Disclaimer Statement

The attached briefing package contains background information prepared by the Food and Drug Administration (FDA) for panel members of the Pulmonary-Allergy Drugs Advisory Committee (PADAC). All assessments made in the briefing package are preliminary and all conclusions and recommendations are subject to reconsideration. These conclusions and recommendations do not represent the final position of the FDA. The FDA will not make a final determination on the issues at hand until input from the PADAC process has been considered, and other assessments that are necessary in determining the approvability of the drug have been completed.