

ESTABLISHMENT EVALUATION REQUEST

DETAIL REPORT

Application:	NDA 22161/000	Action Goal:	
Stamp:	14-MAY-2007	District Goal:	14-JAN-2008
Regulatory Due:	14-MAR-2008	Brand Name:	LEXISCAN
Applicant:	CV THERAP	Estab. Name:	
	3172 PORTER DR	Generic Name:	REGADENOSON
	PALO ALTO, CA 94304		
Priority:	S	Dosage Form:	(INJECTION)
Org Code:	160	Strength:	0.08 MG/ML (5ML)

Application Comment:

Contacts:	T. BROWN	301-796-2050	, Project Manager
	J. BOAL	301-796-1331	, Review Chemist
	R. HARAPANHALLI	301-796-1676	, Team Leader

Overall Recommendation: ACCEPTABLE on 20-DEC-2007by S. FERGUSON(HFD-322)301-827-9009

Establishment: CFN 1833527 FEI 1000115571

BAXTER PHARMACEUTICALS SOLUTIONS, LLC

927 S CURRY PIKE

BLOOMINGTON, IN 474032624

DMF No: AADA:

Responsibilities: FINISHED DOSAGE MANUFACTURER

Profile: SVT OAI Status: NONE

ESTABLISHMENT EVALUATION REQUEST

DETAIL REPORT

DMF No:

AADA:

Responsibilities:

Profile:

CTL

OAI Status:

NONE

Estab. Comment:

[REDACTED]

[REDACTED] (on 03-AUG-2007 by J. BOAL () 301-796-1331)

Milestone Name	Date	Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	03-AUG-2007				BOALJ
OC RECOMMENDATION	06-AUG-2007			ACCEPTABLE BASED ON PROFILE	FERGUSONS

Establishment:

CFN 1021343 FEI 1021343

HOSPIRA INC

4285 NORTH WESLEYAN BLVD

ROCKY MOUNT, NC 278048612

DMF No:

AADA:

Responsibilities:

FINISHED DOSAGE MANUFACTURER

Profile:

SVT

OAI Status:

NONE

Estab. Comment:

HOSPIRA CFN 1021343 DOES THE MANUFACTURE, [REDACTED]

[REDACTED] OF THE 5 ML SYRINGE FINISHED DOSAGE FORM. (on 03-AUG-2007 by J. BOAL () 301-796-1331)

Milestone Name	Date	Type	Insp. Date	Decision & Reason	Creator
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SUBMITTED TO OC 03-AUG-2007 BOALJ

SUBMITTED TO DO 03-AUG-2007 PS KIEL

DO RECOMMENDATION 07-AUG-2007 ACCEPTABLE MWOLESKE

BASED ON FILE REVIEW

A GMP INSPECTION WAS COMPLETED 6/5-7/2007 AND WAS CLASSIFIED AS NO ACTION INDICATED (NAI). PROFILE CLASS SVT WAS JUDGED ACCEPTABLE. THE DISTRICT'S RECOMMENDATION IS ACCEPTABLE.

OC RECOMMENDATION 07-AUG-2007 ACCEPTABLE FERGUSONS

DISTRICT RECOMMENDATION

Establishment: CFN FEI 3004591928

HOSPIRA INC

1401 SHERIDAN RD BLDG MI M3 R1 R1B

NORTH CHICAGO, IL 600644000

No: AADA:

Responsibilities: 

Profile: CTX OAI Status: NONE

ESTABLISHMENT EVALUATION REQUEST

DETAIL REPORT

Estab. Comment: HOSPIRA CFN 1411365 DOES THE ██████████ FOR THE 5 ML SYRINGE
 FINISHED DOSAGE FORM. (on 03-AUG-2007 by J. BOAL () 301-796-1331)
 HOSPIRA OF CFN 1021343 MANUFACTURES, ██████████
 THE FINISHED DOSAGE FORM (5 ML SYRINGE CONFIGURATION).
 HOSPIRA CFN 1411365 ██████████ THE 5 ML SYRINGE FINISHED DOSAGE.
 (on 03-AUG-2007 by J. BOAL () 301-796-1331)

