



Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

To: STN: 125325.0

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Applicant: Kamada

Product: Alpha-1 Proteinase Inhibitor (Human)
Trade name: GLASSIA™

Subject: CMC Review: Original BLA - Viral Safety and Validation

EXECUTIVE SUMMARY

The Biologics License Application (BLA) from Kamada was received by CBER on September 30, 2009 requesting U.S.-licensure of an Alpha-1 Proteinase Inhibitor (Human) (API) product with a trade name of GLASSIA™. It is indicated for chronic augmentation and maintenance therapy in individuals with congenital deficiency of API and clinical evidence of emphysema.

In this submission, Kamada provided viral safety data to support the approval of the BLA. This memorandum includes reviews of: 1) plasma screening regarding product safety; 2) manufacturing procedures that are intended for viral clearance: nanofiltration (NF) and solvent/detergent (S/D) treatment.

This Kamada-API is made from the -----(b)(4)----- provided by -(b)(4)-. However, -(b)(4)- has not yet provided any information regarding -----(b)(4)-----

----- . Because of the proprietary nature of -(b)(4)- methods, FDA recommended Kamada to remove the relevant claims in the Package Insert. Kamada has agreed to FDA's recommendation.

The viral safety information provided by Kamada in the original BLA submission and in their responses to our IRs is otherwise acceptable.

RECOMMENDATION

Approval

BACKGROUND SUMMARY

Kamada-API is prepared from human plasma obtained from U.S.-licensed blood or plasma collection centers. Both Source Plasma (SP) and recovered plasma (RP) are used for manufacturing Kamada-API. Plasma is fractionated using a modified version of the cold ethanol fractionation process and the API is then isolated and purified by a series of ----(b)(4)---- chromatographic procedures. The manufacturing procedures of Kamada-API include two specifically designed steps to remove or inactivate viruses: the nanofiltration step by using a 15 nm filter to remove both enveloped and non-enveloped viruses, and the solvent/detergent (S/D) treatment to inactivate enveloped viruses.

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Note: Parvovirus B19 (B19) in the manufacturing pool is set not to exceed 10^4 IU of B19 DNA per mL.
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Fourteen (14) Pages Determined to be Non-Releasable: (b)(4)