Form 483 posting by US Food and Drug Administration (FDA) – Novartis statement [1]

Publish Date: 24 September 2019 15:15 EDT

Today the FDA posted information provided by the company to the FDA in response to its Form 483 issued on August 2, 2019.

Our submission, which can be read here [2], reiterated our firm commitment to data integrity and transparency in our engagements with regulators. Additionally, we provided detailed explanations of our two-phased investigation and addressed questions regarding the timing of our disclosure to the FDA.

As previously announced, we understand the FDA's concerns and appreciate that the circumstances presented by a new gene therapy is something that should be taken into account with regard to timing of FDA notifications of data integrity investigations. Although we are confident that the actions we are taking will prevent data integrity issues from occurring in the future, going forward we are making a voluntary commitment to notify the FDA within five business days of receipt by our quality organization of any credible allegation related to data integrity impacting any pending application in the Novartis Group. We will take a similar approach in other jurisdictions, absent a specific local regulation to the contrary.

Links
[1] https://www.novartis.us/news/form-483-posting-us-food-and-drug-administration-fda-novartis-statement-0
[2] https://www.fda.gov/media/131007/download