

**CENTER FOR DRUG EVALUATION AND  
RESEARCH**

**APPLICATION NUMBER: 21-145**

**ENVIRONMENTAL ASSESSMENT AND/OR FONSI**

## **Environmental Statement**

The subject of the proposed action will not significantly affect the quality of the human environment and meets the requirements for a categorical exclusion from submitting an environmental assessment as required by 21CFR§25.31(b). In addition, to Bristol-Myers Squibb Company's knowledge, no extraordinary circumstances exist as outlined in 21CFR§25.15(d). This action is not expected to increase the use of the active moiety and the estimated concentration of the substance at the point of entry into the aquatic environment will be below 1 part per billion. Further, the drug and the ingredients in the formulation are not known to be derived from wild-sourced plant and/or animal species.

**APPEARS THIS WAY  
ON ORIGINAL**