

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

*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/BLA #:** NDA 022-063  
**Supplement #:** O-1 (SN0022 SN0023)  
**Drug Name:** Mydayis (mixed salts of a single-entity amphetamine product) Sustained-Release Capsules  
**Indication(s):** Attention-deficit/Hyperactivity Disorder (ADHD)  
**Applicant:** Shire  
**Date(s):** Letter date: Dec 20, 2016  
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**Review Priority:** Priority (resubmission)

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