

# Filing Meeting Summary on Kamada Alpha-1-Proteinase Inhibitor (Human) - GLASSIA, July 13, 2009

## Meeting Summary

**Date:** July 13, 2009

**Time:** 1:00 PM

**From:** Cherie Ward-Peralta

**To:** STN 125325/0

**Re:** Filing Meeting on Kamada Alpha-1-Proteinase Inhibitor (Human)

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## FDA Participants:

Cherie Ward-Peralta, Jiahua Qian, Ewa Marszal, Ross Pierce, Jennifer Reed, Stan Lin, Faith Barash, Dave Doleski, Christine Drabick, Dennis Cato, Dorothy Scott, Iftekhar Mahmood, Douglas Frazier, Lilin Zhong, and Evi Struble

## Background:

The sponsor has submitted an Original BLA submission for Alpha-1 Proteinase Inhibitor (Human), intravenous in the treatment of chronic augmentation and maintenance therapy in individuals with congenital deficiency of alpha-1-proteinase inhibitor (A1-PI) and clinical evidence of emphysema. Clinical study Kamada-API-002 is enclosed within the submission in support of the application. The Integrated Summary of Safety (ISS) and Integrated Summary of Benefits and Risk (ISBR) from Study-API-002 and Study -(b)(4)-API-001 are also enclosed within the submission. A Pharmacokinetic narrative performed within Study -(b)(4)-API can be found within the submission. The submission also encloses a full pediatric waiver for all pediatric groups according to PREA since this is an adult-related condition.

## Discussion:

Most on the review committee believes the submission is fileable, except for some electronic submission problems, and possible clinical and PK data SAS files missing from the submission. The committee will request additional information from the sponsor before the filing date. If the data is not provided by the filing date, we may issue either a refuse to file letter or a filing letter with major deficiencies.

## Action Items:

1. Information Request will need to be prepared to provide the data before the filing date.
2. Resolve electronic submission problems that reviewers are having with the submission.
3. Verify if another DMPQ reviewer can be added to the committee.

<https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/default.htm>

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