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The Food and Drug Administration Amendments Act of 2007

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On September 27, 2007, President Bush signed into law H.R. 3580, the Food and Drug Administration Amendments Act of 2007 (FDAAA). The new legislation grants sweeping new powers to the Food and Drug Administration (FDA or the Agency), enabling the Agency to, among other things, mandate changes to a drug's approved labeling, require post-market clinical trials, and impose new distribution and use restrictions. It also reauthorizes the Prescription Drug User Fee Act (PDUFA) and the pediatric exclusivity and pediatric rule provisions (the Best Pharmaceuticals for Children Act and the Pediatric Research Equity Act, respectively), significantly expands the federal government's clinical trial registry and results databank, and creates new restrictions on the advertising and promotion of drug products. The FDAAA represents one of the most wide-ranging and comprehensive revisions to the Federal Food, Drug and Cosmetic Act (FDC Act) in the past 40 years. Following are highlights of major provisions of the FDAAA that will have a profound effect on the pharmaceutical industry.

- ***User fees will increase dramatically.*** The annual user fee revenue target for fiscal year 2008 will approach $450 million, an increase of over $100 million from the previous year. Companies thus should expect to see hefty increases in product, establishment and application fees. In addition, a new voluntary user fee program for direct-to-consumer (DTC) television advertisements will require companies to notify FDA at the beginning of

the fiscal year as to how many television ads they intend to submit for prior FDA comments in the upcoming fiscal year. This will require careful advanced preparation of marketing plans to avoid late fees or forfeiture of fees.

- ***FDA will have sweeping new powers to regulate drugs after approval.*** Under the FDAAA, the Agency is given new authority and procedures that may require companies to conduct one or more post-market clinical trials to assess or identify a serious risk with a drug product. If FDA believes that new safety information should be included on a drug's approved labeling, it can require the company to make the labeling change by issuing an "order" pursuant to an accelerated label revision process. Finally, FDA is authorized to impose onerous distribution and use restrictions, such as limiting distribution of a drug to certain facilities (e.g., hospitals), under a new process called a Risk Evaluation and Mitigation Strategy, or REMS.
- ***New restrictions can be imposed on advertising.*** Under the FDAAA, the Agency may require companies to submit DTC television advertisements not later than 45 days prior to dissemination. The "major statement" of safety information in television and radio advertisements must be presented in a "clear, conspicuous, and neutral manner," and FDA must issue regulations defining this standard. Finally, the FDAAA authorizes--for the first time--hefty civil money penalties (CMPs) for DTC advertisements (including print ads) that are "false or misleading." These penalties can reach a maximum of $500,000 per violation.
- ***New enforcement tools include substantial civil money penalties (CMP).*** In addition to the new penalties available for violative DTC advertisements, the FDAAA authorizes CMPs for violations of the new REMS provisions, post-market study requirements, and for labeling violations. These CMPs can be extremely large, reaching a maximum of $10 million for all violations adjudicated in a single proceeding.
- ***Pediatric exclusivity is still available, but with important limitations.*** The FDAAA reauthorizes the Best Pharmaceuticals for Children Act (BPCA) for another five years. Significantly, the new law does not include previously proposed provisions for the tiering of pediatric exclusivity based upon a pharmaceutical product's annual revenues, but instead continues to provide a full six-month exclusivity period for drugs that meet the applicable pediatric study requirements. However, important time limitations have been added that may make it more difficult for companies to obtain pediatric exclusivity. Early planning of pediatric studies will be critical.
- ***The government's clinical trial registry will be expanded to cover more trials, more information and information on the results of completed trials.*** Clinical trial information will have to be submitted to the registry databank for all ongoing clinical trials other than Phase I studies, not just those for serious or life-threatening conditions. In addition, results information for completed trials will be added to the databank in stages over a three-year period. FDA's rule-making process will be critical to defining the requirements for the expanded clinical trial registry and results databank.

Issues Pharmaceutical Companies Need to Think about Now:

- Currently approved drug products may be subject to the REMS requirements. Companies

must quickly determine whether any of their products fall into this category and, if so, submit a proposed REMS within 180 days after the effective date of the FDAAA.

- The new DTC user fee goes into effect immediately. Companies that intend to submit TV ads will need to identify all such advertisements within 60 days of enactment. Fees will be due no later than five months after enactment.
- Companies with drugs under development for FDA pre-review will need to analyze how timing of pediatric studies for such products may be affected to qualify for exclusivity.
- Companies should prepare to make publicly available, through the NIH clinical trials database, all clinical trials (other than Phase I studies) they are conducting, keeping in mind that more comprehensive study information will now be required. Companies should also watch for FDA's rule-making process regarding posting requirements for the expanded clinical trial registry and results databank.
- Substantial civil money penalties can be avoided if companies monitor and ensure that they comply with the regulations subject to such hefty penalties.

WilmerHale Webinar Series:

Deciphering the New FDA Reform Legislation - What the FDA Amendments Act of 2007 Means for Research-Based Pharmaceutical Companies

This webinar series is designed to provide pharmaceutical companies with a detailed overview of the new law and a forecast of its impact on all aspects of regulatory compliance and product development, as well as practical tips to prepare for implementation of the new regulatory requirements. Among the elements of the new law to be addressed in the series are the following:

- ***New labeling provisions and their effect on product liability preemption;***
- ***The procedures, scope and effects of Risk Evaluation and Mitigation Strategies (REMS);***
- ***New restrictions on advertising and promotion of drugs;***
- ***Enhanced FDA authority over pediatric studies and new hurdles to obtaining pediatric exclusivity;***
- ***Expansion of the federal government's clinical trials registry and results databank;***
- ***The impact of new enforcement mechanisms, including civil money penalties.***

Session 1: October 17, 2007

Session 2: October 31, 2007

Session 3: November 14, 2007

Registration information and additional details will follow on Monday, October 1.