Office of Generic Drugs

Processing a Tentatively Approved Application to Full Approval

CONTENTS

PURPOSE

- This MAPP outlines policies and procedures for conducting a regulatory assessment of and processing a tentatively approved abbreviated new drug application (ANDA) to full approval when there are no chemistry, manufacturing or controls (CMC) changes to the application.

BACKGROUND

- An assessment of the administrative processes in the Office of Generic Drugs suggests that Chemistry Project Managers are capable of performing administrative tasks that will reduce the burden on the chemistry review staff and increase chemistry review efficiency. Therefore, the Chemistry Project Manager will conduct a regulatory assessment and process tentatively approved applications to full approval. The Project Manager will only perform the assessment for minor amendments requesting final approval, provided the applicant has made no changes to the CMC data since the issuance of the tentative approval letter.

DEFINITION

- **Minor Amendments**: References to minor amendments in this MAPP refer to amendments that are requesting final approval (full approval) and do not require review by the Division of Chemistry or Division of Bioequivalence.

POLICY

- The Project Manager will assess the application upon receipt of "Minor Amendment - Final Approval Requested" according to the procedures outlined in this MAPP. The application will be considered as an exception to the "First-in, First-Reviewed" policy because it does not need to be placed in the review chemist's queue.

RESPONSIBILITIES AND PROCEDURES

- The Project Manager will evaluate the application to determine if the application is eligible for full approval and does not require further chemistry review.

- The Project Manager will check the application to ensure that the applicant:

  – Certified that no changes were made to the CMC section of the application after issuance of the tentative approval letter.

  – Did not submit,

    - additional data requiring review by the Division of Chemistry,

    - additional information requiring review by the Division of Bioequivalence,

    - updates to a United States Pharmacopeia (USP) monograph requiring review by the Division of Chemistry,

    - a Methods Validation Report requiring review by the Division of Chemistry.

- If the above requirements are met, the Project Manager will draft the "Regulatory Assessment for Full Approval Following a Tentative Approval" (Attachment A) and forward the package to the Chemistry Team Leader for endorsement. Once the Chemistry Team Leader's concurrence has been received, the Project Manager will assemble the approval package.

- The approval package will then be processed according to current office procedures.

EFFECTIVE DATE

- This MAPP is effective upon date of publication.

Attachment A

Regulatory Assessment for Full Approval Following a Tentative Approval

1. ANDA #
2. NAME AND ADDRESS OF APPLICANT
3. LEGAL BASIS FOR SUBMISSION
4. PROPRIETARY NAME
5. NONPROPRIETARY NAME
6. CURRENT SUBMISSIONS AND OTHER DATES:
7. PHARMACOLOGICAL CATEGORY
8. Rx or OTC
9. SAMPLES AND RESULTS
10. LABELING STATUS
11. BIOEQUIVALENCY STATUS
12. MICROBIOLOGY STATUS
13. ESTABLISHMENT INSPECTION
14. CONCLUSIONS AND RECOMMENDATIONS

PROJECT MANAGER: DATE COMPLETED: