United States Senate
COMMITTEE ON FINANCE
WASHINGTON, DC 20510–6200

August 9, 2019

VIA ELECTRONIC TRANSMISSION

Mr. Vasant Narasimhan
Chief Executive Officer
Novartis International AG

Dear Mr. Narasimhan,

On August 6, 2019, the Food and Drug Administration (FDA) issued a public statement about Novartis' gene therapy product, Zolgensma, a life-saving treatment for infants with spinal muscular atrophy and the most expensive drug in the world.[1] That statement noted that the FDA approved the drug on May 24, 2019, and then on June 28, 2019, AveXis, a subsidiary of Novartis, informed the FDA that it issued manipulated data "that impacts the accuracy of certain data from product testing performed in animals submitted in the biologics license application…" for Zolgensma.[2] The statement further noted that AveXis became aware of the data manipulation before the FDA approved Zolgensma but intentionally withheld that information from the FDA until after the product was approved. Such conduct is reprehensible and could have an adverse effect on patients. Accordingly, the conduct ought to be investigated and, as appropriate, punished to the fullest extent of the law.

To better understand the decision-making process that led to the intentional withholding of important information from the FDA, please provide the following no later than August 23, 2019:

[1] FDA Statement, *Statement on data accuracy issues with recently approved gene therapy* (Aug. 6, 2019). Available at https://www.fda.gov/news-events/press-announcements/statement-data-accuracy-issues-recently-approved-gene-therapy?utm_campaign=080619_Statement_Statement%20by%20FDA%20on%20data%20accuracy%20issues%20with%20gene%20therapy&utm_medium=email&utm_source=Eloqua
[2] *Id.*

1. All records[3] relating to the withholding of Zolgensma data from the FDA.
2. All records relating to Novartis'[4] internal inquiry into Zolgensma data manipulation.
3. On what date did Novartis learn that it issued manipulated data to the FDA relating to Zolgensma?
4. On what date did Novartis open an internal inquiry into the manipulated data?
5. On what date did Novartis conclude the internal inquiry?
6. How many Novartis employees have been terminated for manipulating Zolgensma data?
7. What steps have you taken to ensure that manipulated data is not sent to the FDA for future products?

Thank you for your attention to this important matter. Should you have questions, please contact Joshua Flynn-Brown of my Committee staff at 202-224-4515.

Sincerely,

Charles E. Grassley
Chairman
Committee on Finance

[3] "Records" include any written, recorded, or graphic material of any kind, including letters, memoranda, reports, notes, electronic data (emails, email attachments, and any other electronically-created or stored information), calendar entries, inter-office communications, meeting minutes, phone/voice mail or recordings/records of verbal communications, and drafts (whether or not they resulted in final documents). The request for "records" applies to Novartis and all its subsidiaries, to include AveXis.
[4] "Novartis" shall also include its subsidiaries, such as AveXis.