CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

201281Orig1s000

CHEMISTRY REVIEW(S)

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application: NDA 201281/000

S[illegible]ate: 19-JAN-2011

Reg[illegible]tory: 30-JAN-2012

Applicant: BOEHRINGER PHARMS
900 RIDGEBURY RD
RIDGEFIELD, CT 06877

Priority: 4

Org. Code: 510

Action Goal:

District Goal: 01-DEC-2011

Brand Name: Linagliptin + Metformin Fixed Dose Combi

Estab. Name: Linagliptin + Metformin Fixed Dose Combination Tablets

Generic Name:

Product Number; Dosage Form; Ingredient; Strengths

001; TABLET; LINAGLIPTIN; 2.5MG
001; TABLET; METFORMIN HYDROCHLORIDE; 500MG
002; TABLET; LINAGLIPTIN; 2.5MG
002; TABLET; METFORMIN HYDROCHLORIDE; 850MG
003; TABLET; LINAGLIPTIN; 2.5MG
003; TABLET; METFORMIN HYDROCHLORIDE; 1000MG

Application Comment: PLEASE SEE BELOW FOR ESTABLISHMENT COMMENTS (on 21-JAN-2011 by K. SHARMA ())

FDA Contacts:			
	K. SHARMA	Project Manager	
	S. TRAN	Team Leader	301-796-1764

Overall Recommendation:				
	ACCEPTABLE	on 20-DEC-2011	by D. SMITH	()
	WITHHOLD	on 15-NOV-2011	by D. SMITH	()
	WITHHOLD	on 22-AUG-2011	by EES_PROD	

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Establishment: **CFN:** (b) (4) **FEI:** (b) (4)

(b) (4)

DMF No: **AADA:**

Responsibilities: FINISHED DOSAGE RELEASE TESTER

FINISHED DOSAGE STABILITY TESTER

Establishment Comment: ALTERNATE SITE OF TESTING (RELEASE NAD STABILITY) FOR DRUG PRODUCT (on 21-JAN-2011 by K. SHARMA ())

Profile: CONTROL TESTING LABORATORY **OAI Status:** NONE

Milestone Name	Milestone Date	Request Type	Planned Completion	Decision	Creator
Comment				Reason	
SUBMITTED TO OC	25-JAN-2011				SHARMAKH
OC RECOMMENDATION	26-JAN-2011			ACCEPTABLE BASED ON PROFILE	INYARDA
SUBMITTED TO OC	02-DEC-2011				PATWARDHAN
OC RECOMMENDATION	04-DEC-2011			ACCEPTABLE BASED ON PROFILE	STOCKM

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Establishment: **CFN:** (b) (4) **FEI:** (b) (4)

DMF No: **AADA:**

Responsibilities: FINISHED DOSAGE RELEASE TESTER

FINISHED DOSAGE STABILITY TESTER

Establishment Comment: ALTERNATE SITE FOR TESTING (RELEASE AND STABILITY FOR THE DRUG PRODUCT) (on 18-FEB-2011 by K. SHARMA ())

Profile: CONTROL TESTING LABORATORY **OAI Status:** NONE

Milestone Name	Milestone Date	Request Type	Planned Completion	Decision	Creator
Comment				Reason	
SUBMITTED TO OC	18-FEB-2011				SHARMAKH
SUBMITTED TO DO	22-FEB-2011	Product Specific			TOULOUSEM
ASSIGNED INSPECTION TO IB	24-FEB-2011	Product Specific			PHILPYE
INSPECTION PERFORMED	(b) (4)				JOSE.CRUZ

Inspection of this contract control-testing facility was conducted as requested by HFC-130 (DFFI), under FACTS assignment # 6757605, to cover the chemical testing activities related to Linagliptin / Metformin HCl Tablets 2.5 mg / 500 mg, 2.5 mg / 850 mg, 2.5 mg / 1000 mg in connection with review of NDA # 201-281.

This is the first time this contract testing facility is inspected by FDA. Current inspection disclosed no objectionable conditions and no FDA-483 was issued. Two verbal observations were discussed with firm's management. The verbal observations were as follows: personnel training procedures have no requirement for the analysts' GMP training on a continued (yearly) basis, and sample intermediate-storage room not mapped-studied under conditions representative of routine sample storage conditions.

e firm's management committed to provide continued GMP training to analysts and to qualify the ple storage area under loaded conditions.

