

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

206073Orig1s000

CHEMISTRY REVIEW(S)

**FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT**

Application: NDA 206073/000	Sponsor: BOEHRINGER INGELHEIM
Or Code: 510	900 RIDGEBURY RD
4	RIDGEFIELD, CT 06877
Stamp Date: 30-JAN-2014	Brand Name: EMPAGLIFLOZIN AND LINAGLIPTIN TABLETS
PDUFA Date: 30-JAN-2015	Estab. Name: EMPAGLIFLOZIN AND LINAGLIPTIN TABLETS
Action Goal:	Generic Name: LINAGLIPTIN
District Goal: 30-AUG-2014	Product Number; Dosage Form; Ingredient; Strengths

001; TABLET; LINAGLIPTIN; 5MG
001; TABLET; EMPAGLIFLOZIN; 10MG
002; TABLET; LINAGLIPTIN; 5MG
003; TABLET; EMPAGLIFLOZIN; 25MG

FDA Contacts: J. LEGINUS	Prod Qual Reviewer	(HFD-810)	3017964102
E. PFEILER	Micro Reviewer	(HF-22)	3017960642
P. KUMAR	Product Quality PM	(HFD-800)	2404023722
C. CAPPEL-LYNCH	Regulatory Project Mgr		3017938436

Overall Recommendation: ACCEPTABLE on 22-JUL-2014 by R. SAFAAI-JAZI () 3017964463

Establishment: CFN: 9610492 FEI: 5002306556
BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG
BINGER STREET 173
INGELHEIM AM RHEIN, RHEINLAND-PFALZ, GERMANY

DMF No: AADA:
Responsibilities: FINISHED DOSAGE MANUFACTURER
Profile: TABLETS, PROMPT RELEASE OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 10-JUN-2014

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

Establishment: CFN: 1510690 FEI: 1510690
BOEHRINGER INGELHEIM ROXANE INC
COLUMBUS, , UNITED STATES 432289579

DMF No: AADA:
Responsibilities: FINISHED DOSAGE LABELER
FINISHED DOSAGE PACKAGER
Profile: TABLETS, PROMPT RELEASE OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 12-FEB-2014

Decision: ACCEPTABLE

Reason: BASED ON PROFILE

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Establishment: CFN: (b) (4) FEI: (b) (4)
DMF No: AADA:
Responsibilities: FINISHED DOSAGE OTHER TESTER
Profile: CONTROL TESTING LABORATORY OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 25-FEB-2014
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

Establishment: CFN: (b) (4) FEI: (b) (4)
DMF No: AADA:
Responsibilities: FINISHED DOSAGE OTHER TESTER
Profile: CONTROL TESTING LABORATORY OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 25-FEB-2014
Decision: ACCEPTABLE
Reason: DISTRICT RECOMMENDATION

Establishment: CFN: (b) (4) FEI: (b) (4)
DMF No: AADA:
Responsibilities: FINISHED DOSAGE OTHER TESTER
Profile: CONTROL TESTING LABORATORY OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 12-FEB-2014
Decision: ACCEPTABLE
Reason: BASED ON PROFILE

FDA CDER ERS
ESTABLISHMENT EVALUATION REQUEST
SUMMARY REPORT

Establishment: CFN: [REDACTED] FEI: [REDACTED] (b) (4)
[REDACTED] (b) (4)

DMF No: AADA:

Responsibilities: FINISHED DOSAGE LABELER
FINISHED DOSAGE PACKAGER

Profile: TABLETS, PROMPT RELEASE OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 22-JUL-2014

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

Establishment: CFN: [REDACTED] (b) (4) FEI: [REDACTED] (b) (4)
[REDACTED] (b) (4)

DMF No: AADA:

Responsibilities: FINISHED DOSAGE LABELER
FINISHED DOSAGE PACKAGER

Profile: TABLETS, PROMPT RELEASE OAI Status: NONE

Milestone: OC RECOMMENDATION

Milestone Date: 12-FEB-2014

Decision: ACCEPTABLE

Reason: BASED ON PROFILE

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/s/

MARY GRACE LUBAO
02/09/2015

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