Appendix 1

Resubmission Acknowledgement Letter

Our STN: BL [#####/0]

[COMPANY NAME] Attention: [AUTHORIZED OFFICIAL'S NAME] [AUTHORIZED OFFICIAL'S TITLE] [ADDRESS]

Dear [AUTHORIZED OFFICIAL'S NAME]:

We have received your [DATE OF RESUBMISSION] resubmission to your [biologics license application or efficacy supplement] for [PROPER NAME] on [FDA STAMPED DATE].

The resubmission contains additional [BRIEF DESCRIPTION OF AMENDMENT e.g., CMC, CLINICAL INFORMATION] that you submitted in response to our [CBER'S ACTION LETTER DATE] complete response letter.

FOR ORIGINAL BLAS, INSERT ONE OF THE PARAGRAPH OPTIONS AS APPROPRIATE.

<u>A. USE FOR CLASS 1 RESPONSE</u>: We consider this a complete, Class 1 response to our action letter. Therefore, the user fee goal date is [2-MONTH GOAL DATE].

<u>B. USE FOR CLASS 2 RESPONSE</u>: We consider this a complete, Class 2 response to our action letter. Therefore, the user fee goal date is [6-MONTH GOAL DATE].

<u>C. USE FOR NON PDUFA PRODUCTS</u>: We consider this a complete response to our action letter. Therefore, the goal date is [6-MONTH GOAL DATE].

FOR EFFICACY SUPPLEMENTS, INSERT ONE OF THE PARAGRAPH OPTIONS AS APPROPRIATE.

<u>A. USE FOR CLASS 1 RESPONSE</u>: We consider this a complete, Class 1 response to our action letter. Therefore, the user fee goal date is [6 TO 2 MONTH GOAL DATE DEPENDING ON FY 02-07. REFER TO PDUFA III GOALS FOR CALCULATING ACTION DUE DATE].

<u>B. USE FOR CLASS 2 RESPONSE</u>: We consider this a complete, Class 2 response to our action letter. Therefore the user fee goal date is [6 MONTH GOAL DATE].

<u>C. USE FOR NON PDUFA PRODUCTS</u>: We consider this a complete response to our action letter. Therefore, the goal date is [6-MONTH GOAL DATE].

If you have any questions, please contact [NAME], Regulatory Project Manager, at (301) [NUMBER].

Sincerely yours,

[NAME] [INSERT TITLE] Division of [INSERT DIVISION] Office of [INSERT OFFICE] Research and Review Center for Biologics Evaluation and Research

Concurrence Page

Application Number: BLA _____

Letter Type: Resubmission Acknowledgement Letter (ACK) (Pending RIMS Approval) Summary Text: [Class 1 Resubmission] or [Class 2 Resubmission] or [Non PDUFA PRODUCTS]

SS & RIS Data Check:

Communication
Milestone: Receipt Date In Ltr. & Milestone (Response To CR) Should Match

RIS Data Check:

• Confirm New Action Due Date

cc: Division BLA Files Review Committee

History:

File Name:

Concurrence box

Office	Name/Signature	Date