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*APPLICATION NUMBER:*

**22-267**

**ENVIRONMENTAL ASSESSMENT**



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**NDA 21-168 Depakote ER (divalproex sodium extended-release tablets)**

**Environmental Assessment – Categorical Exclusion**

NDA 21-168 for Depakote ER (divalproex sodium extended-release tablets) qualifies for categorical exclusion from the requirements to prepare an environmental assessment under 21 CFR 25.31 (b). To the applicant's knowledge, no extraordinary circumstances exist that would prohibit the removal of the environmental assessment from NDA 21-168. For additional information, please refer to Abbott's original NDA submission (Volume 10, page 1) submitted September 30, 1999.

The purpose of this supplemental NDA is for the determination of Pediatric Exclusivity and to provide pediatric labeling for the Depakote drug products.