

Summary Minutes of the Toxicology Sub team
24 August 2011

Objective: Toxicology sub team current status and path forward

HC rep clarified the comment "will not support thresholds" to mean the values not necessarily supported but the concept was.

Also noted that an internal regulatory procedure in ophthalmics but offered to facilitate tox regulatory review of POOP recommendations .

Member inquired as to the status of the ELSIE proposal to share information. Chair responded that IPAC rep exchanged email with Reggie who noted acknowledgment of ELSIE would mean data used to support Validation would need to be made public. This was the last contact and member would follow-up because he felt as long as the information would be equivalent to what POOP would generate it would be advantageous for ELSIE and save months of time. A more formal document may be needed to clarify expectations and commitments. Steve Beck indicated there were currently about 29 compounds in the ELSIE data base. Chair noted that the 60 compounds to be validated should support the threshold levels we are proposing whether it be POOP or ELSIE generated.

Member thought principles rather than absolute values to be stressed at this stage. She will meet to discuss a plan for review and consideration of concepts in the Ophthalmic division.

Member suggested a new strategy to get the FDA attention because the briefing document may be too much information at first pass. A power point presentation will also be distributed with the Briefing Document.

Action Items

1) Update Briefing Document

- * Include Executive Summary
- * Clarify application of leachable or extractable
- * Explain why OINDP does not always directly apply
- * Chern. team add Safety and Quality aspects
- * Differentiate thresholds levels for known compared to unknowns
- * Thresholds facilitates focus of concern compounds
- * Value for early investigations to control or switch materials

The Executive summary will focus on principles/concepts not details and values. This will have a toxicology, chemistry and integration of tox/chem. section. Member will initiate by September 2. Members will draft the chemistry section. Once finalized this will be provided to DTC to distribute and request feedback. A power point summary will also be included. We will note the November meeting at USP and request FDA Tox attendance.

2) Sixty Compounds from the POOP data will be selected for tox Validation.

* These compounds will be compared to the available ELSIE data to see what will need to be generated by POOP. Tox team will provide this second week of September.