Nonclinical Studies Subcommittee

Advisory Committee for Pharmaceutical Science

September 9, 2002

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FDA Recommendation

NCTR provide oversight of this Subcommittee

- NCTR has mandate and structure to lead safety research
- CDER is restructuring ACPS to focus on regulatory implementation
- Appropriate linkage can optimize research and regulatory implementation
- NCTR can coordinate adoption of new methodologies through ICCVAM and OECD processes

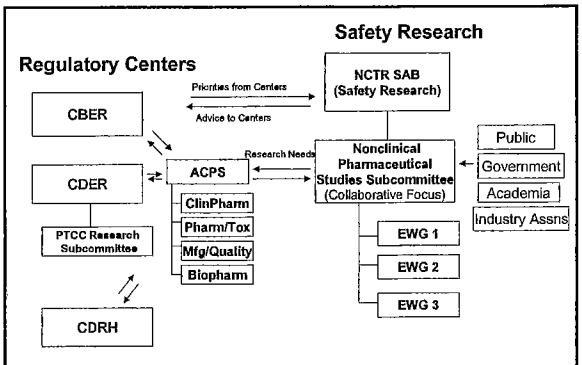
NCSS Objectives

1. To recommend scientific approaches to improve:
   - Nonclinical drug development
   - Predictivity of nonclinical tests for human outcomes
   - Linkage between nonclinical and clinical studies

   and
2. To facilitate collaborative approaches to advancing the scientific basis of drug development and regulation

NCSS: A means to capitalize on scientific opportunities & focus on research needs

- Interact with product Centers & stakeholders
- Implement expert working groups (EWGs) to define state of the art and identify opportunities
  - Federal Register announcements (Public)
  - FDA and "Stakeholders" (Collaborators)
  - Professional Societies
- Steer collaborative projects
- Convene workshops, symposia
- Facilitate reporting & recommendations



Key Linkages and Interactions