Guidance for Industry

Classifying Resubmissions in Response to Action Letters

Comments and suggestions regarding this document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the guidance. All comments should be identified with the docket number provided at the beginning of the notice. Submit comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1-23, Rockville, MD 20857.

After the comment period closes, comments should be provided in writing to the Center for Drug Evaluation and Research (CDER), Food and Drug Administration, 5600 Fishers Lane, Rockville, Md. 20857; or Center for Biologics Evaluation and Research (CBER), 1401 Rockville Pike, Rockville, Md. 20852-1448.

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Center for Biologics Evaluation and Research (CBER)
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GUIDANCE FOR INDUSTRY[1]
Classifying Resubmissions in Response to Action Letters

I. INTRODUCTION

As referenced in the Prescription Drug User Fee Act of 1992, 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 new drug application (NDA) or license application (LA) in six months or less. This guidance for industry explains how the Agency is classifying NDA and LA resubmissions and identifies the Agency's time frames for responding to them. It also provides recommendations on the procedures for making a resubmission. This guidance applies only to resubmissions of human drug applications as defined in section 735(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379g(1)).

In her letter to Congress regarding the reauthorization of PDUFA in November 1997 as part of the Food and Drug Administration Modernization Act of 1997, the Secretary of Health and Human Services committed FDA to recognizing two classes of resubmissions: Class 1 and Class 2. This classification of 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 — percentages of resubmissions that will be reviewed and acted upon within a certain time period from the date the resubmission is received by the Agency based on the fiscal year in which the resubmission is received.

Class 1 Resubmissions — Performance Goals

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

Class 2 Resubmissions — Performance Goals

FY 98 through 02: 90% in 6 months

[1]This guidance has been prepared by the Review Management Working Group comprising individuals in the Centers for Drug Evaluation and Research (CDER) and Biologics Evaluation and Research (CBER) at the Food and Drug Administration. This guidance document represents the Agency's current thinking on classification of resubmissions in response to action letters. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

II. DEFINITION OF TERMS

A. RESUBMISSION

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

B. 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 submissions 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 it will be a Class 2 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. These will be communicated through guidance for industry.

C. CLASS 2 RESUBMISSION

A *Class 2 resubmission* is a resubmission that includes any other items, including any item that would warrant presentation to an advisory committee. Any submission that would warrant a re-inspection is considered to fall into the category of a Class 2 resubmission.

III. POLICIES

A. The classification of the response will be determined, and a letter will be issued to the applicant acknowledging receipt of the resubmission, stating the classification of the response and giving 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 (see 21 CFR 10.75 and 314.103).

B. 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 resubmissions are not covered by PDUFA performance goals.

IV. PROCEDURES

A. Applicants should ensure that their resubmissions are clearly marked as resubmissions and that the cover letter for the resubmission clearly states that the applicant considers this submission a complete response to the deficiencies outlined in the previous action letter on the application (i.e., that this submission is indeed a complete response to those deficiencies and is therefore a *resubmission*.) If the applicant wishes to offer an opinion and the reasons for the opinion on the classification of the resubmission, it may do so in the cover letter.

B. Upon receipt of a resubmission to an action letter, the FDA will determine whether or not the response is a complete response, thereby restarting the review clock, and the appropriate classification of the response. If the FDA 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.

C. An *acknowledgment of receipt* letter for the resubmission will be issued within 14 calendar days of receipt of the resubmission stating the classification of the resubmission and the performance goal date.

D. Although the performance goals for acting on Class 1 resubmissions provide for a gradual yearly decrease in time for review, the FDA will complete review and act upon as many Class 1 resubmissions in two months or less as resources permit.