

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

125486Orig1s000

ENVIRONMENTAL ASSESSMENT

BLA 125486
Obinutuzumab (GAZYVA)

Environmental Assessment

A categorical exclusion is claimed for this BLA in accordance with 21 CFR part 25.31©. The claim of categorical exemption is accepted by Mate Tolnay on page 8 of the product quality review dated 09/27/2013.