

MEMORANDUM

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

DATE: October 23, 2009

FROM: Dennis T. Cato, Bioresearch Monitoring, HFM-664
Division of Inspections and Surveillance
Office of Compliance and Biologics Quality
Telephone: 301-827-2588 Fax: 301-827-6748

THROUGH Patricia Holobaugh, Bioresearch Monitoring Branch Chief, HFM-664

SUBJECT: Bioresearch Monitoring Midcycle Review Memo
BLA: STN 125325/0
Sponsor: Kamada Ltd
Product: Alpha-1-Proteinase Inhibitor (Human) "Kamada-API"

TO: Ewa Marszal HFM-345
Cherie Ward-Peralta HFM-380
Leland Ross Pierce HFM-392

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The above inspections are pending completion. We will update the committee with the results of the inspections as soon as they are available.

Dennis T. Cato
Consumer Safety Officer

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HFM-345 Ewa Marszal, Chair BLA STN 125325/0

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Draft: Cato: 10/23/2009

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