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Pediatric Exclusivity Reauthorized, but with Important Changes

On September 27, 2007, President Bush signed into law the Food and Drug Administration Amendments Act of 2007 (FDAAA), which amended the Federal Food, Drug, and Cosmetic Act (FFDCA) to include provisions reauthorizing the pediatric exclusivity program adopted in the Best Pharmaceuticals for Children Act. Below is a description of the key differences between the existing pediatric exclusivity program and the provisions of the reform legislation:

- **Timing.** FDA must determine whether the studies qualify for pediatric exclusivity within 180 days after submission of the study reports. FDA shall not grant pediatric exclusivity if this eligibility determination is made less than 9 months before expiration of the patent term or exclusivity to which the pediatric exclusivity would attach.
- **Declining the Request.** If an applicant declines to conduct studies specified in a written request, the applicant must state the reasons for declining the request, including the reasons an appropriate pediatric formulation cannot be developed, if the inability to develop such a formulation is the reason for declining the request.
- **Consolidated Request.** FDA can issue a single written request that relates to more than one use of a drug, including approved and unapproved uses.
- **Required Notice.** FDA is required to accept or reject the study reports within 180 days after the sponsor's submission. The legislation requires FDA to publish a notice of any determination that the statutory requirements have been met and exclusivity will be awarded within 30 days after the date of its determination. The publication would also include a copy of the written request. FDA is also required to publish a notice identifying any drug for which, on or after the date of enactment of the legislation (September 27, 2007), a pediatric formulation was developed, studied, and found to be safe and effective in the pediatric population, if the pediatric formulation is not introduced to the market within one year of the date notice of pediatric exclusivity is published.
- **Availability of Information on www.fda.gov.** FDA is required to make available on its website information concerning pediatric studies conducted and labeling changes implemented. The information to be posted includes: the specific drugs and drug uses (including off label



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indications) studied; the types of studies conducted, including trial design, number of subjects, number of sites; the number of pediatric formulations developed and the number of pediatric formulations not developed, along with the reasons such formulations were not developed; the labeling changes made as a result of studies; and an annual summary of labeling changes.

- Information to Health Care Providers. FDA must include in written requests the requirement that sponsors of studies that result in labeling changes listed in the annual summary of labeling changes distribute annually (or more frequently if required by FDA) information concerning labeling changes to physicians and other health care providers.
- Adverse Events. When submitting studies to qualify for pediatric exclusivity, the sponsor is required to submit additional information on adverse events to ensure that the Office of Pediatric Therapeutics established under Best Pharmaceuticals for Children Act has access to adverse event information. Review by the Office of Pediatric Therapeutics would supplement, and not supplant, other reviews of adverse event reports by FDA.
- Sunset. The pediatric exclusivity provisions sunset on October 1, 2012.