please contact
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Staffing

- Dr. Janet Woodcock has been appointed the Chief Medical Officer which will oversee scientific and medical regulatory activities for FDA.
- Mr. John R. Dyer has been appointed the Deputy Commissioner for Operations and the Chief Operating Officer (COO) which will concentrate on strengthening the management, business processes, and information technology for FDA.
- Office of Regulatory Affairs Transformation: Budget cuts have resulted in a hiring freeze within the Office of Regulatory Affairs; some field laboratories may be closing; specific labs to be determined.