

## Note to Advisory Committee Members

The attached package contains the background information (“briefing document”) prepared by the Food and Drug Administration (FDA) for the panel members of the advisory committee. For advisory committee meetings involving the review of pending applications for drug products, the FDA background package often includes initial reviews of sections of the application completed by individual FDA reviewers. These individual reviews may contain the reviewer’s preliminary conclusions and recommendations regarding the adequacy of a particular section of the application to support product approval. These conclusions and recommendations do not necessarily represent the final position of the individual reviewer, nor do they necessarily represent the position of the FDA on the approvability of the application. The final FDA position on the approvability of the application will not be made until input from the advisory committee process has been considered and all reviews of the various sections of the application have been finalized.