

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER: 21-302

ENVIRONMENTAL ASSESSMENT AND/OR FONSI

Environmental assessment exclusion

A claim for categorical exclusion from the Environmental Assessment requirements under 21 CFR 25.31(b) - Action on an NDA, abbreviated application, or a supplement to such applications, or action on an OTC monograph - if the action increases the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 ppb.

As set forth in 21 CFR Part 25.31(b), action on an original NDA is categorically excluded from the requirement to prepare an Environmental Assessment or an Environmental Impact Statement if the action increases the use of the active moiety, but the estimated concentration of the substance at the point of entry into the aquatic environment will be less than 1 part per billion (ppb). "Increased use", as defined in 21 CFR Part 25.5(a), will occur if the drug is "administered at higher dosage levels, for longer duration or for different indications than were previously in effect, or if the drug is a new molecular entity."

Novartis Pharmaceuticals Corporation has filed an original NDA for pimecrolimus cream, 1% which provides for atopic dermatitis.

Novartis Pharmaceuticals Corporation certifies that this submission for pimecrolimus cream, 1% qualifies for a categorical exclusion in accordance with 21 CFR Part 25.31(b) as the concentration of the active moiety, pimecrolimus, will be significantly less than 1 ppb. ✓

Further, Novartis Pharmaceuticals Corporation states that, to the best of its knowledge, no extraordinary circumstances exist which may significantly affect the quality of the human environment and would thus require the preparation of at least an Environmental Assessment.

APPEARS THIS WAY
ON ORIGINAL