PHARMACEUTICAL SCIENCES

COLLECTION OF DOCUMENTS IN DOCKET FOR AGENCY POLICY STATEMENTS, SPEECHES, AND POLICY AND PROCEDURE GUIDES ADDRESSING HUMAN GENERIC DRUGS

CONTENTS

BACKGROUND

- Employees of the Center for Drug Evaluation and Research (CDER) attend meetings with industry to deliver speeches and answer questions regarding CDER activities and human generic drugs in particular. Within CDER's Office of Generic Drugs (OGD), policy statements and policy and procedure guides (guidances) are being disseminated to ensure fair and even-handed dealings with all applicants. These speeches, policy statements and policy and procedure guides currently are being collected and filed in FDA's Docket No. 90S-0308 to make the information accessible to all interested persons. This information was published in the Federal Register on October 22, 1990 (55 FR 42654).

RESPONSIBILITY

- **Dockets Management Branch**. The Dockets Management Branch (Dockets), HFA-305, has primary responsibility for monitoring collection of policy statements, speeches, and policy and procedure guides that are issued by CDER regarding human generic drugs.

- **Employees**. It is the responsibility of all CDER employees to ensure that copies of applicable documents, and their correspondent transmittal memoranda, get to Dockets. Once there, they will be made available to all interested parties.

KINDS OF DOCUMENTS

- **Agency Policy Statements**. Policy statements established by the Agency regarding human generic drugs. New policy statements regarding human generic drugs published in the Federal Register after October 22, 1990, are to be published under Docket No. 90S-0308.

- **Speeches**. Complete narrative copies of speeches, as described below:

  1. Speeches by CDER employees addressing human generic drugs presented to the Generic Pharmaceutical Industry Association (GPIA), the National Association of Pharmaceutical Manufacturers (NAPM), the Pharmaceutical Manufacturers Association (PMA) and other trade associations.

  2. Formal visual aids (e.g., including slides, but excluding flipcharts drawn during a presentation) are considered part of the speech. They should be made into paper copies and attached to the narrative of the speech with which they were presented.

- **Policy and Procedure Guides**. Policy and procedure guides designed for use within the Agency addressing human generic drugs.

- **Transmittal Memorandum**. Transmittal memorandum should be attached to every document submitted.. Each memorandum should summarize the contents of its respective policy statement, speech, or guide and will facilitate the storage and dissemination of the information attached. Each document should be placed in the docket with the transmittal memorandum on top of the document. The transmittal memorandum will differ depending on the type of documents transmitted (see attachments).

PROCEDURES FOR COLLECTION

- **Agency Policy Statements**. When policy statements are established by the Agency regarding human generic drugs, a copy of the statement will be sent to the Regulatory Policy Staff for submission to Dockets. (Please see Attachment A for suggested format for a transmittal memorandum.)

- **Speeches**. Speeches by CDER employees addressing human generic drugs should be sent to the Regulatory Policy Staff for submission to Dockets. If the speech is presented locally, it should be sent within 24 hours of presentation. If it is presented while on travel status, it should be sent to the Regulatory Policy Staff within 24 hours of returning to the office. The copy should have the transmittal memorandum on top of the document. (Please see Attachment B for suggested format for a transmittal memorandum.)

- **Policy and Procedure Guides (Guidances)**. When policy and procedure guides covered by this MAPP are issued, a copy should be sent to the Regulatory Policy Staff for submission to Dockets for inclusion in Docket No. 90S-0308, with the transmittal memorandum on top of the guide. (Please see Attachment C for suggested format for a transmittal memorandum.)

EFFECTIVE DATE

This guide is effective upon date of publication.

Attachment A

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE:

FROM:

SUBJECT: Policy Statement Regarding Human Generic Drugs to Docket 90S-0308

TO: Dockets Management Branch, HFA-305

This memorandum is forwarding a new or revised policy statement regarding human generic drugs to the Dockets Management Branch (Dockets), for inclusion in Docket 90S-0308. The following is information on the policy statement for Dockets records:

Title of item: _____

_____

_____

_____

Topic (if different from title): _____

Date issued or published: _____

Issued or published in: _____

Number of pages attached: _____

_____
Signature

Attachment

Attachment B

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE:

FROM:

SUBJECT: Speech Regarding Human Generic Drugs to Docket 90S-0308

TO: Dockets Management Branch, HFA-305

This memorandum is forwarding a speech to the Dockets Management Branch (Dockets), for inclusion in Docket 90S-0308. The following is information on the policy statement for Dockets records:

Title of speech: _____

_____

_____

_____

Topic (if different from title): _____

Presented to: _____

Presenter: _____

Number of pages in speech: _____

_____
Signature

Attachment

Attachment C

M E M O R A N D U M

DEPARTMENT OF HEALTH AND HUMAN SERVICES
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
CENTER FOR DRUG EVALUATION AND RESEARCH

DATE:

FROM:

SUBJECT: Policy and Procedure Guide Regarding Human Generic Drugs to Docket 90S-0308

TO: Dockets Management Branch, HFA-305

This memorandum is forwarding a policy and procedure guide to the Dockets Management Branch (Dockets), for inclusion in Docket 90S-0308. The following is information on the policy statement for Dockets records:

Title of guide: _____

_____

_____

_____

Topic (if different from title): _____

Date Effective: _____

Number of pages in guide: _____

_____
Signature

Attachment