

MEMORANDUM

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Public Health Service
Food and Drug Administration
Center for Biologics Evaluation and Research

DATE: June 28, 2010

FROM: Patricia A. Holobaugh
Bioresearch Monitoring Branch Chief, HFM-664

APPROVED

By Patricia Holobaugh at 6:59 am, Jun 28, 2010

TO: Ewa Marszal, Ph.D., Committee Chair, HFM-345
Leland Ross Pierce, M.D., Clinical Reviewer, HFM-392
Cherie Ward-Peralta, Regulatory Project Manager, HFM 380

SUBJECT: Bioresearch Monitoring Inspection Results

STN: BLA 125325/0

Sponsor: Kamada Ltd

Product: Alpha-1 Proteinase Inhibitor (Human) "Kamada-API"

The Bioresearch Monitoring discipline review memo dated May 27, 2010, describes the findings of three clinical investigator inspections submitted for the Review Committee's consideration. We conclude that the clinical investigator inspections support approval of the biologics license application.

If you have any questions about this memorandum or any aspect of Bioresearch Monitoring, please contact me at (301) 827-6347.

cc:

paper copy HFM-664 Access/Chron

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