

Record of Telephone Conversation - GLASSIA, March 3, 2010

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA

Submission ID: 125325/0

Office: OBRR

Product: Alpha-1-Proteinase Inhibitor (Human)

Applicant: Kamada Ltd.

Telecon Date/Time: 03-Mar-2010 09:00 AM

Initiated by FDA? Yes

Telephone Number: 703-739-5695

Communication Category(ies): 1. Information Request

Author: NANNETTE CAGUNGUN

Telecon Summary:

FDA Participants:

Dorothy Scott

Ewa Marszal

Jennifer Reed

Nannette Cagungun

Non-FDA Participants:

Ruth Wolfson

David Nakar

Mark Kessler

Hanna Ash

Drorit Lew

----- (b)(4) -----

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

After introductions, FDA stated it wished to discuss the timelines for the submission of outstanding information, additional issues that must be addressed to facilitate the review of the application, and to offer recommendations. In its Kamada-API manufacturing process, the Sponsor proposes to switch from ----- (b)(4) -----
----- (b)(4) ----- . CBER had the following items to discuss related to this change:

With regard to the ----- (b)(4) -----, process parameters and in-process product quality attributes, FDA asked Kamada for a timeframe for when the information would be submitted to the BLA.

Kamada stated they would submit this information by March 9, 2010.

FDA asked Kamada to provide all of the updated data for the lots manufactured after the change because those data were not submitted to the BLA.

Kamada replied that section 2.57 of the submission includes all current stability data up to the end of January.

FDA then asked when the 6 month data would be available and if accelerated stability was being done on the lot. Kamada stated that accelerated stability has not been performed.

FDA advised the company to double check the step where activity was measured. FDA asked if decisions were made based on parameters.

Kamada replied that activity parameters were only used for the production of the drug product -----(b)(4)-----

FDA asked when Kamada planned to submit the justification for potency of specificity standard.

Kamada indicated they would submit it by March 17, 2001.

Kamada indicated that the lot release protocol would be submitted on March 4, 2010 while the package insert would be submitted on March 5, 2010.

FDA then proceeded to make the following recommendations:

1. Please include filters in the package.
2. Recommendations for viral safety will be forthcoming.

3. -----(b)(4)-----

----- (b)(4) -----

4. With regard to the comparability protocol, FDA asked if ----(b)(4)--- from -(b)(4)- would continue to reflect recovered and source plasma and whether it will contain -(b)(4)-.

Kamada replied that ----(b)(4)--- from source and recovered plasma will contain -(b)(4)-.

FDA stated Kamada should in the comparability protocol address both source and recovered plasma -(b)(4)- containing -(b)(4)-.

Kamada indicated they would amend the protocol.

5. Please provide justification for the validation of -(b)(4)- content, mix time, mix speed, -(b)(4)- datasets.
6. FDA asked Kamada to propose a panel of less than 5 protein impurities and compare that to historical data. Kamada mentioned that this information might already be in the protocol. They will look further into this.
7. Please compare quality attributes on the in-process intermediates with -(b)(4)- to those observed historically.

With regard to the -----(b)(4)---, FDA reminded Kamada to include process parameters used to support the change. Kamada should also provide data on process quality attributes for the lot(s) that will support the change.

FDA indicated that it would fax these additional questions and recommendations to Kamada shortly.

Kamada inquired about the status of the proprietary name review. FDA said it is still under review. Kamada notes that they would submit the final packaging to the BLA. Kamada indicated the size of the carton would be adjusted. They will inform FDA of any other changes.

The meeting ended.

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

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