DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Silver Spring MD 20993

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.

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/s/

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04/13/2018

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