

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:
202343Orig1s000

CHEMISTRY REVIEW(S)

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

Application: NDA 202343/000
Orig. Code: 510
Priority: 4
Stamp Date: 07-DEC-2010
PDUFA Date: 07-OCT-2011
Action Goal:
District Goal: 08-AUG-2011

Sponsor: MERCK SHARP DOHME
UG2CD 48
NORTH WALES, PA 194541099
Brand Name: (b) (4) (sitagliptin/simvastatin) Tablet
Estab. Name:
Generic Name:
Product Number; Dosage Form; Ingredient; Strengths
001; TABLET; SITAGLIPTIN PHOSPHATE; 100MG
001; TABLET; SIMVASTATIN; 10MG
002; TABLET; SITAGLIPTIN PHOSPHATE; 100MG
002; TABLET; SIMVASTATIN; 20MG
003; TABLET; SITAGLIPTIN PHOSPHATE; 100MG
003; TABLET; SIMVASTATIN; 40MG

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

Overall Recommendation: ACCEPTABLE on 04-OCT-2011 by D. SMITH ()

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

DMF No: **AADA:**

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

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

Last Milestone: OC RECOMMENDATION

Milestone Date: 27-DEC-2010

Decision: ACCEPTABLE

Reason: BASED ON PROFILE

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

Establishment: CFN: 1036761 FEI: 1036761
MERCK AND CO INC
4633 MERCK RD W
WILSON, NC 278939613

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE STABILITY TESTER
FINISHED DOSAGE PACKAGER
FINISHED DOSAGE STABILITY TESTER

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

Last Milestone: OC RECOMMENDATION

Milestone Date: 27-DEC-2010

Decision: ACCEPTABLE

Reason: BASED ON PROFILE

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

Last Milestone: OC RECOMMENDATION

Milestone Date: 03-JAN-2011

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

Establishment: CFN: 9610180 FEI: 3002807560
MERCK SHARP & DOHME LTD.
CLONMEL, CO. TIPPERARY, , IRELAND

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE MANUFACTURER
FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE RELEASE TESTER

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

Last Milestone: OC RECOMMENDATION

Milestone Date: 30-DEC-2010

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

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

Last Milestone: OC RECOMMENDATION

Milestone Date: 04-OCT-2011

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

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

Establishment: CFN: 2623436 FEI: 2623436
MERCK SHARP AND DOHME QUIMICA
RD 2, KM 56.7
BARCELONETA, PR 00617

DMF No: AADA:

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

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

Last Milestone: OC RECOMMENDATION

Milestone Date: 27-DEC-2010

Decision: ACCEPTABLE

Reason: BASED ON PROFILE

Establishment: CFN: FEI: 3002807653
MERCK SHARP DOHME
SHOTTEN LANE
CRAMLINGTON, , UNITED KINGDOM

DMF No: AADA:

Responsibilities: FINISHED DOSAGE MANUFACTURER

Profile: TABLETS, PROMPT RELEASE OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 30-DEC-2010

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

Establishment: CFN: FEI: 3003431146
MERCK SHARP & DOHME (SINGAPORE), LTD.
21 TUAS SOUTH AVENUE 6
SINGAPORE, , SINGAPORE

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE MANUFACTURER

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

Last Milestone: OC RECOMMENDATION

Milestone Date: 27-DEC-2010

Decision: ACCEPTABLE

Reason: BASED ON PROFILE

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/s/

NIKOO N MANOCHEHRI-KALANTARI
10/13/2011

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