

# OBRR Mid-Cycle Review Checklist Original Applications and Efficacy Supplements

STN/ID: 125426/0

Final Action Date: 4-Feb-13

Mid-Cycle Date: 5-Sept-12

Mid-Cycle Meeting Date: 30-Aug-12

Applicant: Inspiration Biopharmaceuticals, Inc.

Product: Coagulation Factor IX (Recombinant)

Indication/Summary: Control and prevention of bleeding episodes and peri-operative management in patients with hemophilia B

Mid-Cycle Status: Anticipating CR in October 2012

## PeRC Review

☐ Waiver ☐ Deferral ☐ Orphan Status ☐ Fast Track Designation ☐ Fulfilled ☐ N/A  
☐ Assessment Planned/Completed (date) \_\_\_\_\_

## Labeling

Draft Label sent to OBRR PLR Committee ☒ Yes (date) \_\_\_\_\_ ☐ No ☐ N/A  
 Proprietary Name Review submitted ☒ Yes (date) 16-July-12 ☐ No (expected date)

Risk Evaluation and Mitigation Strategy (REMS) required ☐ Yes ☐ No

## BPAC Advisory Committee review:

☐ Planned /Completed (date) \_\_\_\_\_ ☐ Waived (justification memo included) ☐ N/A

## OCBQ

BIMO inspection scheduled ☒ Yes (date) 1&4 June 2012 ☐ No ☐ N/A  
 Establishment Inspection scheduled ☐ Yes (date) POSTPONED ☐ No ☐ Waived ☐ N/A

## Lot Release Testing Plan/ Lot Release

Lot Release Testing Plan Complete ☐ Yes (date) \_\_\_\_\_ ☐ No ☒ Not required

Conformance lots submitted ☒ Yes (date) 9-July-12 ☐ No  
 Lot Release Protocol submitted ☐ Yes (date) \_\_\_\_\_ ☒ No (expected date)

## Post-Market Safety Studies

☐ PMC planned (506B) ☐ PMR Planned (FDAAA) ☐ Non-Regulatory ☐ N/A  
 FDAAA Safety Work Group notified ☐ Yes (date) \_\_\_\_\_ ☐ No (expected date)

**External Communication** ☐ Talk points ☐ Press Release ☐ Heads-up to CBER IOD ☒ N/A

Review Discipline	Reviewer Name	MidCycle Review Done (X)	Minor issues (X)	Major Issues (X)	Comment/ Was issue relayed to the Applicant yet
Clinical	Stephanie Omokaro; Irwin Feuerstein	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	Intend on having mid-cycle complete by end of Sept 2012.
Pharmacology	Iftekhar Mahmood	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	No CR items
Statistical	Chunron Cheng-stats; Include Jessica Kim	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Will require additional datasets for eval IR forthcoming
CMC	Roman Drews	<input type="checkbox"/>	<input type="checkbox"/>	<input checked="" type="checkbox"/>	CR items by 10/31/12
DMPQ	Rabia Ballica; Consult=Donald Ertel	<input type="checkbox"/>	<input checked="" type="checkbox"/>	<input type="checkbox"/>	Draft ready in early Oct
BPB	N/A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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BIMO	Carla Jordan	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	No CR letter items at this time; awaiting BIMO inspections
OBE/ Epidemiology	Bethany Baer, MD	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	Rec'd PVP on 8/30/12
Toxicology	Michael (Keith) Wyatt	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
PNR Review	Loan Nguyen	<input checked="" type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

**Post Mid-Cycle Major Task list and Target Dates**

Task	Responsible Person	Target Date	Completed Date
CR letter	All members of review committee	10/31/12	

Notes:

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Regulatory Project Manager (RPM) Leigh Pracht      Date: 30-Aug-12

Review Team Chairperson Roman Drews      Date: 30-Aug-12