CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

761041Orig1s000

CHEMISTRY REVIEW(S)
Date: 09/09/2016  
To: Administrative File, STN 761041/0  
From: Wayne Seifert, Consumer Safety Officer, CDER/OPQ/OPF/DIA  
Endorsement: Zhihao (Peter) Qiu, Ph.D., Branch Chief, CDER/OPQ/OPF/DIA  
Subject: BLA 761041/0 Original  
US License: 1048  
Applicant: Genentech Inc.  

Mfg Facility:  
Drug Substance: (b)(4)  
Drug Product: (b)(4)  

Product: Atezolizumab (Tecentriq)  
Dosage: Sterile injectable solution provided in vials containing 1200 mg/20mL (60 mg/mL) for Intravenous Infusion.  
Indication: Non-Small Cell Lung Cancer  
Due Date: 09/28/2016

RECOMMENDATION: This submission is recommended for approval from a facilities assessment perspective.

ASSESSMENT

The subject BLA proposes the same facilities for Atezolizumab DS and DP manufacture and testing previously approved under BLA 761034, reference the facility review memo for BLA 761034. These facilities consist of 1)  
; 3) Genentech Hillsboro, Hillsboro, CA (FEI: 3007232634); 4)  
Kaiseraugst, Switzerland (FEI: 3003973536); 6)  
5) F. Hoffmann-La Roche Ltd.,

As of the review date these sites are still in a state of compliance.
CONCLUSION

Based on the compliance review of the subject BLA proposing Atezolizumab for treatment of non-small cell lung cancer, approval is recommended from a facilities assessment standpoint.

Wayne E. Seifert
Consumer Safety Officer
OPF Division of Inspeccional Assessment, Branch 1

Zhihao Qiu
Branch Chief
OPF Division of Inspeccional Assessment, Branch 1