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APPROVAL PACKAGE FOR:

APPLICATION NUMBER

21-371

ENVIRONMENTAL ASSESSMENT/FONSI

NDA 21-371
Estrasorb™ (estradiol topical emulsion)
Novavax, Inc.

Environmental Assessment

A categorical exclusion is claimed for this NDA in accordance with 21 CFR part 25.31(b), as amended in the 29-Jul-1997 Federal Register. This was found to be satisfactory (see Chemistry Review).

**APPEARS THIS WAY
ON ORIGINAL**