



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville, MD 20852

TO: Director, OCOD

FROM: Jay S. Epstein, M.D., Director, OBRR

APPROVED

By Ghette Y. Michaud, MD at 4:05 pm, Jul 01, 2010

RE: Action Package for STN 125325, Alpha-1-Proteinase Inhibitor (Human)

DATE: July 1, 2010

Product Office Point of Contact: Cherie Ward-Peralta

The attached list identifies the documents in CBER's Electronic Document Room (EDR) that are the official Action Package for Posting under Section 916 of FDAAA.

This list identifies the documents for the Action Package that are available in MS Word, MS Excel or, for emails, Rich Text Format (RTF) or Text (TXT) format. The list also identifies the documents for which, after a thorough search, MS Word, MS Excel or, for emails, Rich Text Format or Text format copies are not available. We are providing these in the formats noted in the list (or in PDF or hardcopy if all the same).

Please review and redact these documents and post on CBER's Web page.



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Memorandum

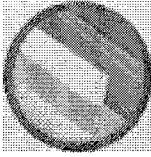
Date: June 30, 2010

From: Cherie Ward-Peralta, DBA/OBRR/CBER/FDA, HFM-380

Subject: FDAAA Section 916 (Action Packages), Officers/Employee List for STN
125325/0

The following officers or employees of FDA participated in the decision to approve this application and consented to be identified on this list.

Ewa Marszal
Nisha Jain
Iftexhar Mahmood
Joseph Doleski
Loan Nguyen
Dennis Cato
Faith Barash
Randa Melhem
Christine Drabick
Patricia Holobaugh
Ghanshyam Gupta
Mark Shields
Sheryl Kochman
Crystal Allard
Trevor Pendley
Mei-ying Yu
Basil Golding
Ginette Michaud
Cherie Ward-Peralta



CBER LETTER

STN 125325\0

CBER Receipt Date: 01-Jun-2009

Applicant: KAMADA LTD.

Product: Alpha-1-Proteinase Inhibitor (Human)
Indication: Alpha-1 Proteinase Inhibitor (human),
Kamada-API, is indicated for chronic augmentation
and maintenance therapy in individuals with
congenital deficiency of alpha-1 proteinase inhibitor
(A1-PI) and clinical evidence of emphysema

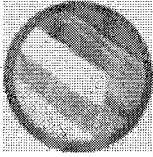
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Content

- | | | |
|---|---|-------------------------|
| ① | 24-Mar-2010 CHERIE WARD-PERALTA (PNA) | Actions |
| ② | 19-Mar-2010 CHERIE WARD-PERALTA (MAA) | Actions |
| ③ | 16-Dec-2009 CHERIE WARD-PERALTA (PNN) | Actions |
| ④ | 31-Jul-2009 CHERIE WARD-PERALTA (FL,DI) | Actions |
| | 17-Jun-2009 CHERIE WARD-PERALTA (ACK) | Actions |
| | STN Assignment Application | |

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**CBER REVIEW MEMO\MEMO**

STN 125325\0

CBER Receipt Date: 01-Jun-2009

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- | | | | |
|---|---|-------------------------|----------|
| ⑤ | 30-Jun-2010 JOSEPH DOLESKI (CM) Final Memo. Recommend Approval. | Actions | |
| ⑥ | 30-Jun-2010 LELAND PIERCE (CL) | Actions | |
| ⑦ | 30-Jun-2010 EWA MARSZAL (RR) Final Review Memo | Actions | 2 docs |
| | 28-Jun-2010 CHERIE WARD-PERALTA (OT) List of Employees #1 for action package | Actions | |
| | 28-Jun-2010 CHERIE WARD-PERALTA (OT) List of Employee #3 for Action Package | Actions | |
| | 28-Jun-2010 CHERIE WARD-PERALTA (OT) List of Employees #2 for Action Package | Actions | |
| ⑧ | 28-Jun-2010 PATRICIA HOLOBAUGH (RA) Bioresearch Monitoring final recommendation | Actions | pdf only |
| | 28-Jun-2010 JOSEPH DOLESKI (CC) no objections to approval | Actions | |
| | 23-Jun-2010 JOSEPH DOLESKI (IRL-IC) FACTS Endorsement / Kamada Pre-License Inspection Close-Out Mem | Actions | |
| | 21-Jun-2010 JOSEPH DOLESKI (CM) Categorical Exclusion | Actions | |
| ⑨ | 17-Jun-2010 FAITH BARASH (RR) OBE/DE Final Review for Pharmacovigilance Planning | Actions | |
| ⑩ | 15-Jun-2010 LILIN ZHONG (RV) CMC Final Review on Viral Safety | Actions | |
| ⑪ | 14-Jun-2010 EWA MARSZAL (RR) Visible particulates in final container | Actions | 2 docs |
| ⑫ | 11-Jun-2010 CHIH (STAN) LIN (SR) Final stat review for efficacy, no change from mid-cycle review | Actions | |
| ⑬ | 11-Jun-2010 JENNIFER REED (RR) final memo JReed | Actions | 4 docs |
| ⑭ | 11-Jun-2010 IFTEKHAR MAHMOOD (CM) Final | Actions | |
| | 04-Jun-2010 ERICA HEIT (LR) | Actions | |
| | 03-Jun-2010 CHERIE WARD-PERALTA (LC) | Actions | |
| ⑮ | 20-May-2010 DOUGLAS FRAZIER (RA) | Actions | |
| | 28-May-2010 LOAN NGUYEN (RV) APLB Review of the revised labeling (PI, carton and vial labels) | Actions | |
| ⑯ | 27-May-2010 DENNIS CATO (RR) Revised Bioresearch Monitoring Final Summary | Actions | |

