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RESEARCH**

*APPLICATION NUMBER:*

**22-058**

**ENVIRONMENTAL ASSESSMENT**

## ENVIRONMENTAL ASSESSMENT CATEGORICAL EXCLUSION

The requested action, approval of NDA 22-058, qualifies for a categorical exclusion from the requirement to submit an environmental assessment (EA) under 21 CFR 25.31(b). To the applicant's knowledge, no extraordinary circumstances exist that would warrant the preparation of an EA (21 CFR 25.15(d)).

(From applicant original submission dated June 30, 2006  
Module 1.12.14)



see page 30 of CMC review #2, dated  
April 20, 2007, for acceptable evaluation  
of this assessment