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**REVIEW MANAGEMENT**

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**PRIORITY REVIEW POLICY**

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**PURPOSE** This MAPP describes the review priority classification of New Drug Applications (NDAs) and effectiveness supplements.

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**BACKGROUND**

The NDA classification system provides a way of describing drug applications upon initial receipt and throughout the review process and prioritizing their review.

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**DEFINITIONS**

**Review Priority Classification.** A determination that is made based on an estimate of its therapeutic preventive or diagnostic value. The designations “Priority” (P) and “Standard” (S) are mutually exclusive. Both original NDAs and effectiveness supplements receive a review priority classification but manufacturing supplements do not.

- **P -- Priority review<sup>1</sup>**

The drug product, if approved, would be a significant improvement compared to marketed products [approved (if such is required), including non-”drug” products/therapies] in the treatment, diagnosis, or prevention of a disease. Improvement can be demonstrated by, for example: (1) evidence of increased effectiveness in treatment, prevention, or diagnosis of disease; (2) elimination or

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<sup>1</sup>The CBER definition of a priority review is stricter than the definition that CDER uses. The biological drug, if approved, must be a significant improvement in the safety or effectiveness of the treatment diagnosis or prevention of a **serious or life-threatening** disease.

substantial reduction of a treatment-limiting drug reaction; (3) documented enhancement of patient compliance; or (4) evidence of safety and effectiveness of a new subpopulation.

- **S -- Standard review**

All non-priority applications will be considered standard applications.

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**POLICY**

- A “priority” designation is intended to direct overall attention and resources to the evaluation of applications for products that have the potential for providing significant preventative or diagnostic therapeutic advance as compared to “standard” applications.
- The priority determination does not take into consideration any information or estimate of price and is based on conditions and information available at the time the application is filed. It is not intended to predict a drug’s ultimate value or its eventual place in the market.
- Disputes in assigning review classifications should be handled in accord with MAPP 4040.1, “Appeals Process in Resolving Disputes over Applications in the Office of New Drug Evaluation” and 4040.2, “Scientific Reviews: Roles of Reviewers, Supervisors and Management; Resolution of Differences.”
- Because the review priority classification determines the review time frame the application receives, the review priority classification should be determined and assigned at the 45-day meeting if the application is to be filed.
- The final review classification of a new drug may change from “P” to “S” during the course of the review of a marketing application (NDA), either because of the approval of other agents or because of availability of new data; however, the review priority classification assigned at the time of filing will not change during the first review cycle and the user fee time frame of the original review cycle will be that based on the original priority.
- The review priority classification 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 work on other projects, such as 30-day safety reviews of a newly submitted investigational new drug application (IND), preparation for end-of-phase 2 conferences, etc.
- Certain *ad hoc* special assignments may also take precedence. The supervisor is to advise the reviewer and team leader when an *ad hoc* assignment is to take precedence.

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- As a general matter, if questions of priority arise, the reviewer should consult with the supervisor and team leader.
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## RESPONSIBILITIES AND PROCEDURES

### Original Review Classification of NDAs and Efficacy Supplements

- **The Division Document Room (DDR) is responsible for:**
  1. upon receipt of an original NDA or efficacy supplement, forwarding the original copy of form FDA 2817, "NDA Assignment and Review Transmittal" to the appropriate medical group/team leader;
  2. after receipt of the completed transmittal form, entering the appropriate review priority classification on form FDA 2772, IND/NDA History Record, in box marked "Classification" and in the Center-wide Oracle-based Management Information System (COMIS) after assigned at the 45-day filing meeting.
- **The Medical Group Team Leader is responsible for:**
  1. determining the review priority classification of each efficacy supplement and NDA application at the 45-day filing meeting if the application is to be filed, after consulting, as needed, with the reviewing medical officer, supervisory chemist, pharmacologist, microbiologist and new drug division director;
  2. completing the appropriate box on the transmittal form;
  3. returning the completed transmittal form to the DDR.
- **Reviewers and Supervisors are responsible for:**

setting priorities of review related activities in accordance with this MAPP.
- **The Consumer Safety Officer (CSO)/Project Manager (PM) is responsible for:**

assuring that the correct classification codes are entered into the COMIS system.

### Changes in classification at the end of the first cycle of review:

- **The Reviewing Medical Officer/Team Leader is responsible for:**
  1. recommending to the new drug division director any changes in classification justified on the basis of, for example, new information in an

IND or NDA, medical literature, advisory committee opinions or approval of a pharmacologically similar drug;

2. notifying the CSO/PM of the recommended change in classification.

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

1. approving or modifying the recommendation;

2. notifying the CSO/PM of the change in classification.

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

1. recommending changes in classification, if necessary;

2. notifying the CSO/PM of the change in classification, if necessary.

- **The CSO/PM is responsible for:**

notifying the DDR of the change in classification.

- **The DDR is responsible for:**

changing the classification on form FDA 2772 and in COMIS.

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#### **EFFECTIVE DATE**

This MAPP is effective upon date of publication.