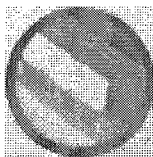
Memo		
17	19-May-2010 JOSEPH DOLESKI (CM) DMPQ to request additional information	Actions pdf only
	03-May-2010 EWA MARSZAL (CM) Finalizing on the preparation of an information request to the sponsor	Actions
	30-Apr-2010 DOROTHY SCOTT (CM) Preparing a carton and labeling information request sent on May 3, 2	Actions
	29-Apr-2010 LOAN NGUYEN (RV) Labeling review of revised vial and carton labels	Actions
	28-Apr-2010 LOAN NGUYEN (PNE) PNR re-evaluation Acceptable	Actions
18	23-Mar-2010 JENNIFER REED (RR) Upper limit for filaments in final product. Comments on comparabili	Actions pdf only
19	23-Mar-2010 JENNIFER REED (RR) Memo to Sponsor requesting update on immunogenicity studies update	Actions
20	15-Mar-2010 EWA MARSZAL (RR) Major amendment - recommended review cycle extension	Actions
21	12-Mar-2010 EVI STRUBLE (PH) Final Memo	Actions
22	12-Mar-2010 MARIA VIRATA-THEIMER (RV) CMC Final Review: sterility, pyrogen, endotoxin, General Safe	Actions
23	09-Mar-2010 FAITH BARASH (RR) Kamada-API Review Memorandum	Actions
	03-Mar-2010 LOAN NGUYEN (RV) PNR Acceptable	Actions
24	31-Jan-2010 LELAND PIERCE (CL) MOR in EDR	Actions 2 docs
	26-Jan-2010 LOAN NGUYEN (RV) APLB Labeling Review	Actions
25	22-Jan-2010 JENNIFER REED (RR) Immunogenicity assay development update	Actions
	11-Dec-2009 LOAN NGUYEN (RV) PNR Unacceptable	Actions
26	27-Nov-2009 EWA MARSZAL (CM) Request to send an information request to sponsor. Attachments are att	Actions 2 docs
27	25-Nov-2009 IFTEKHAR MAHMOOD (RV) Final	Actions
28	25-Nov-2009 MARIA VIRATA-THEIMER (RV) CMC Midcycle review with IR on sterility, endotoxin, pyrogen.	Actions 2 docs
29	23-Nov-2009 LILIN ZHONG (RV) CMC Midcycle review with IR on Viral Clearance	Actions
30	17-Nov-2009 JENNIFER REED (RR) CMC review with IR questions	Actions
31	12-Nov-2009 JOSEPH DOLESKI (CM) Mid-Cycle Review Memo w/ IR Questions (DMPQ: Doleski, Melhem, Schmi	Actions
32	12-Nov-2009 EWA MARSZAL (RR) CMC mid-cycle review memo	Actions 2 docs
	10-Nov-2009 EWA MARSZAL (AM) Assigned Maria Luisa Virata to the review team.	Actions

