

**OFFICE OF TRAINING AND COMMUNICATION**

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

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**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).
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**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.
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**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
  - MAPP 7610.1, Posting Documents on the External World Wide Web Site
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**DEFINITIONS**

- **Approved Labeling Text (ALT):** The approved package insert.
  - **CDER's Web Page:** A publicly accessible Internet site that contains CDER information.
  - **Consumer Drug Information Sheets (CDIS):** Summary sheets derived from the approved labeling text written for consumers.
  - **Medication Guide:** FDA-approved patient information.
  - **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.
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**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.
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## RESPONSIBILITIES

### The Originator will:

- Write the CDIS and ensure their content, timeliness, and quality of information.
- Obtain clearance from the review Division Director or designee, the Division of Drug Marketing Advertising and Communications (DDMAC), and the Division of Surveillance, Research, and Communication Support (DSRCS).
- Review the CDER Consumer Drug Information web page monthly for accuracy and proper links to product labeling information.
- Provide the webmaster with an updated electronic copy of the CDIS when necessary (e.g., new dosage forms, safety updates).

### The Webmaster will:

- Post the CDIS using the priorities established in the policy section of MAPP 7610.1.
- Inform the originator when the CDIS are posted and inform 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 will:

- Review the CDIS for scientific merit, ensuring that translation into lay language does not diminish accuracy.
- Clear 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 DDMAC or DSRCS.

### DDMAC and DSRCS will:

- Review the CDIS for lay language and conformance with CDER policy.
- Review and clear the CDIS drafted from the PPI when no substantive changes are made by the division.
- Clear the CDIS as authorized by the review Division Director or designee.

**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 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 DSRCS and 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 1 business day of receipt of the CDIS from DDMAC, the originator will incorporate any changes to the second draft.
11. The originator will send the third draft to DSRCS for review.
12. DSRCS has 10 business days to review the third draft of the CDIS and make final edits and changes.
13. By the conclusion of this 10-day period, DSRCS will return the third draft of the CDIS to the originator to incorporate changes to create a final draft.
14. Within 2 business days, the originator, or division designee will convert the final draft into html format.
15. The Division of Drug Information (DDI) 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 second draft. If there are substantive modifications by DDMAC, the CDIS must have division level clearance.
7. Within 1 business day of receipt of the CDIS from DDMAC, the originator will incorporate any changes to the second draft.
8. The originator will send the third draft to DSRCS for review.
9. DSRCS has 10 business days to review the third draft of the CDIS and make final edits and changes.
10. By the conclusion of this 10-day period, DSRCS will return the third draft of the CDIS to the originator to incorporate changes to create a final draft. If there are substantive modifications by DSRCS, the CDIS must have division level clearance.
11. Within 2 business days, the originator, or division designee will convert the final draft into html format.
12. DDI will forward the html CDIS to the Webmaster for posting on the CDER Consumer Drug Information web page in accordance with MAPP 7610.1.

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**EFFECTIVE DATE**

This MAPP is effective upon date of publication.



Patient Information Sheet

Generic name (marketed as ....)

FDA ALERT [0/2007]

Delete this section for NMEs

This information reflects FDA’s preliminary analysis of data concerning this drug. FDA is considering, but has not reached a final conclusion about, this information. FDA intends to update this sheet when additional information or analyses become available.

This is a summary of the most important information about X. For details, talk to your healthcare professional.

USE ACTIVE VOICE: you, men, women, EMPHASIZE CONTEXT.....because why.. Check for: could, there are/there is, only, which, that, very Healthcare professional not Health care provider No trademark symbols Don't All Caps the drug name If no generic, use brand name only throughout Do not use caps or periods when bulleting a list unless it's a complete sentence.

What Is X? (\*\*Use brand name if no generics available)

Use product approved indications. Also include if it is NOT to be used for a certain indication, population...men, women or age range.

Accelerated approval AIDS drugs: At present, it is not known whether X keeps the HIV virus at a low level or slows the progress of disease.

Accelerated approval cancer drugs: At this time, it is not known whether X will improve symptoms, keep the disease from getting worse, or help patients live longer.

Who Should Not Use/Take/Be Treated With X?

Use Contraindications section with bulleted style.

You should not take X if you have any of the following conditions:

OR

You should not be given X if you have any of the following conditions:

What Are The Risks?

The following are the major potential risks and side effects of X therapy. However, this list is not complete.

Include warnings and boxed warnings, in the order they appear in the labeling. Boldface the side effect, then continue in normal font.

The last bullet should read:

- Some common side effects that may occur with X include:

Use bulleted style and include most common side effects.

What Should I Tell My Healthcare Professional?

Before you start taking X, tell your healthcare professional if you:

- have or had liver problems
are trying to become pregnant, are already pregnant, or are breast-feeding
are allergic to X or to any of the ingredients in X

Use precautions section. Activities (driving,sun)/ drugs/foods/alcohol to avoid, pregnancy/nursing risks, pediatric/geriatric risks.

Can Other Medicines Or Food Affect X?

X and certain other medicines can interact with each other. Tell your healthcare professional about all the medicines you take including prescription and non-prescription medicines, vitamins, and herbal supplements. Some medicines may affect how X works or X may affect how your other medicines work. Know the medicines you take. Keep a list of them with you to show your healthcare professional.

Especially tell your healthcare professional if you take:

- XX
XX

These medicines may affect how X works, or X may affect how these medicines work.

How Should I Take/Receive X?

In bulleted form, include information about whether or not X should be taken with food, and the time of day it should be taken.

Date Approved:
Date Reviewed
Date Updated

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





*Questions? Call Drug Information, 1-888-INFO-FDA (automated) or 301-827-4570*

*[Druginfo@cder.fda.gov](mailto:Druginfo@cder.fda.gov)*