

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: 22-Feb-2010 10:00 AM Initiated by FDA? No

Telephone Number: 866-866-2244

Communication Categorie(s):

1. Advice

Author: CHERIE WARD-PERALTA

Telecon Summary:

to discuss Immunogenicity results

FDA Participants:

Ewa Marszal,

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Cherie Ward-Peralta

Non-FDA Participants:

Ruthy Wolfson, Ph.D., VP Regulatory Affairs – Kamada Ltd

David Nakar, Ph.D., Sr. Regulatory Affairs Associate – Kamada Ltd

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Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Kamada requested if FDA had additional questions or comments on the analytical methods after receiving the additional information, validation report, and discussion.

Two (2) Pages Determined to be Non-Releasable: (b)(4)