Not for
posting
per email
7116

33	31-Oct-2009 CHIH (STAN) LIN (RR) OBE/DB Midcycle Stat Review	Actions
34	28-Oct-2009 LELAND PIERCE (CL) Mid-Cycle memo in EDR	Actions
35	27-Oct-2009 DOUGLAS FRAZIER (RV)	Actions
36	27-Oct-2009 EVI STRUBLE (CM) Pharm-Tox memo with IR questions.	Actions
37	23-Oct-2009 DENNIS CATO (RR) Bioresearch Monitoring Mid-cycle Review Memo	Actions
38	20-Oct-2009 FAITH BARASH (RR) OBE/DE Mid-Cycle Review for Pharmacovigilance Planning.	Actions
39	31-Jul-2009 IFTEKHAR MAHMOOD (CM) Filing Memo	Actions
	30-Jul-2009 CHIH (STAN) LIN (CM) Submission is fileable	Actions
40	30-Jul-2009 LELAND PIERCE (CM) Fileable - with potential review issues	Actions
	15-Jul-2009 LILIN ZHONG (CM) Lilin Zhong and Pei Zhang agree the submission is fileable.	Actions
	14-Jul-2009 LOAN NGUYEN (CM) APLB states the submission is fileable	Actions
41	13-Jul-2009 EWA MARSZAL (CM) Filing Memo	Actions
	13-Jul-2009 FAITH BARASH (CM) Submission is fileable	Actions
	13-Jul-2009 DENNIS CATO (CM) Filing Memo from BIMO	Actions
	13-Jul-2009 EVI STRUBLE (CM) Submission is fileable	Actions
	08-Jul-2009 DOUGLAS FRAZIER (CM) Filing Memo - submission is fileable	Actions
	15-Jun-2009 MICHAEL KENNEDY (AM) Assigned Doug Frazier, Pei Zhang, Lilin Zhong as CMC reviewers and	Actions
	11-Jun-2009 GHANSHYAM GUPTA (AM) Assigned Stan Lin as statistician	Actions
	08-Jun-2009 PATRICIA HOLOBAUGH (AM) Assigned Chris Drabick and Dennis Cato for BIMO	Actions
	03-Jun-2009 IFTEKHAR MAHMOOD (AM) Assigned as PK reviewer	Actions
	02-Jun-2009 CRAIG ZINDERMAN (AM) Assigned Faith Barash for pharmacovigilance plan.	Actions
	02-Jun-2009 ELENITA IBARRA PRATT (AM) Assigned Loan Nguyen for APLB	Actions
	02-Jun-2009 NISHA JAIN (AM) Assigned Ross Pierce as clinical reviewer	Actions
	29-May-2009 JOSEPH DOLESKI (AM) Assigned Dave Doleski as DMPQ	Actions
	29-May-2009 MICHAEL KENNEDY (AM) Assigned to Ewa Marszal (Chair) and Jennifer Reed (Co-Chair)	Actions

paf only

2 docs

**CBER MEETING SUMMARIES**

STN 125325\0

CBER Receipt Date: 01-Jun-2009

Applicant: KAMADA LTD.

Product: Alpha-1-Proteinase Inhibitor (Human)

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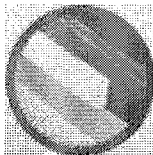
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Content

	21-Jun-2010-EWA-MARSZAL (OT)	Actions
	Discussion on Prolastin Lot in Pivotal Study	
42	16-Jun-2010-CHERIE WARD-PERALTA (OT)	Actions
	Update Meeting	
43	14-Jun-2010-CHERIE WARD-PERALTA (OT)	Actions
	OOS Investigation Discussion	
	03-Jun-2010-EWA-MARSZAL (OT)-OOS	Actions
	Meeting Summary for Statistical Information	
	request. Attachments c	
	02-Jun-2010-EWA-MARSZAL (OT)	Actions
	Discussion for preparing Labeling IR to the	
	Animal Tox and Pharm secti	
	01-Jun-2010-CHERIE WARD-PERALTA (OT)	Actions
	Orphan Drug Status	
	25-May-2010-EWA-MARSZAL (OT) To	Actions
	request a Viral Safety information request	
	from sponsor.	
	26-Apr-2010-CHERIE WARD-PERALTA (OT)	Actions
	Major Amendment Update Meeting	
	22-Mar-2010-CHIH (STAN) LIN (OT)	Actions
	Discussion on Graphs of antigenic and	
	functional A1PI Levels from	
	16-Mar-2010-CHERIE WARD-PERALTA (OT)	Actions
	Update Meeting	
	25-Feb-2010-LELAND-PIERCE (OT)	Actions
	Discussion on changes made to package	
	insert. Attachments can be fou	
	25-Feb-2010-CHIH (STAN) LIN (OT)	Actions
	Package insert discussion with statistician.	
	Attachments can be fo	
	09-Dec-2009-EWA-MARSZAL (OT)-Finalize	Actions
	on an information request to sent to	
	sponsor on Dec 9, 2010.	
	03-Dec-2009-LELAND-PIERCE (OT)	Actions
	Discussion on Nov 30, 2009 to prepare an	
	information request sent on	
44	29-Oct-2009-CHERIE WARD-PERALTA (MC)	Actions
45	13-Jul-2009-CHERIE WARD-PERALTA (FM)	Actions
46	22-Jun-2009-CHERIE WARD-PERALTA (FC)	Actions

