Assessing excipient solutions for generic drug development

FDA Generic Drug Regulatory Science Initiative public meeting
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Multiple stakeholders; **one objective.**

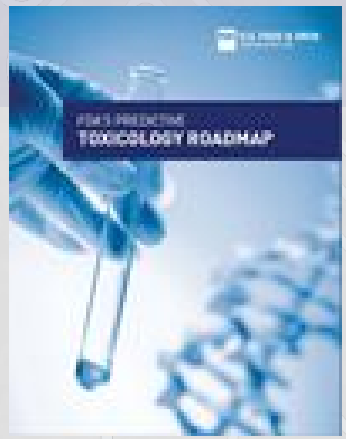
International Pharmaceutical Excipients Council

Collaborative solutions for excipient industry stakeholders

Importance of Excipients in Generic Drugs

- Excipients play an important role in the quality and development of generic drugs.
- New excipients are needed to provide functionality and performance for emerging therapies, lowering the cost of pharmaceutical products and to meet processing needs, e.g. continuous manufacturing. FDA must be able to evaluate new excipients developed to meet these demands
- To improve generic drug development and make things more efficient, it is essential that a process exists to more easily evaluate the safety of all excipients, including new excipients
- IPEC has 2 proposals we believe are essential to facilitate FDA evaluation of these new excipients.

Proposal #1



- **Evaluate how Tox 21 concepts can be integrated into future safety evaluation requirements for novel excipients.**
  - **FDA should:**
    - Sponsor research projects to develop Tox 21 concepts to use in- lieu of current animal study requirements.
    - Update current Guidance to incorporate Tox 21 concepts.

FDA Guidance for Industry Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients

  - **Expected Outcome**
    - CDER aligned with FDA's Predictive Toxicology Roadmap for integrating novel predictive toxicology methods into safety and risk assessments of its products.
    - Reduced animal testing.

Proposal #2

- **Sponsor research to establish safety study requirements designed to cover different grades of the same excipient (families) with similar safety/toxicology profiles and support bridging justifications.**

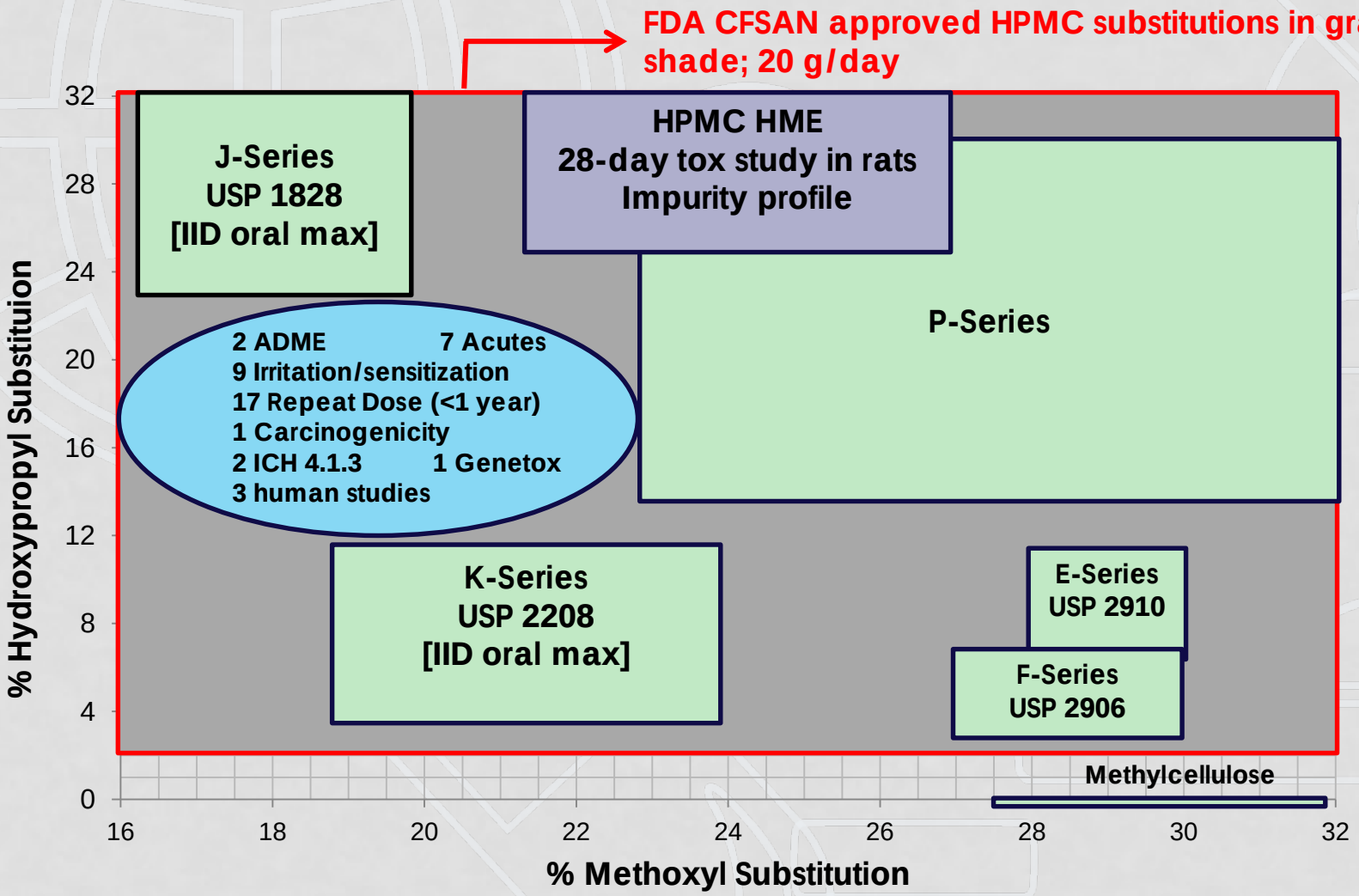
HPMC EXAMPLE

  - **FDA should:**
    - Sponsor research projects to study toxicological effects over a range (e.g. MW and/or viscosity) of two model excipient polymers.
    - Update Excipient Safety Guidance to reflect appropriate studies for similar excipient families that could support a bridging approach.

FDA Guidance for Industry Nonclinical Studies for the Safety Evaluation of Pharmaceutical Excipients

  - **Expected Outcome**
    - Toxicology studies defined which could cover entire “families” of excipients
    - Alignment with FDA’s Tox 21 initiative.
    - Reduced animal testing.

HPMC Family of Polymers



Other Benefits

- Outcomes from these proposals will improve and ensure GSRS nomenclature, chemistry accuracy and integrity

NOTE: IPEC-Americas intends to prepare and submit more detailed information for both of these requests.

Thank You!