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RESEARCH**

*APPLICATION NUMBER:*

**20-839/S-051**

**ENVIRONMENTAL ASSESSMENT**



Sanofi-aventis U.S.  
Bridgewater, NJ

## ENVIRONMENTAL ASSESSMENT

### Claim of Categorical Exclusion from Preparation of an Environmental Assessment for Plavix®

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Property of the sanofi-aventis group - strictly confidential

**1.1.1 Claim of Categorical Exclusion from Preparation of an Environmental Assessment for Plavix<sup>®</sup>**

Sanofi-aventis U.S. LLC is claiming Categorical Exclusion from preparation of an Environmental Assessment per a supplemental application to request an additional six months of exclusivity and to provide an update to the US Prescribing Information for pediatric use for the approved NDA for Plavix<sup>®</sup> (clopidogrel bisulfate).

Compliance with the categorical exclusion criteria is made pursuant to 21 CFR Part 25, Subpart C, Categorical Exclusions, Section 25.31, Human drugs and biologics, paragraph (a) because the action would not result in increased use of clopidogrel, the active moiety.

As with previous submissions for Plavix<sup>®</sup>, extraordinary circumstances per 21 CFR section 25.21 are not indicated since no adverse or other significant effect on the quality of the human environment is predicted from this submission.