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**CBER TELECON**

STN 125325\0

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47	29-Jun-2010 EWA MARSZAL (IR) Requested additional edits to the PI	Actions	} Not for posting per 7/16 email.
48	28-Jun-2010 CHERIE WARD-PERALTA (IR) Discussed additional changes to the package insert	Actions	
49	23-Jun-2010 EWA MARSZAL (IR) Package Insert Information Request	Actions	2 docs } 49 B, 50 B, 2 docs } 51 B Not for posting per 7/16 email
50	23-Jun-2010 CHERIE WARD-PERALTA (IR) Request for Lot Release Protocol Changes	Actions	
51	18-Jun-2010 CRYSTAL ALLARD (IR) to provide a response by June 21, 2010.	Actions	
52	18-Jun-2010 CRYSTAL ALLARD (IR) IR to be responded also on June 21, 2010.	Actions	
53	16-Jun-2010 CHERIE WARD-PERALTA (IR) to discuss the PMC to request information from Baxter	Actions	
54	11-Jun-2010 KELLY LEWIS (IR) IR FAX	Actions	
55	11-Jun-2010 CHERIE WARD-PERALTA (IR) Additional package insert requests	Actions	} Not for posting per 7/16 email
56	04-Jun-2010 CHERIE WARD-PERALTA (IR) Requested some additional information to complete the draft app	Actions	
57	03-Jun-2010 CHERIE WARD-PERALTA (IR) Requested Carton and Container Labeling and PI changes to be p	Actions	2 docs } Not for posting per 7/16 email
58	25-May-2010 CHERIE WARD-PERALTA (IR) Request for correction to PMC/PMR Tables to respond by May 27,	Actions	
59	20-May-2010 CHERIE WARD-PERALTA (IR) Request for updated PMR/PMC Letter	Actions	
60	20-May-2010 CHERIE WARD-PERALTA (IR) PMR/PMC Request to be responded to by May 24, 2010, and questi	Actions	
61	19-May-2010 CHERIE WARD-PERALTA (IR) DMPQ IR to be responded by June 2, 2010	Actions	
62	11-May-2010 EWA MARSZAL (AD) Recommendations: 5-micron in-line filter and 3-hr post-reconstitution	Actions	pdf only
63	03-May-2010 CHERIE WARD-PERALTA (IR) Labeling request	Actions	
64	20-Apr-2010 CHERIE WARD-PERALTA (IR) Request a response by May 4, 2010.	Actions	
65	22-Mar-2010 EWA MARSZAL (IR) viral safety IR	Actions	

66	19-Mar-2010 CHERIE WARD-PERALTA (IR) Additinal IR to include with March 18, 2010 IR	Actions	
67	18-Mar-2010 CHERIE WARD-PERALTA (IR) Request a response by April 1, 2010	Actions	
68	03-Mar-2010 NANNETTE CAGUNGUN (IR)	Actions	
69	03-Mar-2010 NANNETTE CAGUNGUN (IR)	Actions	
70	26-Feb-2010 CHERIE WARD-PERALTA (LTC,IR) Requested a response by March 5, 2010	Actions	2 docs Not for posting per 7/16 email
71	23-Feb-2010 EWA MARSZAL (AD) Provided advice on what to submit in one amendment in response to the	Actions	
72	22-Feb-2010 CHERIE WARD-PERALTA (AD) to discuss Immunogenicity results	Actions	
73	22-Feb-2010 CHERIE WARD-PERALTA (AD) to discuss Immunogenicity results	Actions	- 73 duplicate of 72 per 7/12 email
74	03-Feb-2010 CHERIE WARD-PERALTA (AD) Provide comments on the Immunogenicity Assay Development	Actions	Cherie Ward-peralta - do not post 73.
75	09-Dec-2009 CHERIE WARD-PERALTA (IR) Request complete response to information request by January 9,	Actions	
76	06-Nov-2009 CHERIE WARD-PERALTA (IR) Discuss PK data with Sponsor	Actions	
77	04-Nov-2009 CHERIE WARD-PERALTA (AD) Conformance Lot Advice	Actions	2 docs.
78	03-Nov-2009 CHERIE WARD-PERALTA (IR,AD) Request for conformance lots	Actions	
79	23-Oct-2009 CHERIE WARD-PERALTA (IR) Requested to submit the information requested in the filing le	Actions	
80	09-Sep-2009 CHERIE WARD-PERALTA (IR)	Actions	
81	16-Jul-2009 CHERIE WARD-PERALTA (IR) Response to information request is due by July 27, 2009.	Actions	
82	08-Jun-2009 JENNIFER REED (OT)Kamada described ongoing work toward immunogenicity assay developmen	Actions	

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