CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

217581Orig1s000

NON-CLINICAL REVIEW(S)

MEMORANDUM

Date: July 13, 2023
From: Melissa A. Pegues, PhD
Nonclinical Reviewer
Division of Hematology Oncology Toxicology for Division of Oncology 2
Through: Claudia P. Miller, PhD
Pharmacology/Toxicology Supervisor
Division of Hematology Oncology Toxicology for Division of Oncology 2
To: File for NDA 217581
Re: Supporting Document (SD) 1; New Dosage Form;
Pharmacology/Toxicology Labeling Revisions

On November 29, 2022, Pfizer, Inc. submitted a New Drug Application (NDA) for a new oral granule formulation of crizotinib. Crizotinib is kinase inhibitor targeting anaplastic lymphoma kinase (ALK), ROS1, and c-Met, and previously approved under NDA 202570 for the treatment of ALK-positive non-small cell lung cancer (NSCLC), anaplastic large cell lymphoma (ALCL), and inflammatory myofibroblastic tumor. The Applicant cross-referenced NDA 202570 for nonclinical information to support the current NDA. No new nonclinical data was included in NDA 217581 and the nonclinical team does not object to approval of this application.

The nonclinical team recommended changes to sections 5.7, 8.1, 8.2, 8.3, and 17 of the label. Modification to the language in these sections included advising females of reproductive potential of the risk of embryo-fetal toxicity, as well as removing “at least” and changing “final” to “last” when describing the recommended duration of contraceptive use. All revisions were minor and intended for consistency with current labeling practices.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

MELISSA A PEGUES
07/13/2023 09:19:37 AM

CLAUDIA P MILLER
07/13/2023 09:41:21 AM