OFFICE OF NEW DRUGS

NDAs: "Dear Health Care Professional" Letters

CONTENTS

PURPOSE

- This MAPP describes the policies and procedures in the Center for Drug Evaluation and Research (CDER) for:
  - Reviewing draft "Dear Health Care Professional" (DHCP) letters before the applicant issues them;
  - Reviewing final DHCP letters when an applicant issues them without having previously involved the Food and Drug Administration (FDA) in reviewing the draft; and
  - Ensuring that appropriate CDER personnel are aware that a DHCP letter is planned or has been issued.

SCOPE

- Although DHCP letters can be distributed for a variety of reasons, this MAPP applies only to those DHCP letters that concern information about a significant hazard to health and/or important changes in drug package labeling.

BACKGROUND

- Occasionally, drug manufacturers and distributors mail important information about their drugs to health care professionals, including physicians, pharmacists, physician's assistants, and nurses. The FDA may or may not be involved in reviewing these DHCP letters before they are mailed.

- Although these letters are informally known as "Dear Doctor" letters, they are designated "Dear Health Care Professional" letters in this MAPP because they are frequently

disseminated beyond the physician community.

- Applicants may be asked by FDA to distribute a DHCP letter for the following reasons:

  1. To disseminate information concerning a significant hazard to health

  2. To announce important changes in drug package labeling

  3. To correct prescription drug advertising or labeling (i.e., to emphasize corrections to prescription drug advertising or labeling)

  Applicants may distribute these letters for a variety of other reasons as well.

REFERENCES

- Federal Food, Drug, and Cosmetic Act (the Act), section 201(m), Definition of Labeling
- 21 CFR 201.100(d), Prescription Drugs for Human Use
- 21 CFR 200.5, Mailing of Important Information About Drugs
- 21 CFR 314.81, Other Postmarketing Reports
- MAPP 4112.1 "CDER/FDA Press Office Interactions in the Preparation and Clearance of Written Documents for the Public"

DEFINITIONS

- **Dear Health Care Professional (DHCP) letter:** Correspondence mailed by a manufacturer and/or distributor to physicians and/or other health care professionals to convey important information about drugs. DHCP letters are considered promotional labeling. These letters can be requested by FDA or initiated by the applicant.

- **Executive Operations Staff (EOS):** CDER personnel in the Office of the Center Director responsible for facilitating Agency-wide communication. Among other duties, they work with CDER staff to identify any current or upcoming issues or actions that may warrant a Talk Paper, Press Release, and/or Public Health Advisory. The e-mail address for the EOS is CDEREXSEC@cder.fda.gov.

- **Executive Operations Staff (EOS) Liaison:** A representative of the EOS assigned to a particular new drug review division.

- **MedWatch (www.fda.gov/medwatch):** The FDA safety information and adverse event reporting program in the Office of Drug Safety (ODS), Division of Surveillance, Research, and Communication Support (DSCRS) designed to educate all health professionals to be aware of, monitor for, and report adverse events and problems to FDA and/or the

manufacturer. MedWatch also assists in the communication of new safety information about medical products to the medical community.

- **MedWatch Partners:** A group of organizations representing health professionals, health care consumers, and the pharmaceutical industry. These organizations work collaboratively with MedWatch to disseminate new safety information to prescribers, dispensers, and users of FDA-regulated medical products.

- **MedWatch Safety Alert:** An announcement of new safety information about an FDA-regulated medical product, posted on the MedWatch website at www.fda.gov/medwatch/safety.htm. Among other things, these announcements summarize safety-related labeling changes for medical products and include hyperlinks to any DHCP letters, Talk Papers, Press Releases, and Public Health Advisories. At the time of each posting, e-mail notification of the Alert is sent to MedWatch Partner organizations and individual MedWatch subscribers.

- **Press Release:** A document that provides general information in plain language about a particular subject of current interest. It may contain quotes from Agency personnel and is issued on HHS letterhead (see MAPP 4112.1).

- **Public Health Advisory:** Information about an important public health issue in plain language (see MAPP 4112.1).

- **Talk Paper:** A document that provides more detailed information in plain language about a particular topic to help guide Agency staff in responding to questions on the topic. These documents are actively disseminated to the media and are subject to change as more information becomes available (see MAPP 4112.1).

POLICY

- A DHCP letter can be initiated by either FDA or an applicant in response to any of the three situations described in the BACKGROUND section of this MAPP, among other reasons. Typically, the applicant will issue these letters.

- A DHCP letter is one of several available methods to communicate important public health messages. Because reliance on a single communication avenue is not always optimal, other communication options available to FDA (e.g., letters to editors, FDA Talk Papers, Press Releases, Public Health Advisories) will be considered in addition to the DHCP letter.

