

Major Amendment 16 - GLASSIA, March 15, 2010

Date: 3/15/10

To: To File STN 125325/0

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Applicant: Kamada

Product: Alpha-1-Proteinase Inhibitor (Human)

Proposed names: GLASSIA

Subject: Major amendment – Amendment 16

- **Recommendation:** Review cycle extension. The submitted information in 125325/amendment 16 contains a substantial amount of new manufacturing or facility information not previously submitted to, or reviewed by, the agency. According to CBER SOPP 8402, this submission constitutes a major amendment. Amendment 16 dated 3/11/10, contains new information resulting from a change in the manufacturing process implemented recently due to equipment malfunction and --(b)(4)-- yields resulting from process optimization and the use of ----- (b)(4)----- then that used in the early full scale manufacturing runs. The following information is submitted:
- Validation of ----(b)(4)---- at the ----(b)(4)---- step supported with the following reports (final container lots reported in the original submission were manufactured using only --- (b)(4)---):
 - Summary of Mixing Validation for Vessel -(b)(4)- for the AAT Product (Rep-VL-100332-PQ)
 - Conformance Report: AAT ----(b)(4)---- Process Using a Combination of -(b)(4)- ----- -- in Vessel -(b)(4)- (Rep-VL-100339-PV)
- Validation of the -----(b)(4)----- supported with the following validation protocols and reports:
 - Summary of Alpha-1 Antitrypsin (AAT) Uniformity of Filling Validation (Rep-VL-07704-PV/A2)
 - Protocol for the Validation of -----(b)(4)----- for the -(b)(4)- ----- of API (Alpha 1 Proteinase Inhibitor) Viability Study (VL-100291-PQ)
 - Report: Validation of -----(b)(4)----- for the -----(b)(4)----- of API (Alpha 1 Proteinase Inhibitor) Viability Study (Rep-VL-100291-PQ)
 - Protocol for the Validation of -----(b)(4)----- for the -(b)(4)----- of API Bacterial Challenge Study (VL-100293-PQ)
 - Report for the Validation of -----(b)(4)----- for the --(b)(4)----- of API (Alpha 1 Proteinase Inhibitor) Bacterial Challenge Study (Rep-VL-100293-PQ)
 - Risk assessment for -----(b)(4)----- API Drug Product Formulation Lot ----- (b)(4)----- (RM-017)

- Updated list of process quality attributes based on the agreements reached during the inspection.
- Modification of ---(b)(4)-- reporting requirement at the critical steps to agree with the accuracy level of the ---(b)(4)---.
Also, BLA chapters 3.2.S.2.2, 3.2.S.2.4, 3.2.P.3.2, 3.2.P.3.4, 3.2.P.3.5 and 3.2.P.8, which were updated due to the modifications listed above, and the revised Attachment 43-1 of Amendment 14 are included.
This submission qualifies as a major amendment and, thus, the review cycle should be extended by 3 months.

Page Last Updated: 05/24/2016

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