

Draft Redacted

Parenteral and Ophthalmic Drug Products Leachables and Extractables Working Group; Minutes of the meeting held April 23, 2008

Location: Teleconference

- Chair Diane Paskiet opened the meeting by reading the Admonition Statement
- The Work Plan Schedule previously provided was reviewed and tasks, time frames, and milestones were discussed and agreed to for both Threshold and Best Practices elements of the Work Plan.
- Doug Ball (Toxicology subteam leader) and Dennis Jenke (Chemistry subteam leader) will serve as liaisons between their respective subteams.
- To ensure FDA is aware of the activities of the Working Group, individual informal contacts may be made with key FDA staff (e.g.; David Jacobson-Kram). It was noted and acknowledged that any such contacts and feedback from them would only represent that individual's personal opinion, not official FDA policy. In addition, there is an FDA representative on the Development Technical Committee and the entire DTC will receive regular updates on the Task Force progress.
- As noted above, the DTC will be kept informed of the progress of the Working Group, and Bob Dana will also communicate any DTC questions and comments back to the Working Group.
- The working Group will have face to face meetings every three months, with at least one interim teleconference (1 hour duration) between face to face meetings. The first face to face is tentatively scheduled for June 23 or 24 at the PDA office in Bethesda.