- For FDA-approved DHCP letters and FDA-initiated safety communications such as Talk Papers, Press Releases, and/or Public Health Advisories, MedWatch typically will post a Safety Alert and will e-mail MedWatch Partners and individual MedWatch subscribers.

- Whenever possible, FDA will coordinate with applicants the posting of DHCP letters on the MedWatch website and notification of MedWatch partners and individual MedWatch subscribers. The posting will occur within a few working days after applicant mailing of these letters.

- On rare occasions, when a DHCP letter is expected but applicants fail to issue the DHCP letter by the date agreed upon with FDA, or when distribution of safety information is needed before the DHCP letter can be issued by the applicant, FDA may elect to issue a Talk Paper, Press Release, and/or Public Health Advisory in advance of the DHCP letter to describe the safety concern and/or other important change to drug package labeling (see MAPP 4112.1).

- When FDA is involved in reviewing a DHCP letter before it is issued, the Office of New Drugs (OND) review division will usually take the lead. However, when the purpose of the DHCP letter is to correct misleading or violative promotional materials, the Division of Drug Marketing, Advertising, and Communication (DDMAC) will take the lead.

- The review division will consult DDMAC to ensure that the draft DHCP letter is not false, lacking in fair balance, or otherwise misleading. If available, the draft DHCP letter and intended distribution list (i.e., the target audience) should be reviewed by ODS and the review division's immediate office. The envelope to be used for the mailing should also be reviewed to ensure that it complies with the provisions in 21 CFR 200.5. Other CDER organizations (e.g., the Controlled Substances Staff (CSS), the Office of Generic Drugs (OGD)) will be consulted, as appropriate.

- When FDA is not involved in reviewing a DHCP letter before it is issued, the OND review division, in consultation with DDMAC, and when appropriate, ODS, or other CDER or FDA components (e.g., Office of Compliance, Pregnancy Labeling Team, Office of Women's Health) will verify that the letter is not false, lacking in fair balance, or otherwise misleading and will also determine whether the letter is suitable for posting on the MedWatch website.

- Given the high priority of communicating drug safety information to the medical community and other members of the public, FDA will review and comment on draft DHCP letters as quickly as possible.

- When a DHCP letter is disseminated without FDA input and FDA disagrees with the letter's content, DDMAC will initiate an enforcement action that may lead to corrective actions. These actions may include issuance of an FDA Talk Paper or a request that the applicant issue an appropriately revised letter and labeling and/or promotional materials (as applicable).

RESPONSIBILITIES AND PROCEDURES

When FDA Requests That Applicants Distribute a DHCP Letter

OND Review Division

- **The Reviewer will:**

  - Evaluate submissions from the applicant and other data as necessary, consult with appropriate CDER organizational units as needed, and advise the Division Director on the content of or need for a DHCP letter.

  - Seek input from the supervisor, the Division Director, and other FDA personnel as needed on whether a DHCP letter is warranted. This can occur when the reviewer becomes aware of

important new safety information about a drug or becomes aware of false or misleading information that has been distributed about a drug.

- Document all initial recommendations to develop DHCP letters.

- Evaluate draft DHCP letters (written by the applicant) for factual accuracy, and convey comments to the applicant in a timely manner.

- Request that the Regulatory Project Manager (RPM) send a consult on the draft DHCP letter to DDMAC and ODS.

- In consultation with ODS, review the list of intended DHCP letter recipients for appropriateness. If the list is not available, the reviewer will request this information from the applicant.

- Consider whether consultation with other CDER units (e.g., CSS, OGD) is warranted.

- **The Division Director (or designee) will:**

  - Identify or confirm the need for a DHCP letter.

  - Contact the applicant and request that a draft DHCP letter, envelope, and a description of the letter's intended audience be submitted to the division for review and comment. This communication, whether in writing, in a meeting, or by teleconference, should involve the Regulatory Project Manager and should describe the circumstances that precipitated the request. The Division Director (or designee) should also discuss with the applicant the date on which the letter will be issued.

  - Lead FDA's effort to review, revise, and finalize the content of the DHCP letter.

  - Once the draft DHCP letter, envelope, and list of expected recipients are submitted for review and comment, identify which FDA organizational units and/or personnel will provide consultative review.

  - Ensure that draft DHCP letters are reviewed and that comments are conveyed to the applicant as quickly as possible.

  - Notify the Director of the relevant Office of Drug Evaluation (ODE) that a DHCP letter is being drafted.

  - Consider whether a Talk Paper, Press Release, and/or Public Health Advisory is needed to amplify the message in the DHCP letter, and if so, initiate the appropriate procedures as described in MAPP 4112.1.

- **The RPM will:**

  - Document the request for a DHCP letter with a memo to the file, memorandum of teleconference, meeting minutes, or letter to the applicant.

- Document the date the applicant has agreed to issue the DHCP letter with a memo to the file, memorandum of teleconference, meeting minutes, or letter to the applicant.

