NIAID/NIH – CBER/FDA TB Vaccine Regulatory Workshop

December 9, 2003

MEETING AGENDA

Welcome And Introductions – Goals Of Meeting **8:30 – 8:45**

Christine Sizemore - NIH
Michael Brennan – FDA

All Presentations will be 15 min. each plus 5 min. discussion

Session I. Overview Of The USFDA Regulatory Process **8:45 – 9:45**

General IND issues	*Julienne Vaillancourt – FDA*
GMP Manufacturing & Preclinical testing	*Sheldon Morris – FDA*
Toxicology/Adjuvants	*Marion Gruber – FDA*

Session II. Vaccine Development: From The Laboratory To FDA - Two Perspectives: **9:45 -10:25**

NIAID/NIH	*Lydia Falk - NIH*
The Biologics Consulting Group	*James Kenimer - TBCG*

Break **10:25 – 10:45**

Session III. Clinical Trial Issues **10:45 – 12:30**

Basics of phase I/II clinical trials	*Steve Rosenthal - FDA*

Phase II feasibility trials of TB vaccines for Targeted Populations:

Manufacturers perspectives	*Ripley Ballou – GSK*
FDA perspectives	*Douglas Pratt - FDA* *Rosemarie Tiernan - FDA* *Ann Schwartz - FDA* *Leonard Sacks - FDA*

Clinical endpoints in TB vaccine studies	*Christopher Whalen – CWRU*
Immunological assays in TB vaccine studies	*Daniel Hoft - SLU*
Lunch	**12:30 – 1:30**
Lunch Presentation: A TB vaccine study in the UK	*Adrian Hill - OxU*
Session IV. Specific Vaccine Issues	**1:30 – 2:50**
DNA vaccines	*Dennis Klinman – FDA*
Peptide vaccines	*Hana Golding – FDA*
Live vaccines	*Karen Elkins – FDA*
Subunit/Recombinant vaccines	*Sheldon Morris - FDA*
Session V. Open Discussion	**2:50 – 3:30**
Break	**3:30 - 4:00**
Session VI. Meeting Summary	**4:00 – 5:30**
	Norman Baylor – FDA *Richard Walker - FDA*