Office of Generic Drugs

Processing of Supplemental Applications Providing for Alternate Stand Alone Packaging Operation Site Changes

CONTENTS

PURPOSE

- This MAPP outlines policies and procedures for conducting a regulatory assessment of and processing supplemental applications that provide for alternate stand alone packaging operation site changes to abbreviated new drug applications (ANDA).

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 of the administrative issues and process supplements providing for alternate stand alone packaging operation site changes. Supplemental applications providing for alternate stand alone packaging operation site changes do not require review of scientific data and may be submitted as Changes Being Effected in 30 Days (CBE-30) supplements.

DEFINITION

- **Supplements or Supplemental Applications** - In this MAPP, supplements or supplemental applications refer to supplemental applications that only provide for alternate stand alone packaging operation site changes to ANDAs.

POLICY

- The Project Manager and Chemistry Team Leader will assess a supplemental application at the time of CBE-30 status determination according to the procedures outlined in this MAPP. The supplement 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 and the Chemistry Team Leader will evaluate the supplemental application to determine if sufficient information has been submitted to grant CBE-30 status and will ensure that the following documentation has been submitted to support the change:

    a. Certification that the facility will use the container(s)/closure(s) approved in the application.
    b. Certification that the packaging facility has had a satisfactory cGMP inspection for the type of operation being performed.
    c. A commitment to place the first production batch of the product packaged at the alternate facility on long-term stability studies using the approved protocol in the application and to submit the resulting data in annual reports.

- The Project Manager will contact the sponsor for any missing documentation that should be included in a CBE-30, according to MAPP 5240.7.

- The Project Manager and the Chemistry Team Leader will complete the CBE-30 routing form, which will become part of the supplemental application.

- To determine CBE-30 status, the Project Manager will submit an Establishment Evaluation Request (EER) for cGMP status to the Office of Compliance through the Establishment Evaluation System (EES) and retain the jacket until a response has been received. The Project Manager will be responsible for tracking the status of the EER.

- Upon receipt of an acceptable EER recommendation from the Office of Compliance, the Project Manager will prepare draft copies of the Regulatory Assessment (Attachment A) and an Approval Letter using the Alternate Stand Alone Packaging Operation Site Changes Regulatory Assessment Template and Chemistry Letters program. A copy of the EES report should accompany the Regulatory Assessment.

- If an unacceptable recommendation is received from the Office of Compliance, the Project Manager will consult with the Chemistry Team Leader and prepare draft

copies of the Regulatory Assessment and a Not Approvable Letter. A copy of the EES report should accompany the Regulatory Assessment.

- The Project Manager will send draft copies of the Regulatory Assessment and the Approval or Not Approvable Letter to the secretary to be typed in final. The Project Manager will ensure that the completed CBE routing form is attached to the submission. The final typed package will be processed according to current office procedures.

EFFECTIVE DATE

- This MAPP is effective for all supplements filed after (MAPP approval date).

Attachment A

Alternate Stand Alone Packaging Operations Site Change
Abbreviated New Drug Supplemental Application Regulatory Assessment

REVIEW#

ANDA
XXX

SUPPLEMENT
XXX

NAME AND ADDRESS OF APPLICANT:
XXX

PURPOSE OF AMENDMENT/SUPPLEMENT
SPECIAL SUPPLEMENT – CHANGES BEING EFFECTED IN 30 DAYS:
To add the following facility for stand alone packaging operations:

XXX

DATE(S) OF SUBMISSION(S)
XXX

NONPROPRIETARY NAME
XXX

DOSAGE FORM	POTENCY
XXX	XXX

Rx or OTC
XXX

DOCUMENTATION
In support of the proposed additional stand alone packaging facility, the firm submitted the following:

ESTABLISHMENT INSPECTION

REMARKS AND CONCLUSION

PROJECT MANAGER: DATE COMPLETED:

Attachment A, Page 2

cc: ANDA
Division File
Field Copy

Endorsements:

HFD-XXX/PM

HFD-XXX/TL

XXXXX

F/T by /

TYPE OF LETTER: