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Welcome Everyone!

- Consultation with experts and stakeholders
  - Central to FDA's public health mission
  - Essential to meeting our goals
- In any organization, getting results means welcoming change, modernizing what we do and how we think.
  - Product complexities
  - Scientific advancements and uncertainties
  - New knowledge, new expectations, new standards
  - Altered national priorities

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PDUFA Has Evolved, Too

- 10 years ago the promise of PDUFA was timeliness and access.
- Most recently, PDUFA has sought stability.
- 10 years from now…?? we are here today to lend shape to that future.

PDUFA Reauthorization:
Just 10 Months Remaining

- Since September 15, 2000 public meeting
  - On-going discussions with stakeholders
- Final Public Meeting on December 7, 2001
- Formulation of options
- Draft legislative language -- introduce to Congress
- House and Senate hearings, mark-up, amendments
- Floor debates, House-Senate conferences, passage
- President signs PDUFA III by midnight, Oct 1, 2002

Last Year's Diversity of Views

- General agreement expressed:
  - Resources are key to performance
  - FDA's non-PDUFA responsibilities are vital
- Divergent ideas expressed:
  - Appropriateness of fees (conflicts, impact on Congress support)
  - Performance goals (accountability, predictability, establishing)
  - Fees for other safety functions (non-drug, post-market, advertising)

September 2000 Meeting
Patient Advocacy groups
Consumer Protection groups
Industry
Health Professional Groups
Academia
FDA

Today's Meeting Focus: Three Key Topics

- Public Health: Has PDUFA supported FDA's public health mission? What are your ideas for changes or enhancements?
- Postmarket Safety: Should fees be used to monitor safety after new drug/biologic approval? What are your thoughts?
- Funding: How can FDA ensure program viability when funds fall short? What suggestions do your have?

The Advantage of Experience and the Challenges We Face

- Let's draw on our experiences with PDUFA I and II
- Let's draw on new knowledge in science, medicine, public health
- Let's work to the best of our ability to apply our resources toward our common goal
- Let's shape PDUFA III together

Let's Commit to Recognizing and Addressing the Challenges

- The public health outcomes have been tremendous -- can we keep it going? Panel #1
- Postmarket safety is more significant -- can it be addressed more directly? Panel #2
- PDUFA is financially fragile -- can we add assurances for the future? Panel #3

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