OFFICE OF REVIEW MANAGEMENT

Classifying Resubmissions of Original NDAs in Response to Action Letters

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PURPOSE

The purpose of this MAPP is to describe how CDER will classify resubmissions of original new drug applications (NDAs) received in response to action letters as Class 1 or Class 2 resubmissions.

BACKGROUND

As referenced in the Prescription Drug User Fee Act of 1992 (PDUFA), the FDA committed to certain user fee performance goals including the goal of reviewing and acting on an applicant's resubmission of an original NDA in six months or less. For the past five years, CDER only had to track one goal date for resubmissions in its Center-Wide Oracle-Based Management Information System (COMIS). In her letter to Congress regarding the reauthorization of PDUFA in November 1997, the Secretary of Health and Human Services committed FDA to recognizing two classes of resubmissions: Class 1 and Class 2. The classification of the resubmissions is based on the information submitted by the applicant in response to an action letter. The two types of 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 based on the fiscal year in which the resubmission is received. The performance goals are:

Class 1 Resubmissions

FY 98- at least 90% in 6 months, at least 30% in 2 months
FY 99- at least 90% in 4 months, at least 50% in 2 months
FY 00- at least 90% in 4 months, at least 70% in 2 months
FY 01- at least 90% in 2 months
FY 02- at least 90% in 2 months

Class 2 Resubmissions

FY 98 through 02: at least 90% in 6 months

REFERENCES

- Letter from Donna Shalala, Secretary, Health and Human Services, to Senator Jeffords, Chairman, Committee on Labor and Human Resources, United States Senate, November 12, 1997.

- Guidance for Industry, *Classifying Resubmissions in Response to Action Letters*, April 1998.

DEFINITIONS

Resubmission: Throughout this document, *resubmission* refers to a complete response to an action letter on an original NDA (i.e., a submission that purports to answer all of the deficiencies that needed to be addressed by the sponsor prior to approval of the original NDA as set forth in a previous CDER action letter [approvable, not approvable, or complete response letter]).

Class 1 Resubmission: A Class 1 resubmission is a resubmission that includes the following items only (or combination of these 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. Commitments to perform Phase 4 studies, including proposals for such studies.

6. Assay validation data.

7. Final release testing on the last 1-2 lots used to support approval.

8. A minor re-analysis of data previously submitted to the application (determined by the Agency as fitting the Class 1 category).

9. Other minor clarifying information (determined by the Agency as fitting the Class 1 category).

10. Other specific items may be added later as the Agency gains experience with the scheme and will be communicated via guidance documents to industry.

Class 2 Resubmission: A Class 2 resubmission is a resubmission that includes any other items, including any item that would require a presentation to an advisory committee. A resubmission that requires a reinspection would also be a Class 2.

POLICY

- The review team and division director will determine the classification of the response, and a letter will be issued to the applicant acknowledging receipt of the resubmission within 14 calendar days stating the classification of and the due date for action on the resubmission. Any appeals of the classification should be made to the Office Director under established formal appeals mechanisms (21 CFR 10.75 and 314.103).

- CDER will complete the review and act on Class 1 resubmissions within two months of receipt, as resources permit.

- CDER will complete the review and act on Class 2 resubmissions within six months of receipt, as resources permit.

- If CDER does not agree that the submission is a complete response, the applicant will be so informed, and the review clock will not start until a complete response is

received.

- The Class 1/Class 2 distinction does not pertain to resubmissions of supplements. Responses to these resubmissions will have an internal goal date of six months from receipt. These types of resubmissions are not covered by PDUFA performance goals.

RESPONSIBILITIES AND PROCEDURES

- **Review Team and Division Director**

  1. Determine the classification of a resubmission.

  2. Complete the review and act on all Class 1 and 2 resubmissions within the time frames agreed in conjunction with the reauthorization of PDUFA.

- **Regulatory Project Management Staff**

  1. Upon receipt of the resubmission from the sponsor, consults with the review team and division director on the classification of the resubmission. This should be determined so that a letter can be sent to the sponsor within 14 calendar days of receipt of the resubmission.

  2. Ensures that an *acknowledgment of receipt* letter is drafted for the resubmission, stating the classification of the resubmission and the review goal date. This letter should be issued to the sponsor within 14 calendar days of receipt of the resubmission.

  3. Informs the applicant if the division does not agree that the submission is a complete response and ensures that the entry in COMIS is corrected to reflect this determination.

EFFECTIVE DATE

This MAPP is effective upon date of publication.