Chemistry Sub Team June 24, 2008-Approved Redacted

Minutes:

The meeting was called to order by the Team Leader, at 11:00 AM EST.

The chemistry sub-team plans to investigate the possibilities for acquiring a unique six component container closure system in which the individual components would be profiled as well as conducting a leachable study on the assemble system. The system would be representative of base thermoset and thermoplastic materials, adhesives, overwrap and labels. In addition, the potential post-filled processing conditions, such as terminal sterilization, and priming of materials of construction, such as irradiation of plastic, will be considered to determine the effect on the leachable profile for the proposed 'six component container closure system'.

The materials would be consistent with a combination of those used in each of the four categories and would serve as a model to acquire data to demonstrate a controlled extraction study followed by a leachable study.

A number of solvents are currently being considered for the study with special attention given to aqueous systems. These solvent systems represent worse case conditions (e.g., hexane [class 2] and IPA [class 3] Q3R3) that can be used in the manufacturing of parenteral products.

The protocols and plan for Best Practices are scheduled to be completed as per the work plan.

Meeting concluded at 04:00 PM EST.