

Voting Questions for the Committee

Question 1: Mass Concentration Measurements

Does measurement of mass concentrations by ELISA of their major allergens provide a scientifically sound approach for expressing and reporting potencies of cat hair and pelt allergen extracts, and of short ragweed pollen allergen extracts?

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Question 2: CBER's Allergenic Standardization Program

Are the revised assays for cat hair/pelt and ragweed pollen allergen extracts scientifically appropriate templates for expanding CBER's allergenic standardization program to include major food allergens and environmental allergens?

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Question 3: LC/MS/MS Analytics

Does LC/MS/MS technology, compared with the currently used analytic technology, provide sufficient fit-for-purpose analytical capability for better characterization of complex allergen extracts to improve product quality?

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Question 4: House Dust Mite (HDM) Source Material

Do the available data support inclusion of both house dust mite (HDM) bodies and fecal pellets as source materials for HDM allergen extracts to more adequately mimic clinically relevant allergen exposure?



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