

Postmarket Advisory Panel Presentations

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Postapproval Studies Program

- Collaborative effort to transfer program from ODE to OSB
- Development of automated study tracking system; all studies from 2005
- Routine assignment of epidemiologist to PMA team
- Publication of guidance “Procedures for Handling Post-Approval Studies by PMA order

- Development of PAS Website of studies and status
- Development of Postmarket Plan for all PMAs with postapproval studies (MDR analysis, literature review, exploration of other databases, product diffusion data)

Postmarket Panel Presentation Goals

- Feedback to our external experts
- Transparency for the public
- Advice from the panel
- Keep postmarket learning at high profile

What to Expect

- Typically both FDA and the sponsor will present
- Studies may be complete or in progress
- Specific questions may be asked
- General discussion and questions are encouraged
- Separate postmarket update at every Advisory Panel meeting