- As requested, circulate the draft DHCP letter to appropriate FDA personnel and organizational units, including ODS and DDMAC, for review and comment.

- Provide the ODE immediate office with the draft letter, envelope, and intended distribution list for review and comment.

- If requested, arrange any internal or external meetings needed to facilitate the review and finalization of the letter's content.

- Verify that the draft DHCP letter and accompanying envelope comply with the regulations at 21 CFR 200.5.

- Notify the EOS liaison that a DHCP letter is being planned for dissemination.

- Request that the applicant submit a final copy of the DHCP letter and current professional labeling, preferably in electronic format, to the NDA and to MedWatch.

- Inform MedWatch that the DHCP labeling text has been approved by the Division Director (or designee) and of the projected mailing date of the DHCP letter. Verify that MedWatch has a final copy of the letter and professional labeling, preferably in electronic format, for posting on the MedWatch website.

- If requested by the Division Director (or designee), work with the EOS liaison and the Office of Public Affairs so that a Talk Paper, Press Release, and/or Public Health Advisory amplifying the message of the DHCP letter can be drafted and cleared (see MAPP 4112.1).

The ODE Immediate Office will:

- Review and provide comment as needed on draft DHCP letters.

DDMAC will:

- Review DHCP letters for false or misleading representations, fair balance, and consistency with the approved drug product labeling.

- If applicable, follow up with applicant to ensure that promotional materials are revised to reflect the new safety information.

- Ensure that the applicant submits a final copy of the DHCP letter to DDMAC.

ODS will:

- Review the draft list of expected recipients for appropriateness.

MedWatch will:

- Confirm that the DHCP letter was issued by the applicant, then post a copy of the letter on the MedWatch website within a few working days of the date the applicant issues the letter.

- When the applicant sends a copy of the DHCP letter directly to MedWatch, ensure that it is acceptable to the review division prior to posting on the MedWatch website.

- Disseminate news of the DHCP letter to all MedWatch Partners and individual MedWatch subscribers, along with a copy of the most recent professional labeling.

The EOS Liaison will:

- Ensure that the appropriate FDA personnel are aware that a DHCP letter will be disseminated. These personnel include, but may not be limited to

  Commissioner
  Office of Public Affairs Director
  Center Director
  Deputy Center Director
  OND Director
  Deputy OND Director
  Office of Pharmacoepidemiology and Statistical Science (OPaSS) Director
  Office of Training and Communication (OTCOM), Division of Drug Information (DDI) Director
  Office of Pharmaceutical Science Director
  Office of Generic Drugs Director

When FDA Does Not Review a DHCP Letter Before it is Mailed

Occasionally, FDA does not learn about a DHCP letter until after it has been distributed by the applicant. The following procedures will apply when FDA is not at all involved in the review of a particular DHCP letter.

OND Review Division

- **The Division Director (or designee) will:**

  - Review the DHCP letter, in consultation with DDMAC, and when appropriate, ODS, or other CDER or FDA components (e.g., Office of Compliance, Pregnancy Labeling Team, Office of Women's Health) to ensure that the letter is not false, lacking in fair balance, or otherwise misleading.

  - If the DHCP letter is found to be false, lacking in fair balance, or otherwise misleading, work with DDMAC to initiate an enforcement action that can lead to corrective actions. These actions may include issuance of an FDA Talk Paper, Press Release, and/or Public Health

Advisory, or a request that the applicant issue an appropriately revised letter and labeling/promotional materials (as applicable).

- Inform the RPM whether the document is acceptable for posting on the MedWatch website.

- **The RPM will:**

  - Facilitate consultation of the DHCP letter to DDMAC and other CDER organizational units as requested by the Division Director (or a designee).

  - If the letter is found suitable for posting on the MedWatch website, notify MedWatch and ensure that MedWatch has a copy of the DHCP letter and accompanying professional labeling, preferably in an electronic format, for posting on the MedWatch website.

  - Notify the EOS liaison and the ODE Director that a DHCP letter has been disseminated.

MedWatch will:

- When requested to do so by the OND review division, post a copy of the DHCP letter on the MedWatch website and notify the MedWatch partners and individual MedWatch subscribers that the letter has been issued.

- When the applicant sends a copy of the DHCP letter directly to MedWatch, ensure that it is acceptable to the review division prior to posting on the web.

The EOS Liaison will:

- Ensure that the appropriate CDER personnel are aware that a DHCP letter has been disseminated. These personnel include, but may not be limited to

  Commissioner
  Office of Public Affairs Director
  Center Director
  Deputy Center Director
  OND Director
  Deputy OND Director
  OPaSS Director
  OTCOM, DDI Director
  ODS Director
  Office of Pharmaceutical Science Director
  Office of Generic Drugs Director

EFFECTIVE DATE

This MAPP is effective upon date of publication.