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CDER

Role of the Advisory Committee for Pharmaceutical Science

- Science advisors to address scientific and technical issues and questions
- Represent a number of different scientific disciplines that affect the OPS regulatory decision-making processes
- Provide recommendations to help in the development of regulatory policies and standards

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HHS
Health and Human Services

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Role of NCSS

- Subcommittee under ACPS
- Set up to develop recommendations on drug development and approaches in nonclinical area
- Has identified areas where research was needed to solve problems
- Foster scientific collaboration for targeted research areas

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Proposed Structure of ACPS

- Have started to set up subcommittees that are focused on various scientific disciplines
 - CMC - Manufacturing
 - Pharmacology/Toxicology
 - Clinical Pharmacology
 - Microbiology
- Help in addressing more specific issues

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Establishment of Pharmacology/Toxicology Subcommittee and Its Role

- In process of setting up subcommittee
- Need chair and members (5 or 6)
- Need two members from the ACPS – with focus on Pharm/Tox
- Address specific scientific questions arising from review process

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Establishment of Pharmacology/Toxicology Subcommittee and Its Role (cont.)

- Discuss questions and make recommendations to main committee on how to directly answer question or on what additional information is required (research, etc.) to answer question
- Provide follow-up on questions

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How Pharm/Tox Subcommittee and NCSS Will Interact

- Need for connections between Pharm/tox review and research is important
- Member of NCSS on Pharm/Tox Subcommittee
- Member of PTCC Research Subcommittee on NCSS
- NCSS could independently identify areas of concern which it could bring before Subcommittee
- Pharm/Tox Subcommittee could identify perceived research needs and propose them to NCSS

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