REVIEW MANAGEMENT

Over-the-Counter (OTC) Labeling and Use Studies

CONTENTS

PURPOSE This MAPP describes the policies and procedures to be used by the Center for Drug Evaluation and Research (CDER) staff to:

- Process OTC drug actual use studies; and
- Process OTC label comprehension studies.

BACKGROUND

Sponsors often conduct OTC drug actual use studies and OTC label comprehension studies for prescription-to-OTC switch candidates. Individual reviewing divisions have handled these studies differently. This guide describes standardized procedures to process documents related to OTC drug actual use and label comprehension studies.

DEFINITIONS

- **Clinical investigation.** Any experiment in which a drug is administered, dispensed to, or used involving one or more human subjects. (See 21 CFR

312.3(b).)

- **Experiment.** Any use of a drug except for the use of a marketed drug in the course of medical practice. (See 21 CFR 312.3(b).)

- **OTC drug actual use study.** A controlled experiment in which a prescription drug or an unapproved new drug is used by subjects under OTC-like conditions.

- **OTC label comprehension study.** A study to evaluate proposed OTC product labeling. In such studies, no drug is used.

POLICY

- Controlled actual use studies for proposed OTC drugs should be conducted under an investigational new drug application (IND) because OTC usage is intended to support a significant change in the labeling for the drug (21 CFR 312.2(b)(1)(i)).

- An epidemiology study to support OTC use should be conducted under an IND.

- Protocols for controlled OTC drug actual use studies should be reviewed under an IND.

- An OTC label comprehension study does not have to be conducted under an IND. However, if a sponsor wants CDER advice and consultation on such a study protocol, then it should be submitted to an existing IND or new drug application (NDA).

RESPONSIBILITIES AND PROCEDURES

- **Sponsors of NDAs for prescription-to-OTC switch candidates should:**

  1. Consult about OTC drug actual use and label comprehension studies with the new drug review divisions that have responsibility for the particular product.

  2. Interact with review divisions whenever necessary to discuss study

goals.

- **Review divisions should inform the sponsor to:**

  1. Submit all OTC drug actual use studies and protocols for such studies to an existing IND or NDA.

  2. Submit OTC label comprehension studies to an existing IND or NDA, only when CDER advice and consultation on such studies are desired.

  3. Send a desk copy of any studies under 1 or 2 above to the Division of OTC Drug Products (DODP) (HFD-560) and a desk copy of any studies under 2 above to the Division of Drug Marketing, Advertising, & Communications (DDMAC) (HFD-40).

- **Review divisions are responsible for:**

  1. Promptly logging in the submissions for these studies and coordinating CDER reviews with DODP and DDMAC.

  2. Forwarding a copy of all OTC drug actual use or label comprehension study reviews, correspondence, meeting minutes, telephone contact reports, or outgoing correspondence to DODP and DDMAC and any other review divisions (depending on the subject matter) involved in reviewing these studies.

  3. Coordinating all reviews, resolving outstanding issues, and responding to the sponsor.

  4. Coordinating meetings with the sponsor and other FDA reviewers, as needed.

- **DODP is responsible for:**

  1. Reviewing all study protocols/results and forwarding a copy of its review to the appropriate review divisions and DDMAC.

  2. Working with the appropriate review divisions and DDMAC to

resolve any outstanding issues.

3. Interacting with sponsors as necessary to achieve these goals.

- **DDMAC is responsible for:**

1. Reviewing the protocols/results from label comprehension studies and forwarding a copy of its review to the review divisions, including DODP.

2. Working with the review divisions, including DODP, to resolve any outstanding issues.

3. Interacting with sponsors as necessary to achieve these goals.

EFFECTIVE DATE

This MAPP is effective upon date of publication.