SUMMARY OF ARMWG Subgroup Teleconference Meeting on May-06-2002

The following ARMWG subgroup held a teleconference to review the statistician's report on analyses of the laboratory data for particle concentration and for infectious titer assignments to the Adenovirus Reference Material:

Estuardo Aguilar-Cordova (Harvard U, ARMWG Co-Chair)
Steven Bauer (CBER/FDA)
Andrew Byrnes (CBER/FDA)
Janice Callahan (Callahan & Associates, project statistician)
Keith Carson (Williamsburg BioProcessing Foundation)
Beth Hutchins (Canji, ARMWG Co-Chair)
Stephanie Simek (CBER/FDA)
Paul Shabram (Canji)
Barry Sugarman (Canji)

MEETING SUMMARY:

[1] CBER/FDA representatives accepted the particle assignment of 5.825 x 10e11 p/mL based on the statistical analysis provided by Dr. Callahan and will recommend this to the WG.

[2] CBER/FDA representatives accepted the infectious titer assignment of 7.37 x 10e10 IU/mL calculated from the raw data using the Maximum Likelihood method as provided by Dr. Callahan and will recommend this to the WG.

[3] The Working Group will be provided with the Statistician's report on the analyses and asked, based on CBER/FDA's recommendation, whether they agree or disagree with the assignment for particle concentration.

[4] The Working Group will be provided with the Statistician's report on the analyses and asked, based on CBER/FDA's recommendation, whether they agree or disagree with the assignment for infectious titer.

[5] The teleconference also addressed FDA's need to provide guidance to sponsors, and in particular to individual sponsors, on how to use the Ad Ref Mat to validate their own methods. Because sponsors may use any method they choose that is scientifically sound, the group asked Dr. Callahan to provide sample size tables based on obtaining 95% confidence that a sponsor's assay will report data within a range of 2, 5, or 10 percent of the assigned particle per mL concentration, and on obtaining 95% confidence that a sponsor's assay will report data within a range of 25, 50, 75, and 100% of the assigned particle per mL concentration.

[6] The WG will include a more complete explanation of the Maximum Likelihood method of analysis in the publication concerning the label infectious titer assignment so that the public may understand this method better. A Maximum Likelihood spreadsheet, based on the ARMWG SOP, will be completed as an available tool for laboratories wishing to duplicate the ML analysis.

[7] A follow-up teleconference will be arranged between CBER/FDA and Dr. Callahan as needed to address FDA's need to have tools that can be provided to sponsors looking for guidance on validation of assays based on the Ad Ref Material.