

Applicant Name: Kamada Ltd.

License Number (if any): US license 1826

Address: MP Negev, Beit Kama, Israel 8532500

Product: KEDRAB, Human rabies immune globulin

Manufacturing Location:

Kamada Ltd.

MP Negev

Beit Kama, Israel 85325

FEI number 1000630279

The previous inspection (Pre license inspection for BLA 125325/0 for Alpha-1 Antitrypsin (AAT or Glassia), licensed in 2010), held in February 3-4 and 7-11, 2010 resulted in the issuance of a 13-items FDA 483, Inspectional Observations and classification of Voluntary Action Indicated (VAI). There were no major outstanding issues at the time of the Kamada Pre-license Inspection (PLI)/cGMP joint inspection in 2017.

Kamada most recent inspection was conducted from March 26 to 31 and April 2 to 5, 2017. This pre-license (PLI) and cGMP join inspection was conducted at Kamada's Negev, Israel manufacturing facility under US license 1826. This joint inspection (Center for Biologics Evaluation and Team-bio joint inspection) was initiated in association with Biologics License Application (BLA) 125613/0 for the new product Rabies Immune Globulin, Human (HRIG) and CGMP inspection for the license product Alpha-1 Antitrypsin (AAT), licensed in 2010. Kamada provided formal responses to the 483 items on May 04, 2017 and in subsequent amendments. This inspection was classified as VAI and all inspectional 483 observations were resolved.

STN: 125613/0

Summary: Biologics License Application (BLA) for Human Rabies Immune Globulin (KEDRAB)

There are no ongoing or pending investigations or compliance actions with respect to the above facility or its product(s). Therefore, the Office of Compliance and Biologics Quality, Division of Case Management does not object to the approval of this supplement.

