OFFICE OF TRAINING AND COMMUNICATION

Providing General Consumer Information on New Molecular Entities on CDER's Web Site

CONTENTS

PURPOSE

- This MAPP outlines the policies and procedures for writing, clearing, and posting consumer drug information sheets (CDIS) for the Internet web page of the Center for Drug Evaluation and Research (CDER).

BACKGROUND

- The Food and Drug Administration Modernization Act of 1997 (the Modernization Act) recognized the value of making clear information on new drug products available to consumers and patients. Providing clear and accurate information can improve the quality of health care by reducing the number of adverse events caused by inappropriate use of drugs. It can also reduce the cost of health care through the appropriate use of drugs, biological products, and devices.

- CDER stakeholders have frequently requested that FDA/CDER be more involved in educating consumers.

- The Agency's consumer education efforts are critical to public understanding of the importance of the appropriate use of drugs and avoidance of unsafe products. Widespread availability of understandable information is a powerful tool in accomplishing FDA's public health objectives and risk management goals.

- Providing consumer information in a standard format makes it easier for consumers to locate particular information and provides an opportunity to reinforce important aspects of

prescription medicine use (e.g., potential side effects) each time a consumer refers to this information.

REFERENCES

- Food and Drug Administration Modernization Act of 1997 (Public Law 105-115)
- Action Plan for the Provision of Useful Prescription Medicine Information, December 1996, http://www.fda.gov/cder/ddmac/workshop2.htm
- Message to Stakeholders, Dr. Janet Woodcock, 1998
- Prescription Drug Product Labeling; Medication Guide Requirements, Final Rule 1998
- MAPP 4520.1, Communicating Drug Approval Information (March 1998)
- MAPP 7610.1, Posting Documents on the External World Wide Web Site (July 1996)

DEFINITIONS

- **Approved Labeling Text (ALT):** The approved package insert
- **CDER's Web Page:** A publicly accessible Internet web site that contains CDER information
- **Consumer Drug Information Sheet (CDIS):** A summary sheet derived from the approved labeling text written for consumers
- **Medication Guide:** FDA-approved patient labeling
- **New Molecular Entity (NME):** Therapeutic moiety in a dosage form that has not been approved for marketing in the United States
- **Patient Package Insert (PPI):** Consumer-oriented information written and produced by product manufacturers and approved by FDA
- **Originator:** CDER Consumer Safety Officer (CSO) in the Office of Training and Communications (OTCOM) who writes the CDIS for posting on CDER's web page
- **Webmaster:** CDER staff member in OTCOM who maintains CDER's web page

POLICY

- The consumer drug information sheets (CDIS) are summaries and do not contain all possible information about a drug.
- The CDIS provide general information about newly approved prescription drugs.
- The CDIS are written for NMEs approved after January 1998.
- Only final versions of the CDIS with proper clearance will be posted on CDER's web page.
- The content of the CDIS is based on approved product labeling.

RESPONSIBILITIES

The Originator is responsible for:

- Writing the CDIS and ensuring their content, timeliness, and quality of information
- Obtaining clearance from the review Division Director or designee
- Reviewing the CDER Consumer Drug Information web page monthly for accuracy and proper links to product labeling information
- Providing the webmaster with an updated electronic copy of the CDIS when necessary (e.g., new dosage forms, safety updates)

The Webmaster is responsible for:

- Posting the CDIS using the priorities established in the policy section of MAPP 7610.1
- Informing the originator when the CDIS are posted and informing the FDA Internet Work Group (through its CDER listserv) when new CDIS of potential interest to other parts of the Agency are posted

The Review Division is responsible for:

- Reviewing the CDIS for scientific merit, ensuring that translation into lay language does not diminish accuracy

- Clearing the CDIS as authorized by the Division Director or designee, unless the CDIS are drafted from a PPI or Medication Guide with no substantive modifications by the Division of Drug Marketing, Advertising, and Communications (DDMAC)

DDMAC is responsible for:

- Reviewing the CDIS for lay language and conformance with CDER policy

- Reviewing and clearing the CDIS drafted from the PPI when no substantive changes are made by the division

- Clearing the CDIS as authorized by the review Division Director or designee

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PROCEDURES

- **For NMEs *without* approved patient package insert (PPI) or Medication Guide**

1. When an NME is approved by CDER, approval notification will be sent from the Office of New Drugs (OND) review division in accordance with the policies outlined in MAPP 4520.1.

