

**CENTER FOR DRUG EVALUATION AND
RESEARCH**

APPLICATION NUMBER:

205395Orig1s000

CHEMISTRY REVIEW(S)

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

Application: NDA 205395/000
Code: 530
Priority: 4Y
Stamp Date: 31 MAR-2014
PDUFA Date: 31 JAN 2015
Action Goal:
District Goal: 02-DEC 2014

Sponsor: JANSSEN PRODS
 1125 TRENTON HARBOURTON RD
 TITUSVILLE, NJ 08560
Brand Name: DARUNAVIR/COBICISTAT
Estab. Name:
Generic Name:
Product Number; Dosage Form; Ingredient; Strengths

001; TABLET (IMMED/COMP. RELEASE), FILM COATED;
 DARUNAVIR; (b) (4) MG
 001; TABLET (IMMED/COMP. RELEASE), FILM COATED;
 COBICISTAT; 150MG

FDA Contacts:	R. XU	Facility Reviewer		3017966187
	F. LIU	Prod Qual Reviewer		3017961469
	E. PFEILER	Micro Reviewer	(HF-22)	3017960642
	A. CUFF	Product Quality PM	(HF 01)	3017964061
	N. MANI	Regulatory Project Mgr	(HFD-530)	2404020333
	S. MILLER	Team Leader		3017961418

Overall Recommendation:	ACCEPTABLE	on 04-SEP 2014	by R. MOORE	()	2404029988
	PENDING	on 03-SEP 2014	by EES PROD		
	ACCEPTABLE	on 20-AUG 2014	by EES PROD		
	PENDING	on 23-APR 2014	by EES PROD		
	PENDING	on 09-APR 2014	by EES PROD		

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

DMF No: **AADA:**

Responsibilities: DRUG SUBSTANCE MANUFACTURER
 DRUG SUBSTANCE OTHER TESTER
 DRUG SUBSTANCE RELEASE TESTER
 INTERMEDIATE MANUFACTURER

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

Last Milestone: OC RECOMMENDATION

Milestone Date: 24-APR-2014

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

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

Establishment: CFN: 9615378 FEI: 3001027806
GILEAD ALBERTA ULC
1021 HAYTER RD NW
EDMONTON, ALBERTA, CANADA

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: 11 APR 2014

Decision: ACCEPTABLE

Reason: BASED ON PROFILE

Establishment: CFN: 2952384 FEI: 1000523075
GILEAD SCIENCES, INC.
FOSTER CITY, , UNITED STATES 944041147

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE RELEASE TESTER
DRUG SUBSTANCE STABILITY TESTER

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

Last Milestone: OC RECOMMENDATION

Milestone Date: 04 SEP 2014

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

Establishment: CFN: 2650104 FEI: 3002942061
JANSSEN ORTHO L.L.C.
GURABO, , UNITED STATES 00778

DMF No: AADA:

Responsibilities: FINISHED DOSAGE LABELER
FINISHED DOSAGE MANUFACTURER
FINISHED DOSAGE PACKAGER
FINISHED DOSAGE RELEASE TESTER

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

Last Milestone: OC RECOMMENDATION

Milestone Date: 22-APR 2014

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

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

Establishment: CFN: 9610034 FEI: 3002807337
JANSSEN PHARMACEUTICA N.V.
JANSSEN PHARMACETICALAAN 3
GEEL, , BELGIUM

DMF No: AADA:

Responsibilities: INTERMEDIATE MANUFACTURER
INTERMEDIATE RELEASE TESTER

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

Last Milestone: OC RECOMMENDATION

Milestone Date: 11 APR 2014

Decision: ACCEPTABLE

Reason: BASED ON PROFILE

Establishment: CFN: 9611011 FEI: 3002807361
JANSSEN PHARMACEUTICAL, LTD.
LITTLE ISLAND
CORK, , IRELAND

DMF No: AADA:

Responsibilities: DRUG SUBSTANCE MANUFACTURER
DRUG SUBSTANCE OTHER TESTER
DRUG SUBSTANCE RELEASE TESTER

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

Last Milestone: OC RECOMMENDATION

Milestone Date: 10 JUN-2014

Decision: ACCEPTABLE

Reason: DISTRICT RECOMMENDATION

Establishment: CFN: 2242843 FEI: 2242843
JANSSEN PHARMACEUTICALS, INC.
,, UNITED STATES

DMF No: AADA:

Responsibilities: FINISHED DOSAGE STABILITY TESTER

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

Last Milestone: OC RECOMMENDATION

Milestone Date: 11-APR-2014

Decision: ACCEPTABLE

Reason: BASED ON PROFILE

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