NDA 214410/Original 1
NDA 210854/S-004

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 214410/Original 1	Xofluza (baloxavir marboxil) granules for oral suspension	November 23, 2020
NDA 210854/S-004	Xofluza (baloxavir marboxil) tablets	November 23, 2020

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

PMR 3961-1: Deferred until February 29, 2024

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 NDA and sNDA 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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