

Quick Summary of the Allergenic Products Advisory Committee Meeting

The Allergenic Products Advisory Committee met on March 15, 2002. The committee listened to presentations on the current status of the following topics: the Laboratory of Immunobiochemistry and a review of its research program, particulates in allergen extracts and related compliance issues, and reduction of possible exposure to TSE agents in allergen extracts. The committee then listened to presentations and discussed the following regulatory issues: considerations for the regulation of recombinant allergens for the diagnosis and treatment of allergic disease, and glycerol in allergen extracts. While formal questions were not posed to the committee for voting, there was an extensive discussion on all of these topics, which provided FDA many useful suggestions from individual committee members. Please see the transcripts for the detailed comments.

In closed session the committee discussed, modified and approved a site visit report for the Laboratory of Immunobiochemistry in the Division of the Bacterial, Parasitic and Allergenic Products in OVRP.