
POLICY AND PROCEDURES

OFFICE OF NEW DRUGS

**Classifying Resubmissions of Original NDAs, BLAs, and
Efficacy Supplements in Response to Complete
Response Letters**

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PURPOSE

- This MAPP describes how the Center for Drug Evaluation and Research (CDER) will classify resubmissions of original new drug applications (NDAs), biologics license applications (BLAs), and efficacy supplements, received in response to complete response letters,¹ as Class 1 or Class 2 resubmissions.

BACKGROUND

- As referenced in the Prescription Drug User Fee Act of 1992 (PDUFA), the Food and Drug Administration (FDA) committed to certain user fee performance goals, including the goal of reviewing and acting on an applicant’s resubmission of an original application in 6 months or less. In the November 1997 letter to Congress regarding the reauthorization of PDUFA, the Secretary of Health and Human Services committed the FDA to recognizing two classes of resubmissions: Class 1 and Class 2. The classification of a resubmission is based on the information submitted by the applicant in response to an action letter. The two classes of

¹ Complete response letters replaced approvable (AE) and not approvable (NA) actions letters for NDAs on July 10, 2008 (see 21 CFR 314.110). This MAPP also applies to resubmissions received in response to AE and NA action letters.

resubmissions also have different performance goals — expressed as the percentage of resubmissions that will be reviewed and acted upon within a certain time period from the date the resubmission is received by CDER (receipt date) based on the fiscal year in which the resubmission is received. These goals have been codified under 21 CFR 314.110.

- Applications for which an action has been taken are considered filed; therefore, no filing determination is made for resubmissions.
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POLICY

- The review team and division director will determine whether the resubmission constitutes a complete response that addresses all deficiencies in the complete response letter. If so, the review team and the division director will classify the resubmission as Class 1 or Class 2.²
- The regulatory project manager will issue a letter to the applicant within 30 calendar days, acknowledging receipt of the resubmission.
 - If CDER does not agree that the submission is a complete response addressing all deficiencies in the complete response letter, CDER will inform the applicant in the letter and the review clock will not start until a complete response is received.
 - If CDER agrees the submission constitutes a complete response, the letter will state the classification and provide the due date for action.
- CDER will complete the review and act on Class 1 resubmissions within 2 months of the receipt date.
- CDER will complete the review and act on Class 2 resubmissions within 6 months of the receipt date.

² The Class 1 or Class 2 distinction does not pertain to resubmissions of nonefficacy supplements (i.e., labeling and manufacturing supplements). CDER will complete the review and act on these resubmissions with an internal goal date that begins on the receipt date and is the same length as the initial review cycle (excluding an extension caused by a major amendment of the initial supplement).

RESPONSIBILITIES AND PROCEDURES

The Review Team and Division Director will:

- Determine whether the submission is a complete response addressing all the deficiencies in the complete response letter
- Determine the classification of the resubmission
- Complete the review and act on all Class 1 and Class 2 resubmissions within 2 months or 6 months of the receipt date, respectively

The Regulatory Project Management Staff will:

- Upon receipt of the submission, consult with the review team and division director on whether the submission is a complete response and, if so, the classification of the resubmission
- Ensure that the submission in the electronic archive is correctly coded (i.e., complete response or incomplete response)
- If the submission is not a complete response, send the applicant *an acknowledgment of incomplete response to an action letter*
- If the resubmission is a complete response, send the applicant an *acknowledgment of receipt* letter stating the classification of the resubmission and the review goal date
- Issue an acknowledgement letter to the applicant within 30 calendar days of receipt of the resubmission

REFERENCES

- The PDUFA legislation at <http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm144411.htm>
- 21 CFR 314.110, Complete response letter to the applicant

DEFINITIONS

- **Resubmission** — A submission to an NDA, BLA, or efficacy supplement that purports to answer all of the deficiencies that need to be addressed by the applicant before approval as set forth in the complete response letter.
 - **Class 1 Resubmission** — A resubmission that includes one or more of the following items:
 1. Final printed labeling
 2. Draft labeling
 3. Safety updates submitted in the same format, including tabulations, as the original safety submission with new data and changes highlighted (except when large amounts of new information, including important new adverse experiences, not previously reported with the product are presented in the resubmission)
 4. Stability updates to support provisional or final dating periods
 5. Discussions of postmarketing requirements/commitments, including proposals or protocols for such requirements/commitments
 6. Assay validation data
 7. Final release testing on the last 1 to 2 lots used to support approval
 8. A minor re-analysis of data previously submitted to the application (determined by CDER as fitting the Class 1 category)
 9. Other minor clarifying information (determined by CDER as fitting the Class 1 category)
 - **Class 2 Resubmission** — A resubmission that includes any item not specified as a Class 1 item, including any item that would require a presentation to an advisory committee. A resubmission that requires a reinspection also would be a Class 2 resubmission.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

Effective Date	Revision Number	Revisions
5/1/98	N/A	N/A
11/7/07	Rev. 1	
2/26/15	Rev. 2	The time frames for completing the review of Class 1 and Class 2 resubmissions were specified as 2 months and 6 months, respectively, per 21 CFR 314.100; the time frame for issuing an acknowledgment letter was changed from 14 days to 30 days; language was added to clarify that a filing determination is not made for resubmissions; minor editorial changes were made to make clearer the process for determining whether a submission constitutes a complete response that addresses all the deficiencies in the complete response letter.