2. The originator (OTCOM CSO) will obtain approved labeling text (ALT) from CDER's web page.

3. From the ALT, the originator will draft a standard format CDIS written for the consumer. This initial draft will be complete within 5 business days of ALT availability on CDER's web page.

4. The originator will route an electronic copy of the first draft through the Division File System (DFS) to the OND Division Director or designee.

5. The Division Director or designee will have 10 business days within which to return comments, edits based on scientific merit, and modifications to the originator's first draft. If at the end of this 10-day period there is no reply from the division, the originator will make a second request with courtesy copies to OTCOM's Drug Information Division Director and the OTCOM Office Director. The originator must obtain division clearance prior to forwarding the CDIS to DDMAC.

6. Within 1 business day of receipt of the CDIS from the division, the originator will incorporate any changes to the first draft.

7. The originator will send the second draft to DDMAC for review.

8. DDMAC has 10 business days to review the second draft of the CDIS and make final edits and changes.

9. By the conclusion of this 10-day period, DDMAC will return the second draft of the CDIS to the originator to incorporate changes to create a final draft.

10. Within 2 business days, the originator will forward an electronic copy of the final draft to the Division of Public Affairs (DPA) for conversion into html format.

11. DPA will forward the html CDIS to the Webmaster for posting on the CDER Consumer Drug Information web page in accordance with MAPP 7610.1.

- **For NMEs *with* approved patient package insert (PPI) or Medication Guide**

1. When the NME is approved by CDER, approval notification will be sent from the OND review division in accordance with the policies outlined in MAPP 4520.1.

2. The originator will obtain the ALT from CDER's web page.

3. From the ALT's PPI or Medication Guide, the originator will draft a standard format of the CDIS. This initial draft will be complete within 5 business days of the ALT's availability on CDER's web page. The content of the PPI or Medication Guide will be arranged to fit the standard format of the CDIS. The language in the CDIS will be copied verbatim from the PPI or Medication Guide, with no changes in content except to exclude information that is unnecessary when providing general drug information (e.g., dosage and administration).

4. The originator will send an electronic copy of the first draft to DDMAC with another copy sent to the OND review Division Director.

5. DDMAC will have 10 business days in which to make comments, edits, and changes to the originator's first draft.

6. By the conclusion of this 10-day period, DDMAC will return the CDIS to the originator to incorporate changes to create a final draft. If there are substantive modifications by DDMAC, the CDIS must have division level clearance.

7. Within 2 business days, the originator will forward an electronic copy of the final draft to DPA for conversion into html format.

8. DPA will forward the html CDIS to the Webmaster for posting on the CDER Consumer Drug Information web page in accordance with MAPP 7610.1.

EFFECTIVE DATE

This MAPP is effective upon date of publication.

Attachment A — Format of a Consumer Drug Information Sheet

Brand Name:
Active Ingredient(s):
Strength(s):
Dosage Form(s):
Company Name:
Availability:
*Date Approved by FDA:
**Approval by FDA does not mean that the drug is currently marketed and available for consumers at this time.*

What is _____ used for?
*Use product approved indications***.**

Who should not take _____? Who should not be given ____?
Use Contraindications section.

Special Warning(s) with ____:
This section is for boxed, bolded, or other major warnings.

Warning(s) with _____:
This section is for warnings that are not boxed, bolded, or major warnings.

General Precautions with ____:

What should I tell my doctor or health care provider?
Use precautions section.

What are some possible side effects of _____?
Use only the top 5% or most frequent as determined by the division.

Reports of patients' experience after _____ became available:
Include this section if it is provided in ALT.

For more detailed information about _____, ask your health care provider.

Date posted:
Date revised/updated:

Link to approved labeling … and patient information (if PPI or Medication Guide)