

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.

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

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

C. USE FOR NON PDUFA PRODUCTS: 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.

A. USE FOR CLASS 1 RESPONSE: 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].

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

C. USE FOR NON PDUFA PRODUCTS: 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

