CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204592Orig1s000

<u>CHEMISTRY REVIEW(S)</u>

ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

lication:	NDA 204592/000	Action Goal:	
mp Date:	20-DEC-2012	District Goal:	21-AUG-2013
ju___:	20-OCT-2013		

licant:	IROKO PHARMS LLC	Brand Name:	ZORVOLEX (DICLOFENAC ACID)
	1 KEW PL 150 ROUSE BLVD	Estab. Name:	
	PHILADELPHIA, PA 19112	Generic Name:	

rity:	3	Product Number; Dosage Form; Ingredient; Strengths
. Code:	170	001; CAPSULE; DICLOFENAC; 18MG
		002; CAPSULE; DICLOFENAC; 35MG

lication Comment:

Contacts:	Y. WANG	Prod Qual Reviewer		3017961479
	S. DONALD	Micro Reviewer	(HFD-805)	3017960586
	L. RIVERA	Product Quality PM		3017964013
	S. PATWARDHAN	Regulatory Project Mgr	(HF-01)	3017964085
	J. PINTO	Team Leader		3017961733

rall Recommendation:	ACCEPTABLE	on	(b) (4)	by C. CAPACCI-DANIEL	()	3017963532
	PENDING	on 31-JAN-2013		by EES_PROD		

ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

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

(b) (4)

F No: **AADA:**

ponsibilities: DRUG SUBSTANCE RELEASE TESTER

FINISHED DOSAGE MANUFACTURER

ablishment nment: ile: TEST RAW MATERIALS, MANUFACTURE DRUG PRODUCT, TEST (b) (4) MATERIALS, RELEASE TESTING OF DRUG PRODUCT, STORE AND PERFORM. STABILITY TESTING. (on (b) (4) by L. RIVERA () 3017964013) CAPSULES, PROMPT RELEASE

OAI Status: NONE

stone Name Comment	Milestone Date	Request Type	Planned Completion	Decision Reason	Creator
BMITTED TO OC	31-JAN-2013				RIVERAL
BMITTED TO DO CHG INITIAL	31-JAN-2013	10-Day Letter			SHARPT
RECOMMENDATION (b) (4) AN ABBREVIATED CGMP/PAI FOR THE SAME PROFILE CLASS (CHG) WAS CONDUCTED (b) (4) (b) (4) NO FDA 483 WAS ISSUED. BASED ON FILE REVIEW, KAN-DO RECOMMENDS APPROVABLE.				ACCEPTABLE BASED ON FILE REVIEW	SBERRYMA
RECOMMENDATION (b) (4)				ACCEPTABLE DISTRICT RECOMMENDATION	SHARPT

ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

ablishment:	CFN:	(b) (4)	FEI:	(b) (4)

(b) (4)

F No: AADA:

ponsibilities: FINISHED DOSAGE PACKAGER

ablishment   PACKAGING AND LABELING OF DRUG PRODUCT, CONTROL OF PACKAGING CONTAINER CLOSURE COMPONENT (on
nment: (b) (4) by L. RIVERA () 3017964013)
ile: CAPSULES, PROMPT RELEASE   OAI Status: NONE

stone Name	Milestone Date	Request Type	Planned Completion	Decision	Creator
Comment				Reason	
BMITTED TO OC	31-JAN-2013				RIVERAL
RECOMMENDATION	(b) (4)			ACCEPTABLE	SHARPT
				BASED ON PROFILE	

ESTABLISHMENT EVALUATION REQUEST
DETAIL REPORT

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

(b) (4)

F No: **AADA:**

ponsibilities: DRUG SUBSTANCE RELEASE TESTER

ablishment   DRUG SUBSTANCE LABORATORY TESTING (on (b) (4) by L. RIVERA () 3017964013)
nment:

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

stone Name	Milestone Date	Request Type	Planned Completion	Decision	Creator
Comment				Reason	
BMITTED TO OC	31-JAN-2013				RIVERAL
RECOMMENDATION	(b) (4)			ACCEPTABLE	SHARPT
				BASED ON PROFILE	

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