

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

761069Orig1s000

OFFICE DIRECTOR MEMO

MEMORANDUM

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

DATE: 5/1/17

SUBJECT: Office Director Summary Review

APPLICATION/DRUG: BLA 761069/Imfinzi (durvalumab)

Proposed indication:

Treatment of patients with locally advanced or metastatic urothelial carcinoma (b) (4)

Please refer to the combined Division Director and Office Director review of 5/1/17 under BLA 761069 for the Office Director summary review for this application.

APPEARS THIS WAY ON ORIGINAL

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/s/

TAMY E KIM
05/01/2017