

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
22-307

ENVIRONMENTAL ASSESSMENT

Environmental Assessment
or
Claim of Categorical Exclusion

This was addressed on p. 216 of the CMC review. It states:

“The sponsor conducted environment studies for both prasugrel itself and the primary metabolite excreted from humans. The sponsor claimed that no information indicated that there is any significant potential harm to the environment from the use of prasugrel; no information existed which established that endangered or threatened species would be harmed. The sponsor also claimed that less than _____ of prasugrel is expected to be used during the peak year in the US. The daily discharge of water to sewage treatment facilities in the US is ~1.3 X10¹¹ liters. Therefore the predicted concentration of prasugrel that may be discharged into the aquatic environment would be less than _____”

b(4)

Based on a review of the available data and the expected introduction concentration of less than 1 $\mu\text{g/L}$, the sponsor requested a categorical exclusion from the requirement from an environment assessment according to 21 CFR25.31(b).

Evaluation: Adequate”