CENTER FOR DRUG EVALUATION AND RESEARCH

APPLICATION NUMBER:

204592Orig1s000

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

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

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

Product Number; Dosage Form; Ingredient; Strengths

prity: 3

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

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

(b) (4)

F No: **AADA:**

ponsibilities: DRUG SUBSTANCE RELEASE TESTER

FINISHED DOSAGE MANUFACTURER

**ablishment
nment:** 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)
file: CAPSULES, PROMPT RELEASE

OAI Status: NONE

stone Name	Milestone Date	Request Type	Planned Completion	Decision	Creator
Comment				Reason	
3MITTED TO OC	31-JAN-2013				RIVERAL
3MITTED TO DO	31-JAN-2013	10-Day Letter			SHARPT
CHG INITIAL					
RECOMMENDATION (b) (4)				ACCEPTABLE (b) (4)	SBERRYMA
AN ABBREVIATED CGMP/PAI FOR THE SAME PROFILE CLASS (CHG) WAS CONDUCTED ___(b) (4)___ NO FDA 483 WAS ISSUED. BASED ON FILE REVIEW, KAN-DO RECOMMENDS APPROVABLE.				BASED ON FILE REVIEW	
RECOMMENDATION (b) (4)				ACCEPTABLE	SHARPT
				DISTRICT RECOMMENDATION	

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

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