MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE: 04/13/2018

TO: File for BLA 125276/S-115

THROUGH: Anshu Marathe, PhD

FROM: Suryanarayana Sista, PhD

SUBJECT: Clinical Pharmacology Primary Review

APPLICATION/DRUG: BLA 125276/S-115 ACTEMRA (tocilizumab)

Genentech submitted supplement 115 to BLA 125276 on November 13, 2017 seeking to revise the prescribing information (PI) with updated pediatric information regarding treatment with intravenous tocilizumab (TCZ) in patients with systemic juvenile idiopathic arthritis in patients less than 2 years of age and a determination that the post-marketing requirement and the relevant portion of the pediatric written request have been fulfilled. No indications are being sought in the current supplement. The submitted data includes the results of Study NP25737, an open-label PK and safety study in patients < 2 years of age with SJIA who were treated with intravenous TCZ 12 mg/kg every 2 weeks for 12 weeks.

The Office of Clinical Pharmacology (OCP) recommends approval of supplement 115 with updates to Section 8.4 of the PI provided agreement can be reached with the Applicant on revisions to the proposed label.

The clinical pharmacology review has been completed. A multi-disciplinary unireview has been used for this supplement, and the clinical pharmacology review will be archived as part of this unireview.
This is a representation of an electronic record that was signed electronically and this page is the manifestation of the electronic signature.

/s/

SURYANARAYANA M SISTA
04/13/2018

JING NIU
04/13/2018

JINGYU YU
04/13/2018

ANSHU MARATHE
04/13/2018