OFFICE OF NEW DRUGS

Review Classification Policy: Priority (P) and Standard (S)

CONTENTS

PURPOSE

- This MAPP describes the review classification of new drug applications (NDAs), biologics license applications (BLAs), and efficacy supplements in the Center for Drug Evaluation and Research (CDER). This classification establishes the timeline, milestones, and a goal date by which an application is reviewed under the Prescription Drug User Fee Act (PDUFA) performance goals.

BACKGROUND

- The review classification policy provides a way of describing whether the drug product provides safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement compared to marketed products in treating, preventing, or diagnosing disease upon initial receipt of NDAs, BLAs, and efficacy supplements. The classification also allows CDER staff to prioritize the review of such applications.

REFERENCES

- The Best Pharmaceuticals for Children Act — http://www.fda.gov/opacom/laws/pharmkids/contents.html

- The Prescription Drug User Fee Act — http://www.fda.gov/oc/pdufa/default.htm

DEFINITIONS

- **Drug products:** For the purposes of this MAPP, *drug* or *drug product* refers to human prescription drug and biological products that are regulated by CDER.

- **Review classification:** A determination based on whether the drug product provides safe and

effective therapy where no satisfactory alternative therapy exists or a significant improvement compared to marketed products in treating, preventing, or diagnosing disease. The designations *Priority (P)* and *Standard (S)* are mutually exclusive. Original NDAs, original BLAs, and efficacy supplements receive a review classification, but manufacturing supplements do not.

- **Priority (P) review —** Preliminary estimates indicate that the drug product, if approved, has the potential to provide, in the treatment, prevention, or diagnosis of a disease, one of the following: (1) safe and effective therapy where no satisfactory alternative therapy exists; or (2) a significant improvement compared to marketed products (approved, if approval is required), including *nondrug* products or therapies. Significant improvement is illustrated by the following examples: (1) evidence of increased effectiveness in treatment, prevention, or diagnosis of disease; (2) elimination or substantial reduction of a treatment-limiting drug reaction; (3) documented enhancement of patient compliance; or (4) evidence of safety and effectiveness in a new subpopulation. Although such evidence can come from clinical trials directly comparing a marketed product with the investigational drug, a priority designation can be based on other scientifically valid information.

- **Standard (S) review —** All nonpriority applications are considered standard applications.

POLICY

- A priority designation is intended to direct overall attention and resources to the evaluation of applications for drug products that have the potential for providing a significant improvement in the treatment, prevention, or diagnosis of a disease when compared to standard applications.

- The review classification is based on conditions and information available at the time the application is filed. Such a determination does not take into consideration economic factors (e.g., an estimate of price) and is not intended to predict a drug's ultimate value or its eventual place in the market.

- Such a classification must be made expeditiously since it determines a review's timeline and milestones. Within 14 days of receipt of an original NDA, original BLA, or efficacy supplement, divisions will identify whether such an application may qualify for a priority designation. If an application is expected to qualify for a priority designation, the filing meeting should be scheduled to occur by Day 30, instead of by Day 45 (the date for standard reviews). The final determination of the review classification and timeline for the first review cycle will be determined by the division director at the filing meeting.

- Any supplement to an application under section 505 of the Federal Food, Drug, and Cosmetic Act (the Act) that proposes a labeling change pursuant to a report on a pediatric study under this section shall be considered to be a priority supplement per section 505A of the Act as amended by section 5(b) of the Best Pharmaceuticals for Children Act.

- Applications that are not filed do not receive a review classification.

- The division will inform the applicant in writing of a priority designation by Day 60 of the review. The division will inform the applicant of a standard designation in the filing communication by Day 74 of the review.

- An independent determination of review classification will be made for each review cycle by the review team, with concurrence from the division director (although PDUFA goals for review are only affected by the determination in the first review cycle). After it is assigned at the time of filing, the review timeline will not change during the first review cycle, even if a redetermination of review status were made because of the approval of other drugs or the availability of new data.

- A priority designation determines the overall approach to setting review priorities and user fee review time frames but is not intended to preclude work on other projects. It does not imply that staff working on a priority application cannot perform other work (e.g., 30-day safety reviews of a newly submitted investigational new drug application (IND), preparation for end-of-phase 2 meetings).

  – Certain ad hoc special assignments may take precedence over the review of a priority application. The supervisor will advise the reviewer and team leader when an ad hoc assignment is to take precedence.

  – In general, if questions arise as to which assignments take precedence, the reviewer should consult with the supervisor or team leader.

RESPONSIBILITIES AND PROCEDURES

Original Review Classification of NDAs, BLAs, and Efficacy Supplements

- **The White Oak Document Room (DR1) is responsible for:**

  – Attaching the User Fee Validation Form to each application, when applicable.

- **The Clinical Team Leader is responsible for:**

  – Recommending a review classification to the division director for each NDA, BLA, and efficacy supplement within 14 days so that the division director can make a filing decision by the filing meeting (day 30 or day 45). The recommendation is made only if the application is to be filed and after consulting, as needed, with the reviewing medical officer and other team members.

- **The Division Director is responsible for:**

  – The final determination of review classification for each NDA, BLA, or efficacy supplement, no later than the filing meeting if the application is to be filed. Such a determination should take place after considering the recommendation of the clinical

team leader and consulting, as needed, with the clinical team leader, reviewing medical officer, and other team members.

– Communicating the final review classification to the regulatory project manager (RPM).

- **The Regulatory Project Manager is responsible for:**

  – Ensuring that the review classification code is entered into the appropriate tracking system by sending notification (e.g., User Fee Validation Form, e-mail) to data entry personnel according to established document processing instructions. After the review classification code has been communicated, the RPM should ensure that the respective review classification code and PDUFA deadlines are correct.

  – Notifying the applicant in writing of the final review classification by either Day 60 for a priority review or by Day 74 for a standard review.

Changes in Review Classification

- **The Reviewing Medical Officer/Team Leader is responsible for:**

  – Recommending to the division director any changes in review classification. Examples of justification for changes are as follows: new information in an IND, marketing application, and/or medical literature; advisory committee opinions; or approval of a pharmacologically similar drug.

  – Notifying the RPM of the potential change in review classification.

- **The Division Director is responsible for:**

  – Determining whether a change in review classification is justified.

  – Notifying the RPM of the change in review classification, if necessary.

  – Notifying the office director of the change in review classification, if necessary.

- **The Office Director is responsible for:**

  – Communicating any concerns about the change in review classification to the division director, if applicable.

- **The RPM is responsible for:**

  – Communicating (e.g., e-mail) a change in review classification to appropriate data entry personnel.

  – Notifying CDER's Office of Compliance of a change in review classification so that inspections can be scheduled relative to PDUFA goal dates.

- **DR1 is responsible for:**
  - Changing the review classification in the appropriate tracking system.

EFFECTIVE DATE

- This MAPP is effective upon date of publication.