OFFICE OF GENERIC DRUGS

Review of Dissolution Data in Supplemental ANDAs

CONTENTS

PURPOSE

- This MAPP specifies the responsibilities of the Office of Generic Drugs' Division of Chemistry I, Division of Chemistry II, Division of Chemistry III, and Division of Bioequivalence for the review of dissolution data in supplemental abbreviated new drug applications (ANDAs).

BACKGROUND

- A memorandum of understanding was drafted in 1991 by the (then) Divisions of Chemistry I and II and the Division of Bioequivalence (DBE) to specify dissolution testing review responsibilities for immediate-release products in supplemental applications. This memo was revised March 27, 1992, by the Directors of the Office of Drug Evaluation I, the Office of Drug Evaluation II, and the Office of Generic Drugs, to include the review of dissolution testing for specific changes to extended-release products in NDAs as well as ANDAs.

- This document describes the chemistry and bioequivalence staff responsibilities for review of dissolution testing submitted in supplemental ANDAs.

REFERENCES

- SUPAC-IR: FDA guidance for industry on *Immediate-Release Solid Oral Dosage Forms Scale-Up and Post-Approval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation.*

- SUPAC-MR: FDA guidance for industry on *Modified-Release Solid Oral Dosage Forms Scale-Up and Post-Approval Changes: Chemistry, Manufacturing, and Controls, In Vitro Dissolution Testing and In Vivo Bioequivalence Documentation.*

POLICY

- If in vitro dissolution testing calls for the use of the compendial or ANDA-approved method, whether single-point or multi-point dissolution profiles, the reviewers of the Divisions of Chemistry I, II, and III will evaluate the data (except for the situations detailed below).

- If new dissolution methods are requested, if there are changes to the formulation, or if there is a request for a waiver of in vivo bioequivalence testing for a new strength, the reviewer in DBE will evaluate the dissolution data. The DBE will also review dissolution data for drugs requiring dissolution in multiple media (e.g., extended-release products) in all instances.

RESPONSIBILITIES

Document Room Personnel will:

- Initially assign all supplements that appear to be chemistry, manufacturing, and controls (CMC) supplements to one of the chemistry divisions.

- Assign supplements to the DBE after consultation with the chemistry project manager and/or chemistry team leader if the supplements contain in vivo studies, in vivo/in vitro correlations, multiple media dissolution data, requests for new dissolution methods, changes in formulation, or new strengths.

The Chemistry Project Manager and Team Leader will:

- Assess all supplements to determine whether a bioequivalence review is needed, and instruct Document Room personnel to make the review assignments accordingly.

The Chemistry Reviewer will:

- Review submitted dissolution data using USP- or ANDA-approved methods for changes specified in the guidances.

The Bioequivalence Project Manager will:

- Ensure that bioequivalence supplements are assigned to the next available reviewer.

The Bioequivalence Reviewer will:

- Review supplements containing changes in formulation, new strengths, dissolution testing containing multiple media (e.g., extended-release products), new dissolution methods, and/or new dissolution specifications.

PROCEDURES

- The Document Room receives the supplements and verifies the appropriate review disciplines for assignments with the chemistry project manager and/or team leader. The chemistry division reviewer will review the CMC data. If a DBE review is necessary, the supplement is forwarded to the DBE project manager for assignment to the next available bioequivalence reviewer, who will review the dissolution data.

- When the bioequivalence review is completed, it is forwarded by the bioequivalence project manager to the chemistry project manager, who will inform the chemistry reviewer. The chemistry reviewer will complete the supplement review and the chemistry division will inform the sponsor of the results.

EFFECTIVE DATE

- This MAPP is effective upon date of publication.