

FDAAA and the Evolving Pharmaceutical Marketplace

Johnson & Johnson Perspective

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FDAAA Provisions

Johnson & Johnson Perspective (1)

- Prescription Drug User Fee Act (IV)
 - Review goals
 - DTC User Fee program
 - IT modernization
- Risk Evaluation and Mitigation Strategies
 - FDA/Sponsor partnership
 - Healthcare delivery system
 - Assessment toolbox

FDAAA Provisions

Johnson & Johnson Perspective (2)

- Advisory Committees
 - Greater frequency
 - Qualified advisors
- Pediatric Provisions
 - BPCA success
 - Increased planning and transparency