Novartis announces Complete Response Resubmission for inclisiran New Drug Application

Jul 06, 2021

Novartis today announced the Complete Response resubmission to the US Food and Drug Administration (FDA) for the inclisiran New Drug Application (NDA). Novartis is listing its own site in Schaftenau, Austria, as the manufacturing location for the final finished product within the resubmission.

- The inclisiran Complete Response resubmission addresses the FDA Complete Response Letter (CRL) issued in December 2020, stating unresolved facility inspection-related conditions at a third-party manufacturing facility. The FDA did not raise any concerns related to the efficacy or safety of inclisiran.
- The transfer of the manufacturing of inclisiran to the Novartis-owned facility at Schaftenau, Austria, was planned and initiated in 2020, prior to the receipt of the CRL.

Novartis will provide an update after the FDA has determined that the response resubmission is complete.
