



BLA 761074/S-005

**APPROVAL LETTER**

Mylan GmbH  
Attention: Suzanne Kiani  
Sr. Director, Regulatory Science, Biologics  
781 Chestnut Ridge Road  
P.O. Box 4310  
Morgantown, WV 26504-4310

Dear Ms. Kiani:

Please refer to your Supplemental Biologics License Application (sBLA) dated and received December 28, 2018, and your amendment, submitted under section 351(k) of the Public Health Service Act for Ogivri (trastuzumab-dkst) for injection, 420 mg/vial, multiple-dose vial.

This “Changes Being Effected” supplemental biologics license application provides for a change in color of the logo associated with the proprietary name as well as the product strength identifier. In addition, the manufacturer’s address for Mylan GmbH was updated.

**APPROVAL & LABELING**

We have completed our review of this application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

**CARTON AND CONTAINER LABELS**

We acknowledge your April 29, 2019, submission containing final printed carton and container labeling.

If you have any questions, call Andrew Shiber, Regulatory Business Process Manager, at (301) 796 - 4798.

Sincerely,

*{See appended electronic signature page}*

Kathleen A. Clouse, Ph.D.  
Director  
Division of Biotechnology Review and Research I  
Office of Biotechnology Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosures: Carton and Container Labeling



Kathleen  
Clouse Strebel

Digitally signed by Kathleen Clouse Strebel  
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