

Record of Telephone Conversation - GLASSIA, June 24, 2010

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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: 16-Jun-2010 08:30 AM

Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s): 1. Information Request

Author: CHERIE WARD-PERALTA

Telecon Summary: to discuss the PMC to request information from Baxter

FDA Participants: Cherie Ward-Peralta, Dorothy Scott, Ewa Marszal, and Lilin Zhong

Non-FDA Participants:

Dr. Ruth Wolfson – Sr. VP, Quality & Regulatory Affairs, Kamada

Dr. David Nakar – Sr. Regulatory Affairs Associate, Kamada

------(b)(4)----- – Consultant to Kamada

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Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

FDA questioned what is the specification for the --(b)(4)-- at release. Is it the same as the specification for the shelf-life, which is -----(b)(4)-----? FDA will be sending more questions and informed Kamada that the PMC annual reports are provided separately from the other CMC and Clinical annual reports to be submitted annually.

FDA asked whether Kamada tried to receive viral validation information requested from -(b)(4)-.

Kamada informed that they have been trying to get the information from -(b)(4)-. Several discussions have been held with -(b)(4)-, but they have had to go through many obstacles to get this information. Kamada could not assure that they will be able to obtain the required information in a timely manner and wondered whether there was another way to obtain this information from -(b)(4)- to meet the requested commitment. Kamada suggested that -(b)(4)- should be required to submit this information, as they could not answer any questions about the validation. Since they were having difficulty in obtaining this information, they did not want to commit to a date in providing the information but would try to provide it as soon as they can. According to their agreement, they will be performing a GMP audit on -(b)(4)- and will request their

auditors to review the validation, but they will not be able to get copies of SOPP or the validation. When the audit is performed, they can share with FDA any problems that are found during the audit although in a previous audit, they did not have any questions on the validation.

FDA informed that the PMC request was not for Kamada to obtain the document, but to request that -(b)(4)- commits to providing these documents to FDA.

Kamada informed that they have requested -(b)(4)- to provide this information to FDA. They had to go through several obstacles with -(b)(4)- management in order to gain approval in submitting the information. Since the validation reports are in -(b)(4)-, this was difficult to obtain.

FDA requested Kamada to provide the name of their contact via email.

Kamada asked if it is possible for the agency to put pressure on -(b)(4)-.

FDA informed that there has been internal discussion on this situation but we would need to know who Kamada has spoken to, and we would try to determine a solution.

FDA also asked whether Kamada has reviewed this validation during inspection.

Kamada informed that yes, they have looked at the validation and will be reviewing this information in the next inspection.

Kamada consultant suggested to reword the commitment to not include -(b)(4)- in the wording.

FDA will discuss this further, but it seems Kamada has made progress and -(b)(4)- is willing to provide this information. FDA will discuss what can be done on our end, and agree to not utilize the name of the other company for the Kamada's PMC, but request for Kamada to control the contract with them.

Kamada is in the process to acquire another material but they are currently tied with -(b)(4)- product.

FDA is willing to work with Kamada in supplying the information to the FDA within a cross-reference submission, but we need to put dates on PMC.

Kamada does commit to providing the information as soon as they receive the information from -(b)(4)-.

FDA questioned again what the specification for the -(b)(4)- is at the time of release.

Kamada stated that it is -----(b)(4)-----, and lots at release do not have -----(b)(4)----- content. Since this is a specification for the end of shelf-life, therefore they look at this all the time, and have statistically analyzed the -----(b)(4)----- . This specification is for release and up to the end of shelf-life, -----(b)(4)-----.

FDA believed the product was -----(b)(4)----- during the time of release therefore Kamada would need to set a specification for release. FDA will send this question by email.

Kamada restated that FDA would like a separate specification for release and for the end of shelf life, which is -(b)(4)-.

FDA confirmed that the drug product needs to have a separate specification for release and for the end of shelf-life.

End of Meeting

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

Players.

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