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APPLICATION NUMBER:

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STATISTICAL REVIEW(S)



U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research
Office of Translational Sciences
Office of Biostatistics

STATISTICAL REVIEW AND EVALUATION

CLINICAL STUDIES

NDA Number: 210875

Drug Name: Kynmobi (Apomorphine Hydrochloride Sublingual Film)

Indication: Acute, intermittent treatment of “OFF” episodes associated with Parkinson’s disease

Applicant: Sunovion Pharmaceuticals, Inc.

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