3 TOPICS TO JUMP START THE DISCUSSION

- First things first
- Plan Goals, Targets and Actions
- Insights From a Previous Experience
PRIORITIES
(FIRST THINGS FIRST)

- Keep OMB happy (or at least satisfied)

- Be opportunistic in using plan to “advertise” NSF (anecdotes in plan are powerful stuff)

- Monitor plan implementation and abandon items that are no longer relevant to conserve scarce resources and retain goodwill
OVERVIEW GOALS, TARGETS AND ACTIONS

- Three Strategic Goals
  - Transform the Frontiers
    - 4 Performance Goals
  - Innovate for Society
    - 3 Performance Goals
  - Perform as a Model Agency
    - 3 Performance Goals

- 72 Action Items
ANALYSIS OF 72 ACTION ITEMS
(Looking for criteria to design an implementation process)

- Horizons:
  - Near term (annual or 1–2 years)
  - Mid term (2–5 years)
  - Long Term/Assessment (5 – 10 years)

- Nature: Project or Process

- Scope: Staff (with outreach) or Line/NSF
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## ACTION ITEMS
### HORIZON AND SCOPE

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Ideas From A Previous Implementation Experience

- APRES – Action Plan Reporting and Evaluation System

- Action Plan
  - New FDA Commissioner
  - Evening brainstorming consensus building meetings
  - 10 Goals and 49 Objectives (objectives = NSF action items)
  - Staggered starts

- APRES
  - 258 Milestones
  - Used existing organizational structure
  - Exceptional staff support
  - Ownership of goals, objectives and milestones
  - Face to face activity and progress reporting
  - Always positive and with a light touch
GOAL 2: FDA will improve premarketing evaluation procedures for drugs and devices.

OBJECTIVE 2 - 4: Implement the drug review process modifications identified during the IND rewrite

**MILESTONES**

- **2-4.1** Identify administrative changes that must be made to implement the IND rewrite

- **2-4.2** Develop new review forms for changed requirements

- **2-4.3** Develop the guidelines for sponsors and investigators for the changed requirements

FINISH