INSPECTION SCHEDULED	(b) (4)				IRIVERA
DO RECOMMENDATION	19-SEP-2011			ACCEPTABLE INSPECTION	STOCKM
OC RECOMMENDATION	20-SEP-2011			ACCEPTABLE DISTRICT RECOMMENDATION	INYARDA
SUBMITTED TO OC	02-DEC-2011				PATWARDHAN
OC RECOMMENDATION	04-DEC-2011			ACCEPTABLE BASED ON PROFILE	STOCKM

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Establishment: **CFN:** 9610492 **FEI:** 3002806556

BOEHRINGER INGELHEIM PHARMA GMBH & CO. KG

BINGER STREET 173
INGELHEIM AM RHEIN, , GERMANY

DMF No: **AADA:**

Responsibilities:
DRUG SUBSTANCE LABELER
DRUG SUBSTANCE MANUFACTURER
DRUG SUBSTANCE PACKAGER
DRUG SUBSTANCE STABILITY TESTER
FINISHED DOSAGE LABELER
FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE PACKAGER
FINISHED DOSAGE RELEASE TESTER
FINISHED DOSAGE STABILITY TESTER

Establishment Comment:
IN ADDITION, ALSO RESPONSIBLE FOR TESTING OF EXCIPIENTS AND METFORMIN (on 02-DEC-2011 by S. PATWARDHAN (HF-01) 301-796-4085)
ALL ASPECTS OF MANUFACTURING, PACKAGING, LABELING AND TESTING (RELEASE AND STABILITY) FOR DRUG PRODUCT (on 21-JAN-2011 by K. SHARMA ())
ALL ASPECTS OF THE MANUFACTURING (b) (4) PACKAGING, LABELING, QUALITY CONTROL OPERATIONS, AND STABILITY TESTING FOR DRUG SUBSTANCE LINAGLIPTIN (on 21-JAN-2011 by K. SHARMA ())

Profile: NON-STERILE API BY CHEMICAL SYNTHESIS **OAI Status:** NONE

TABLETS, PROMPT RELEASE NONE

Milestone Name / Comment	Milestone Date	Request Type	Planned Completion	Decision / Reason	Creator
SUBMITTED TO OC	25-JAN-2011				SHARMAKH
O OMMENDATION	26-JAN-2011			ACCEPTABLE BASED ON PROFILE	INYARDA
SUBMITTED TO OC	02-DEC-2011				PATWARDHAN
OC RECOMMENDATION	04-DEC-2011			ACCEPTABLE BASED ON PROFILE	STOCKM
SUBMITTED TO OC	25-JAN-2011				SHARMAKH
SUBMITTED TO DO	26-JAN-2011	10-Day Letter			INYARDA
DO RECOMMENDATION	31-JAN-2011			ACCEPTABLE BASED ON FILE REVIEW	PHILPYE
OC RECOMMENDATION	02-FEB-2011			ACCEPTABLE DISTRICT RECOMMENDATION	SMITHDE
SUBMITTED TO OC	02-DEC-2011				PATWARDHAN
SUBMITTED TO DO	04-DEC-2011	10-Day Letter			STOCKM
DO RECOMMENDATION	20-DEC-2011			ACCEPTABLE BASED ON FILE REVIEW	PHILPYE

DOCKET ALARM

Explore Litigation Insights

Docket Alarm provides insights to develop a more informed litigation strategy and the peace of mind of knowing you're on top of things.

Real-Time Litigation Alerts

Keep your litigation team up-to-date with **real-time alerts** and advanced team management tools built for the enterprise, all while greatly reducing PACER spend.

Our comprehensive service means we can handle Federal, State, and Administrative courts across the country.

Advanced Docket Research

With over 230 million records, Docket Alarm's cloud-native docket research platform finds what other services can't. Coverage includes Federal, State, plus PTAB, TTAB, ITC and NLRB decisions, all in one place.

Identify arguments that have been successful in the past with full text, pinpoint searching. Link to case law cited within any court document via Fastcase.

Analytics At Your Fingertips

Learn what happened the last time a particular judge, opposing counsel or company faced cases similar to yours.

Advanced out-of-the-box PTAB and TTAB analytics are always at your fingertips.

API

Docket Alarm offers a powerful API (application programming interface) to developers that want to integrate case filings into their apps.

LAW FIRMS
Build custom dashboards for your attorneys and clients with live data direct from the court.

Automate many repetitive legal tasks like conflict checks, document management, and marketing.

FINANCIAL INSTITUTIONS
Litigation and bankruptcy checks for companies and debtors.

E-DISCOVERY AND LEGAL VENDORS
Sync your system to PACER to automate legal marketing.