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RESEARCH**

APPLICATION NUMBER:

21-881

ENVIRONMENTAL ASSESSMENT

1.4.8 Request for Categorical Exclusion from Environmental Assessment

The requested action, approval of NDA 21-881, qualifies for a categorical exclusion from the requirement to prepare an environmental assessment under 21CFR§25.31(a). To the applicant's knowledge, no extraordinary circumstances exist that would warrant the preparation of an environmental assessment [21 CFR§25.15(d)].

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On Original