

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

22-001

ENVIRONMENTAL ASSESSMENT

NDA 20-907
Activella®
estradiol/norethindrone acetate tablets
1.0mg/0.5mg

Efficacy Supplement

Date:
Version:
Status:
Page:

February 2006 | *Novo Nordisk*
Final
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Categorical Exclusion Claim

The requested action, approval of NDA 22-001 for a lower strength, dosage form of Activella (containing 0.5mg estradiol and 0.1mg norethindrone acetate per tablet) intended for the same indications, qualifies for a categorical exclusion from the requirements to prepare an environmental assessment under 21 CFR § 25.31(b). It is not expected that the introduction of a lower dosage form of Activella will increase the use of the total amount of each of the two active moieties, 17 β estradiol and norethindrone acetate. Additionally, to Novo Nordisk's knowledge, no extraordinary circumstances exist that would warrant the preparation of an EA.