Statements

Find information and the latest updates and background information on recent events related to a few of our key products.

**Accordion:**
Form 483 posting by US Food and Drug Administration (FDA) – Novartis statement

September 24, 2019

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][1], 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.

Novartis statement on Zolgensma

Novartis stands behind Zolgensma® for the treatment of children less than 2 years of age with spinal muscular atrophy.

Read more [2]

The Novartis comment letter submitted July 16, 2018 to the Department of Health and Human Services (HHS) in response to the “HHS Blueprint to Lower Drug Prices and Reduce out-of-Pocket-Costs.”

Novartis response to the **HHS Blueprint to Lower Drug Prices and Reduce Out-of-Pocket Costs** [3]

Novartis Pharmaceuticals Corporation (Novartis) Statement on Recall Outside the United
Specific batches of Sandoz valsartan and Sandoz Valsartan and Hydrochlorothiazide Film-Coated Tablets were recalled outside of the United States earlier this month.

This recall does NOT impact any Novartis or Sandoz valsartan products in the United States or any Novartis Pharma products that contain valsartan, including Diovan® (valsartan), Diovan HCT® (valsartan/hydrochlorothiazide), Exforge® (amlodipine and valsartan), Exforge HCT® (amlodipine, valsartan and hydrochlorothiazide) or Entresto® (sacubitril/valsartan). Also, Sandoz valsartan products outside the specifically defined markets below are not impacted by the issue.

The valsartan API (active pharmaceutical ingredient) in these products does not come from the same source as those products affected outside the United States. Patients in the United States currently taking Sandoz valsartan tablets, Sandoz valsartan and hydrochlorothiazide tablets, Sandoz amlodipine and valsartan tablets, Sandoz amlodipine, valsartan, hydrochlorothiazide tablets, Diovan®, Diovan HCT®, Exforge®, Exforge HCT® or Entresto® should continue to take their medication as directed by a physician.

The recall was initiated in the following countries after an impurity above the typically established limit was confirmed: Germany, Norway, Finland, Sweden, Hungary, Netherlands, Austria, Ireland, Bulgaria, Italy, Spain, Portugal, Belgium, Luxembourg, France, Poland, Croatia, Lithuania, Greece, Canada, Bosnia and Herzegovina, Bahrain and Malta.

The health authorities in the concerned countries were notified about the issue as per local regulations on June 27, 2018. Novartis is in close contact with the health authorities and the supplier.

On July 13, 2018, the United States Food and Drug Administration announced a separate recall of valsartan from non-Sandoz companies. This recall does NOT impact any Novartis or Sandoz valsartan products in the United States.

Novartis and Sandoz are committed to meeting the highest quality standards for all of our marketed products, and the recall outside the United States is being conducted in agreement with the local health authorities impacted.
Hero title:
AveXis data integrity

Accordion Type:
Collapsible

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Links
[1] https://www.fda.gov/media/131007/download