

CENTER FOR DRUG EVALUATION AND RESEARCH

Application Number 50-777

ENVIRONMENTAL ASSESSMENT and/or FONSI

From pgs 21-22 of
Chemical Review

D. ENVIRONMENTAL ASSESSMENT

ACCEPTABLE

Fujisawa Healthcare, Inc. is requesting categorical exclusion from the requirement to submit an Environmental Assessment for tacrolimus ointment under 21 CFR 25.31(b).

The requested action qualifies for categorical exclusion under 21 CFR 25.31(b). Although approval of the action would increase the use of the active moiety in Tacrolimus (FK506) ointment, the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion. As required under 21 CFR 25.15(d), FHI is unaware of any extraordinary circumstances, as addressed in 21 CFR 25.21 and 40 CFR 1508, indicating that the proposed action could significantly affect the quality of the human environment.

**APPEARS THIS WAY
ON ORIGINAL**