# CENTER FOR DRUG EVALUATION AND RESEARCH

***APPLICATION NUMBER:***

# 761041Orig1s000

# CHEMISTRY REVIEW(S)

DEPARTMENT OF HEALTH AND HUMAN SERVICES Public Health Service

Food and Drug Administration
Center for Drug Evaluation and Research
WO Bldg. 51,10903 New Hampshire Ave.
Silver Spring, MD 20993

**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

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

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## ASSESSMENT

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

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 -A

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Date: 2016.09.09 14:18:56 -04'00'

Wayne Seifert
Consumer Safety Officer
OPF Division of Inspectional Assessment, Branch 1

Zhihao Qiu -S

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Zhihao (Peter) Qiu, Ph.D.
Branch Chief
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