## PMC Annual Report Review Form (PARRF)

For 601.70 Reportable Commitments

## **Application Information**

Reviewers for the AR

BLA/NDA	105669	
	Biologic	
Product		
Applicant	Acme Biologics	
Annual Report/PMC STN	105669/5294	
Annual Report Received Date	April 20, 2007	
Annual Report Action Due Dt	July 15, 2007	

Office	OBRR
<b>Reg Project</b>	Smith, William
Manager	
Reviewer	Jones, Frank
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## Verification of the Reported Status and Status Explanation for Open Commitments

STN Generating the PMC	RMS- BLA PMC #	Commitment Description (May be truncated below. For full text, see RMS- BLA) (PMC # is generally the # in the approval letter and may not be the same as the RMS-BLA PMC #)	System Status as of the annual report receipt date	Reported on? (Yes/No) (If any 601.70 PMCs are not reported on, the applicant must be contacted to amend the annual report to include all such PMCs.)	Applicant's Reported Status	Do you agree with the Applicant's reported status? (Yes/No/NA)	Do you agree with the Applicant's reported status explanation? (Yes/No/NA) Explain disagreements below	Was the incomplete information requested and/or the corrected Status and/or Status explanation communicated to the Applicant? (Yes/No/NA)
105669	6	Monitor hemostatic efficacy in 100 surgical patients using the chromogenic assay at the local lab to measure Biologic Product levels	Ongoing					
105669	7	Conduct a study to determine an appropriate dosage in children ages 2 through 16	Ongoing					
105669/5002	1	Conduct a study to determine the safety of the Biologic Product when given intravenously	Pending					

## Review

For each FDAMA commitment where you do not agree with the applicant's reported status and/or status explanation, please address the following:

- Explain the disagreement.
- State concisely the correct status and/or status explanation that should be reflected in RMS-BLA and on the Web site.

Reviewer Signatur	e

Date
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Supervisor Signature	9
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**RETURN TO THE RPM WHEN COMPLETED** 

Date\_\_\_\_\_