**"QUICK SUMMARY" OF THE**
**ALLERGENIC PRODUCTS ADVISORY COMMITTEE TELECONFERENCE**
April 8, 2003 at 1:00 p.m. EDT

The Allergenic Products Advisory Committee meeting was held by videoconference originating in NIH 29B/4NN15. There was a video screen and speaker phone for public participation located on the first floor of this building, in Conference Room A. Dr. Samuel B. Lehrer presided as Chairman for this committee meeting.

Dr. Jay E. Slater, Chief of the Laboratory of Immunobiochemistry, CBER/FDA, made several presentations to the advisory committee. First he presented an overview of the Laboratory, its staffing and lot release activities. Next he addressed operational issues encountered in the replacement of cat and ragweed antisera. Two sheep being immunized to generate new antisera were exposed to sheep that were subsequently diagnosed with scrapie (a transmissible spongiform encephalopathy). Since there have not been any cases of transmission of scrapie to humans, the sera from the exposed sheep is almost certainly safe. However, to assure the highest degree of safety possible, sera from these exposed sheep were frozen, but will not be used unless CBER runs out of existing sera before new sera are harvested.

In his next presentation, Dr. Slater explained CBER's new Laboratory Quality Management Initiative. Under this initiative the Laboratory will come into compliance with International Organization for Standardization (ISO) standard 17025, entitled "General requirements for the competence of testing and calibration laboratories ". This will require some revision of laboratory protocols, improved documentation, and internal and third-party audits.

The Committee was then updated on the Laboratory's research on the endotoxin content in allergenic extracts. The laboratory found variable endotoxin content in different sources of allergenic extracts. These initial studies are being expanded and will be confirmed by a different methodology.

Finally, Dr. Slater presented the laboratory's progress in standardizing cockroach allergen extracts. He reported that commercially available cockroach allergen extracts vary widely in protein content and potency. Proposed clinical studies include skin testing to establish biological unitage and ideal dosing ranges for cockroach allergen. OVRR/CBER and the NIAID Inner City Asthma Consortium will collaborate to perform the necessary clinical and scientific studies to standardize cockroach allergen vaccines. This, in turn, will enhance the safety and efficacy of these allergenic products, and will facilitate studies on the role of cockroach allergy in the etiology of asthma in the inner city.

Throughout all of these presentations the committee evaluated the current and proposed studies, made comments and recommendations pertaining to the operational,

research and regulatory activities of the Laboratory. Please see the transcripts for details of these discussions.

(revised JES, 4/10/03)