

MEMORANDUM

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

DATE: May 27, 2010

FROM: Dennis T. Cato, Bioresearch Monitoring Branch, HFM-664
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality

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

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"

SUMMARY

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