POLICY

OFFICE OF COMMUNICATIONS

Communicating Drug Approval Information[1]

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PURPOSE

This MAPP establishes procedures for clearing and publishing new drug application (NDA), biologic license application (BLA), and abbreviated new drug application (ANDA) approval information on CDER's Web site.

BACKGROUND

The approval or tentative approval of drug applications is of interest both inside and outside of FDA. FDA district offices, the trade press, the pharmaceutical industry, individual practitioners, patients, and international FDA counterparts are interested in this information. When an application is approved, FDA makes the information available according to the priorities and time periods specified in this MAPP.

[1] Communicating Drug Approval Information refers to approved drug and biologic applications managed by CDER.

POLICY

1. Approval and tentative approval letters for original and supplemental drug applications will be made available via CDER's Web site, generally within three business days of the approval, for the following categories:
    1) Original NDAs and BLAs
    2) NDA and BLA efficacy supplements
    3) NDA and BLA labeling supplements
    4) ANDAs identified by the Office of Generic Drugs (OGD)

2. Approved labeling for drug approvals, but not for tentatively approved applications, will be made available on CDER's Web, generally site within two business days of approval, for the following categories:
    1) Original NDAs and BLAs
    2) NDA and BLA efficacy supplements
    3) NDA and BLA labeling supplements
    4) ANDA products designated as the reference listed drug (RLD)

3. Approved risk evaluation and mitigation strategy (REMS) (i.e., the enclosure to the approval letter) will be made available on CDER's Web site, generally within three business days of approval, for the following categories:
    1) NDA and BLA products
    2) ANDA products designated as the RLD or as requested
    3) Shared system REMS that may include multiple NDAs and/or ANDAs (one copy)

4. Action packages for approved original NDAs, BLAs, and efficacy supplements will be made available on CDER's Web site after they are processed by the Division of Information Disclosure Policy (DIDP) based on the following redaction prioritization scheme[2]:

    Redaction Priority 1: New molecular entity (NME) NDA and original BLA (signed by the Office Director) action packages

    Redaction Priority 2: NDAs (non-NME), original BLAs (can be approved by the Division Director), and efficacy supplements subject to Section 505(l)(2)(A)(ii) of the Federal Food, Drug, and Cosmetic Act

    Redaction Priority 3: NDA and BLA action packages for original approvals, not covered in Redaction Priority 1 or 2

5. Action packages or the equivalent for approvals not identified in the redaction prioritization scheme above, such as NDAs approved before 1998, ANDAs, chemistry supplements, and labeling supplements, are published on CDER's Web site

[2] The prioritization scheme applies to approvals after December 31, 1997 (Priorities 1 and 3) or September 27, 2007 (Priority 2).

after the information is processed by the Division of Information Disclosure Policy (DIDP) to respond to Freedom of Information Act (FOI) requests.

REFERENCES

1. Federal Food, Drug, and Cosmetic Act
2. Freedom of Information Act (FOIA), 1966
3. Americans With Disabilities Act (ADA), 1990, Section 508
4. 21 U.S.C. § 355
5. 21 CFR 314.105, Drugs
6. 21 CFR 601.4, Biologics
7. 21 CFR 314.3, Drugs
8. 21 CFR 314.3 (b), Definitions
9. FDA, 2002, Center for Drug Evaluation and Research, MAPP 6020.8: Action Packages for NDAs and Efficacy Supplements
10. Rehabilitation Act of 1973 (29 U.S.C. § 701)

RESPONSIBILITIES

Office of New Drugs (OND) regulatory project manager (RPM) assigned to the NDA or BLA:

1. Check the approval or tentative approval letter with any enclosures (e.g., final agreed upon labeling text, REMS) into the electronic archive.

2. Ensure a copy of the signed approval or tentative approval letter, with any enclosures, is promptly sent via a rapid form of communication, such as fax or secure email, to the applicant's official regulatory contact. Confirm applicant receipt of the letter.

3. If a press communication has been prepared, the RPM will notify the press office as soon as receipt of the approval letter has been confirmed by the applicant.

