NDA 210854
NDA 214410/Original 1

NOTIFICATION OF
NON-COMPLIANCE WITH PREA

Genentech, Inc.
Attention: Shweta Kotwal, MBBS, MA
Regulatory Program Management
1 DNA Way
South San Francisco, CA 94080

Dear Shweta Kotwal:

Please refer to your new drug applications (NDAs) submitted under section 505(b) of the Federal Food, Drug, and Cosmetic Act (the Act) for the following:

Application Number	Product Name	Date Approved
NDA 210854	Xofluza (baloxavir marboxil) tablets	October 24, 2018
NDA 214410/Original 1	Xofluza (baloxavir marboxil) granules for oral suspension	November 23, 2020

The Agency has determined that you have failed to meet the postmarketing requirement(s) (PMRs) of the Pediatric Research Equity Act (PREA) for these applications because you have not yet submitted your pediatric assessment for the following PMRs which were deferred until the date listed:

PMR 3503-1: Deferred until December 31, 2023

PMR 3984-1: Deferred until December 31, 2023

Therefore, we are hereby notifying you that due to your failure to submit either a pediatric assessment or a request for a deferral extension, you are not in compliance with federal law.

Under the provisions of section 505B(d)(1) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) [21 U.S.C. 355c(d)(1)], you must respond in writing within 45 calendar days of the date of this letter. Your response should include the reason(s) for the delayed pediatric assessment and a date by which you expect to submit the assessment. You may also include a request for a deferral extension, if applicable, which should be identified as a "**DEFERRAL EXTENSION REQUESTED**" in your response.

In accordance with the FD&C Act, FDA will post this letter and your response to the website at https://www.fda.gov/drugs/development-resources/non-compliance-letters-under-505bd1-federal-food-drug-and-cosmetic-act with redactions for any trade secrets and confidential commercial information 60 calendar days from the date of this letter.

Please identify your response to this letter as a "**RESPONSE TO PREA NON-COMPLIANCE LETTER.**" To facilitate our review, submit this information to your NDAs with a cross-reference letter to the investigational new drug application (IND) to which your protocol has been submitted.

If you have any questions, please contact Saebyeol Jang, PhD, RAC-US, Senior Regulatory Project Manager, at Saebyeol.Jang@fda.hhs.gov .

Sincerely,

{See appended electronic signature page}

Wendy Carter, DO
Director (Acting)
Division of Antivirals
Office of Infectious Diseases
Center for Drug Evaluation and Research

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/

YODIT BELEW
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