CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

202270Orig1s000

CHEMISTRY REVIEW(S)

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Application: NDA 202270/000
S[illegible]n Date: 23-SEP-2010
[illegible]atory: 03-FEB-2012

Action Goal:
District Goal: 24-MAY-2011

Applicant: MERCK SHARP DOHME
UG2CD 48
NORTH WALES, PA 19454

Brand Name: Sitagliptin + Metformin Extended Release
Estab. Name:
Generic Name:

Priority: 3
Org. Code: 510

Product Number; Dosage Form; Ingredient; Strengths
001; TABLET; SITAGLIPTIN; 50MG
001; TABLET; METFORMIN HYDROCHLORIDE; 500MG
002; TABLET; SITAGLIPTIN; 50MG
002; TABLET; METFORMIN HYDROCHLORIDE; 1000MG

Application Comment: SEE ESTABLISHMENT COMMENTS FOR THIS NEW NDA (on 01-OCT-2010 by K. SHARMA ())

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

Overall Recommendation:	ACCEPTABLE	on 25-JAN-2012	by S. HERTZ	(HFD-320)	301-796-3203
	PENDING	on 05-JAN-2012	by EES_PROD		
	WITHHOLD	on 05-JAN-2012	by EES_PROD		
	WITHHOLD	on 04-DEC-2011	by EES_PROD		
	WITHHOLD	on 10-AUG-2011	by EES_PROD		
	PENDING	on 04-AUG-2011	by EES_PROD		
	PENDING	on 04-AUG-2011	by EES_PROD		
	PENDING	on 04-AUG-2011	by EES_PROD		
	PENDING	on 04-AUG-2011	by EES_PROD		
	PENDING	on 03-AUG-2011	by EES_PROD		
	WITHHOLD	on 03-AUG-2011	by EES_PROD		
	WITHHOLD	on 21-JUL-2011	by EES_PROD		
	WITHHOLD	on 25-MAY-2011	by EES_PROD		

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DETAIL REPORT

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

DMF No: **AADA:**

Responsibilities: DRUG SUBSTANCE MANUFACTURER
DRUG SUBSTANCE PACKAGER
DRUG SUBSTANCE RELEASE TESTER
DRUG SUBSTANCE STABILITY TESTER

Establishment Comment: DRUG SUBSTANCE (SITAGLIPTIN PHOSPHATE) MANUFACTURING, PACKAGING, AND RELEASE/STABILITY TESTING (on 01-OCT-2010 by K. SHARMA ())

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

Milestone Name	Milestone Date	Request Type	Planned Completion	Decision	Creator
Comment				Reason	
SUBMITTED TO OC	05-OCT-2010				SHARMAKH
OC RECOMMENDATION	05-OCT-2010			ACCEPTABLE BASED ON PROFILE	STOCKM
SUBMITTED TO OC	04-AUG-2011				SHARMAKH
OC RECOMMENDATION	04-AUG-2011			ACCEPTABLE BASED ON PROFILE	STOCKM

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

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

DMF No: **AADA:**

Responsibilities: DRUG SUBSTANCE MANUFACTURER
DRUG SUBSTANCE RELEASE TESTER
DRUG SUBSTANCE STABILITY TESTER

Establishment Comment: DRUG SUBSTANCE (METFORMIN HYDROCHLORIDE) MANUFACTURING, TESTING AND RELEASE (on 01-OCT-2010 by K. SHARMA ())

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

Milestone Name	Milestone Date	Request Type	Planned Completion	Decision	Creator
Comment				Reason	
SUBMITTED TO OC	05-OCT-2010				SHARMAKH
OC RECOMMENDATION	05-OCT-2010			ACCEPTABLE BASED ON PROFILE	STOCKM
SUBMITTED TO OC	04-AUG-2011				SHARMAKH
OC RECOMMENDATION	04-AUG-2011			ACCEPTABLE BASED ON PROFILE	STOCKM

FDA CDER EES
ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

Establishment: **CFN:** 2650235 **FEI:** 1000131917

MERCK & CO., INC.

RD 2, KM 60.3
ARECIBO, PR 00688

DMF No: **AADA:**

Responsibilities: FINISHED DOSAGE MANUFACTURER

FINISHED DOSAGE RELEASE TESTER

Establishment Comment: DRUG PRODUCT MANUFACTURING AND RELEASE TESTING (on 01-OCT-2010 by K. SHARMA ())

Profile: TABLETS, EXTENDED RELEASE **OAI Status:** NONE

Milestone Name	Milestone Date	Request Type	Planned Completion	Decision	Creator
Comment				Reason	
SUBMITTED TO OC	05-OCT-2010				SHARMAKH
SUBMITTED TO DO	05-OCT-2010	Product Specific			STOCKM
ASSIGNED INSPECTION TO IB	14-OCT-2010	Product Specific			RHERNAND
INSPECTION SCHEDULED	15-OCT-2010		05-NOV-2010		RHERNAND
INSPECTION PERFORMED	14-APR-2011		14-APR-2011		JOSE.MELENDEZ

The FDA-483 Observation reads as follows:

(b) (4)

[redacted]

DO RECOMMENDATION	06-MAY-2011	WITHHOLD	RHERNAND
	(b) (4) [redacted]	FIRM NOT READY	

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