4. Within one business day of approval, the RPM will issue an e-mail to the CDER-APPROVALS distribution list to notify personnel of the approval. If the application is for a NME or original BLA, the RPM should include the Center Director on the e-mail. The e-mail should include the following information:
   - NDA/BLA/supplement number
   - Product names (proprietary and established/proper names)
   - Applicant (not agent) name
   - Approval date
   - Chemical, review priority, and any other application classification codes
   - Indications

- Route(s) of administration
- Rx or OTC

The RPM should attach to the email the action letter with its enclosures and the Summary Review(s). Note: an email to CDER-APPROVALS does not need to be sent for tentative approvals. If division management requests that the Summary Review(s) be published shortly after approval (e.g., high profile approvals), contact Office of Regulatory Policy, Division of Information Disclosure Policy (DIDP) approximately 3 days before the planned approval date.

5. Send an email notification to the Document Room at CDER-DRTL-ALL within one business day of the application approval. Attach a copy of the email to the outside cover of the action package. The email should include the following:

    1) Application number
    2) NME/original BLA Office Director Signature or non-NME/original BLA Division Director Signature
    3) Number of action package volumes and thickness in inches (e.g., 3 x 4" binders)
    4) Whether the pages are printed single or double-sided

6. Within two business days of the application approval, deliver the completed action package to the reception area of the document room for scanning.

Office of Generic Drugs project manager (PM) assigned to the ANDA:

1. Check the approval or tentative approval letter with any enclosures, such as labeling or REMS, into the electronic archive.

2. Ensure a copy of the signed approval or tentative approval letter for an original ANDA, with any enclosures, is promptly sent via a rapid form of communication, such as fax or secure email, to the applicant's official regulatory contact. Confirm applicant receipt of the letter.

3. For original ANDA approvals, send an email containing the following to the distribution list CDER-OGDAPPROVALS within one business day of receiving letter receipt confirmation:

    1) ANDA number
    2) Proprietary name (if there is one, as it would appear in the Orange Book)
    3) Established name
    4) Reference Listed Drug (RLD)
    5) Applicant name
    6) Approval or tentative approval date (if tentative, make bold)
    7) Indication(s)
    8) Dosage form

9) Strength(s)
10) Rx or OTC marketing status

4. For those original ANDA approval or tentative approval letters to be published on CDER's web site within three business days of approval, add "PRIORITY APPROVAL" to the subject line of the email sent to the distribution list CDER-OGDAPPROVALS. Attach a copy of the letter and any enclosures, such as approved labeling or REMS. Specify if any of the enclosures to an approval letter are to be published on CDER's Web site.

5. Send an email to DIDP and the Division of Online Communication (DOC) to make a special request that supplemental ANDA approval letters or enclosures such as RLD labeling, or RLD REMS be published on the Internet. The requesting email should include a copy of the approval letter and any enclosures.

Office of Business Informatics, Division of Data Management Services and Solutions, Document Management Services:

1. For action packages (NDA and BLA approvals only):
   - Within three business days of an approval for new molecular entities (NME)/original BLAs signed by the Office Director, or
   - Within five business days of an approval for non-NMEs/original BLAs signed by the Division Director:

     1) Notify the OND RPM and DIDP that the action package has been received.

     2) Process action packages according to standard Document Processing Manual procedures. Scan the action package and insert the Portable Document Format (PDF) bookmarks.

     3) Electronically archive the scanned action package. Upload the scanned action package into the electronic archive.

     4) Send an email to the OND RPM and DIDP to inform them the scanning and archiving process is complete after the documents have been uploaded and the original action package is available for the RPM to pick-up from the document room.

Office of Regulatory Policy, Division of Information Disclosure Policy (DIDP):

1. Perform a disclosure review of the letter and enclosures and deliver the redacted information to the Division of Online Communications (DOC) within two business days of approval or tentative approval.

   - Ensure all letters are in a format that will facilitate compliance with Section 508 of the Rehabilitation Act of 1973.

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