Office of Training and Communications

Communicating Drug Approval Information

CONTENTS

PURPOSE

- This MAPP establishes procedures for clearing drug approval information through Freedom of Information (FOI) staff and posting it to CDER's Internet Web Page and the CDER Fax-on-Demand system. For new drug applications (NDAs), this MAPP addresses approval letters and approved labeling text, or final printed labeling (FPL), and tentative approval letters without labeling. For abbreviated new drug applications (ANDAs), this MAPP addresses approval and tentative approval letters only.

BACKGROUND

- NDA and ANDA approval and tentative approval actions are of considerable interest both inside and outside the U. S. Food and Drug Administration (FDA). MedWatch, the FDA district offices, the trade press, competitor companies, individual practitioners, consumers and international FDA counterparts are among those interested in the status of approval actions. Therefore, when an application is approved, it is important that FDA make this information available as quickly as possible.

DEFINITIONS

- **Applicant**: The pharmaceutical firm or other party that submits a drug marketing application to FDA for approval.

- **Approval Letter (21 CFR 314.105)**: A letter from FDA to an applicant approving an application for marketing a drug product in the United States. Use of the term *approval letter* throughout this MAPP refers both to approval letters and tentative approval letters.

- **Approvals Distribution List**: An internal e-mail system distribution list that identifies key FDA individuals who receive information about just-approved drug products.

- **Approved Labeling Text**: The final approved text and graphics of the package insert component of labeling. This document is ordinarily a word-processing document that provides the applicant with the approved package insert text and graphics for use in final printed labeling (FPL). It does not contain hand-written notes.

- **CDER Fax-on-Demand**: A computerized telecommunication system that allows users to request certain FDA/CDER releasable documents by phone and to receive them via facsimile.

- **CDER's Web Page**: An Internet web site containing CDER information that is accessible to the public. Only information that is disclosable to the public will be available on the CDER Web Page.

- **Final Printed Labeling (FPL)**: Denotes the approved package insert.

- **Tentative Approval Letter [21 CFR 314.105(a) and (d)].** A letter from FDA to an applicant stating that all scientific and procedural conditions for approval have been met; however, the approval has a delayed effective date usually because product marketing is blocked by some form of marketing exclusivity. An approval with a delayed effective date does not become final until FDA issues an approval letter. Use of the term *approval letter* throughout this MAPP refers both to approval letters and tentative approval letters.

- **Webmaster**: CDER staff who manage the CDER Internet Web Page.

POLICY

- Approval and tentative approval letters for new and generic drugs will be made available to all interested parties via CDER's Web Page and the CDER Fax-on-Demand system within the time frames specified in this MAPP, a period not to exceed three working days.

- Approved labeling text or final printed labeling for new drugs, but not for tentatively approved new drugs or for generic drugs, also will be made available on CDER's Web Site and the CDER Fax-on-Demand system within the time frames specified in this MAPP, a period not to exceed three working days.

- For original NDAs, the Office of Review Management (ORM) will include with the approval letter the approved labeling text if the application was approved based on draft labeling. Otherwise, the FPL will be included. For ANDAs, only the approval or tentative approval letter will be made available.

RESPONSIBILITIES AND PROCEDURES

- Office of Review Management project management (PM) staff assigned to the new drug product:

    1. Request an electronic version of the draft labeling text (preferably in Word or PDF format) if the applicant has not submitted an electronic version of the draft package insert with the application. If an applicant cannot provide the draft package insert in electronic format, the division will be responsible for producing an electronic version.

    2. Until an electronic system supplies the approval or tentative approval letter's date, type within the letter header information area the date the approval letter is signed.

    3. Ensure that a copy of the approval letter and the approved labeling text is sent via fax to the applicant's official regulatory contact within one business day of the signing of the approval letter and confirm receipt by phone. For applications approved with FPL, only the approval letter needs to be sent to the applicant.

    4. Within one business day of receipt confirmation:

a. Send an e-mail to the Approvals Distribution List (APPROVALS:) that contains the following information:

- NDA number
- drug name (generic and trade name)
- applicant name
- approval or tentative approval date
- possible effective date for a tentative approval
- chemical and therapeutic classification
- indication(s)
- route of administration
- Rx or OTC

b. Transmit the dated approval letter and approved labeling text to the secured computer shared area (**cdfda\drugapp**). The preferred format for these documents is Word or Portable Document Format (PDF). If labeling is hard-copy FPL only, it should be faxed to CDER FOI at (301) 827-4576. The naming convention for these electronic documents is as follows:

- The file name is the application number without the leading zero followed by ***ltr*** for the approval letter, ***lbl*** for the approved labeling text, and ***fpl*** for the final printed labeling.

- ***.doc*** is the extension for documents submitted in Word format and ***.pdf*** for PDF format. Plain text formats, such as ANSI (Windows) or ASCII (DOS) should have ***.txt*** as the extension. Documents may also be submitted in WordPerfect format using ***.wpd*** as an extension during the transition period to the recommend word processing package.

For example, application number 020701 would have two files transmitted: *20701ltr.doc* for an approval letter in Word format and *20701lbl.pdf* for the approved labeling text in PDF format. If the documents cannot be transferred in any of the above formats, a copy should be faxed to FOI.

5. Ensure the confidentiality and useability of the secured computer shared area (**cdfda\drugapp**) by promptly notifying OIT staff of personnel changes due to incoming or departing project managers and consumer safety officers.

- Office of Generic Drugs project management (PM) staff assigned to the generic drug product:

1. Until an electronic system supplies the approval or tentative approval letter's date, type within the header information area the date the approval letter is signed.

2. Ensure that a copy of the approval letter is sent via fax to the applicant's official regulatory contact within one business day of the signing of the approval letter and confirm receipt by phone.

3. Within one business day of receipt confirmation:

   a. Send an e-mail to the Approvals Distribution List (APPROVALS:) that contains the following information:

   - ANDA number
   - drug name (generic and trade name)
   - applicant name
   - approval or tentative approval date
   - possible effective date for a tentative approval
   - dosage form
   - strength
   - Rx or OTC

   b. Transmit the dated approval letter to the secured shared area (**cdfda\drugapp**) in the same fashion, using the same naming conventions, as ORM project management staff.

4. Ensure the confidentiality and useability of the secured computer shared area (**cdfda\drugapp**) by promptly notifying OIT staff of any personnel changes that need to be made to permissions because of incoming or departing project managers and consumer safety officers.

- Freedom of Information (FOI) staff:

  1. Within one business day of availability on the shared area (electronic transmittal) or receipt from the review divisions (when documents are transmitted directly to FOI):

     a. Redact approval letters and post the letters and, if applicable, the approved labeling text or FPL to the shared directory <**cdfda\foiread\approvals**>.

     b. Alert, via e-mail, the Webmaster and the Drug Information Branch that

redacted material is available in the shared directory for posting to the Internet and Fax-on-Demand.

2. Maintain the secured shared area **(\\cdfda\drugapp)** by periodically removing outdated material.

- Webmaster:

1. Within one business day of alerting by FOI staff, convert the redacted approval letters and, if applicable, the final approved labeling text or FPL to web format(s) and post them to CDER's Web Page.

2. Periodically remove outdated material from the shared area **<\\cdfda\foiread\approvals>.**

- Drug Information Branch/Division of Communications Management/OTCOM staff:

1. Each business-day morning, copy redacted material from the redacted approvals directory **<\\cdfda\foiread\approvals>** to CDER's Fax-on-Demand system by 10:00 a.m.

2. Maintain and update the Approvals Distribution List (APPROVALS:).

EFFECTIVE DATE

- This MAPP is effective upon date of publication.