

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

202429Orig1s000

ENVIRONMENTAL ASSESSMENT



**CLAIM FOR CATEGORICAL EXCLUSION FROM THE
ENVIRONMENTAL ASSESSMENT REQUIREMENT FOR
RO5185426 TABLETS
(240 mg)
NEW DRUG APPLICATION**

Hoffmann-La Roche Incorporated claims a categorical exclusion from the requirement to prepare an environmental assessment in accordance with 21 CFR 25.31(b). The proposed action, approval of an NDA, will increase 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 part per billion. No extraordinary circumstances exist that would significantly affect the quality of the human environment as a result of the proposed action.