



NDA 211651/S-001

**SUPPLEMENT APPROVAL**

Pfizer, Inc.  
Attention: Mindy Mercado  
Associate Director, Regulatory Affairs  
100 Cambridge Park Drive, Suite 505  
Cambridge, MA 02140

Dear Ms. Mercado:

Please refer to your Supplemental New Drug Application (sNDA) dated and received October 30, 2018, and your amendments, submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (FDCA) for Talzenna (talazoparib) Capsules, 0.25 mg and 1 mg.

This “Changes Being Effected” supplemental new drug application provides for the introduction of physician samples for the 1 mg capsule.

**APPROVAL & LABELING**

We have completed our review of this supplemental 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 January 12, 2021, submission containing final printed carton and container labeling.

**REPORTING REQUIREMENTS**

We remind you that you must comply with reporting requirements for an approved NDA (21 CFR 314.80 and 314.81).

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If you have any questions, call Laya Keyvan, Regulatory Business Process Manager, at (240) 402 - 4598.

Sincerely,

*{See appended electronic signature page}*

Ramesh Raghavachari, Ph.D.  
Branch Chief, B1  
Division of Post-Marketing Activities I  
Office of Lifecycle Drug Products  
Office of Pharmaceutical Quality  
Center for Drug Evaluation and Research

Enclosure(s):

Carton and Container Labeling



Ramesh  
Raghavachari

Digitally signed by Ramesh Raghavachari  
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