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RESEARCH**

APPLICATION NUMBER:

125388Orig1s000

ENVIRONMENTAL ASSESSMENT

STN 125388/0
Brentuximab Vedotin

Environmental Assessment

A categorical exclusion is claimed for this BLA in accordance with 21 CFR part 21.31 (a). The environmental assessment is justified and acceptable per Bo Chi on page 34 of the CMC review dated August 3, 2011.