Milestone Name	Date	Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	03-AUG-2007				BOALJ
SUBMITTED TO DO	03-AUG-2007	10D			KIEL
DO RECOMMENDATION	13-AUG-2007			ACCEPTABLE BASED ON FILE REVIEW	LJARRELL
GMP INSPECTION CONDUCTED IN MAY, 2007. INSPECTION WAS VAI.					
OC RECOMMENDATION	13-AUG-2007			ACCEPTABLE DISTRICT RECOMMENDATION	FERGUSONS

Establishment: CFN FEI ██████████

DMF No: AADA:

Responsibilities:

Profile: CSN OAI Status: NONE

Estab. Comment: ██████████
 (on 21-AUG-2007 by J.
 BOAL () 301-796-1331)

Milestone Name	Date	Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	21-AUG-2007				BOALJ
SUBMITTED TO DO	21-AUG-2007	10D			FERGUSONS
ASSIGNED INSPECTION T	28-AUG-2007	PS			NROLI
INSPECTION PERFORMED	12-OCT-2007		12-OCT-2007		JOY.KLENA
DO RECOMMENDATION	01-NOV-2007			ACCEPTABLE INSPECTION	NROLI
OC RECOMMENDATION	01-NOV-2007			ACCEPTABLE DISTRICT RECOMMENDATION	FERGUSONS

Establishment: CFN **_____** FEI **_____**

DMF No: AADA:

Responsibilities: **_____**

ESTABLISHMENT EVALUATION REQUEST

DETAIL REPORT

FINISHED DOSAGE STERILITY TESTER

Profile: CTX OAI Status: NONE

Estab. Comment:

_____ (on 03-AUG-2007 by J. BOAL () 301-796-1331)

Milestone Name	Date	Type	Insp. Date	Decision & Reason	Creator
SUBMITTED TO OC	03-AUG-2007				BOALJ
SUBMITTED TO DO	06-AUG-2007	10D			FERGUSONS
DO RECOMMENDATION	07-AUG-2007			ACCEPTABLE BASED ON FILE REVIEW.	MFADDEN
MIN-DO CONDUCTED A CGMP INSPECTION ON 10/25-27/06. THAT INSPECTION COVERED _____					
_____ NO FD 483 WAS ISSUED AS A RESULT OF					
THAT INSPECTION. BASED UPON THAT INSPECTION MIN-DO IS RECOMMENDING APPROVAL OF THIS					
APPLICATION.					
OC RECOMMENDATION	07-AUG-2007			ACCEPTABLE DISTRICT RECOMMENDATION	FERGUSONS

Milestone Date: 20-DEC-07
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION

Establishment : CFN : ██████████ FEI : ██████████

DMF No: AADA:

Responsibilities:

Profile : CTL OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 06-AUG-07
Decision : ACCEPTABLE
Reason : BASED ON PROFILE

Establishment : CFN : 1021343 FEI : 1021343
HOSPIRA INC
4285 NORTH WESLEYAN BLVD
ROCKY MOUNT, NC 278048612

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

DMF No: AADA:

Responsibilities: FINISHED DOSAGE MANUFACTURER

[REDACTED]

Profile : SVT OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 07-AUG-07

Decision : ACCEPTABLE

Reason : DISTRICT RECOMMENDATION

Establishment : CFN : FEI : 3004591928

HOSPIRA INC

1401 SHERIDAN RD BLDG MI M3 R1 R1B

NORTH CHICAGO, IL 600644000

DMF No: AADA:

Responsibilities:

[REDACTED]

Profile : CTX OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 13-AUG-07

Decision : ACCEPTABLE

Reason : DISTRICT RECOMMENDATION

Establishment : CFN : FEI : [REDACTED]

[REDACTED]

DMF No: AADA:

Responsibilities:

Profile : CSN OAI Status: NONE

Last Milestone: OC RECOMMENDATION

Milestone Date: 01-NOV-07

Decision : ACCEPTABLE

Reason : DISTRICT RECOMMENDATION

Establishment : CFN : FEI :

DMF No: AADA:

Responsibilities:

ESTABLISHMENT EVALUATION REQUEST

SUMMARY REPORT

Profile : CTX OAI Status: NONE
Last Milestone: OC RECOMMENDATION
Milestone Date: 07-AUG-07
Decision : ACCEPTABLE
Reason : DISTRICT RECOMMENDATION
