

POLICY

OFFICE OF COMMUNICATIONS

Communicating Drug Approval Information¹

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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 scheme²:
 - 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(1)(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 after the information is processed by the Division of Information Disclosure Policy (DIDP) to respond to Freedom of Information Act (FOI) requests.

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

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.

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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.

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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.
 - Save the redacted letter in the shared directory, using the DIDP established file-naming convention for DOC retrieval.
2. When OND division management requests early publication of the summary review, perform a disclosure review of the summary review and save the redacted summary review in the DIDP and DOC shared directory using the DIDP established file-naming convention, for DOC retrieval.
3. Perform a disclosure review of the action package consistent with the established redaction prioritization scheme. Save the redacted action package in the shared directory, shared with the DOC.

- Save the redacted action package into PDF format in files based on the CDER's Web site display design using the DIDP established file-naming convention. Ensure each individual file does not exceed the size limit set by DOC.
- Save the multiple files that constitute the redacted action package in the appropriate priority folder located in the shared directory for DOC.

Office of Communications, Division of Online Communications:

1. Enter the basic approval information into CDER's Web site, no sooner than one business day but within three business days for all approvals.
2. Retrieve the signed approval letter from the electronic archive for OND approvals no sooner than one business day but within three business days of approval. Extract the approved labeling text that needs no disclosure review by DIDP from the approval letter. Convert the labeling to Web format. Publish the label on CDER's Web site. Make the appropriate links from CDER's Web site. By request, the labeling can be published on approval day if receipt of the approval letter has been confirmed by the RPM.
3. Convert to a format in compliance with Section 508 and publish on CDER's Web site, upon receipt from DIDP, the redacted approval letter and any enclosures or tentative approval letter no sooner than one business day but within three business days of approval. Make the appropriate links in CDER's Web site. By request, publishing the letter on approval day can occur if receipt of the applicant's letter is confirmed by the RPM.
4. Convert the redacted summary review to a 508-compliant Web format and publish it on CDER's Web site within two business days of receipt from DIDP.

5. Convert the redacted action package reviews to Web format. Publish the action packages on CDER's Web site according to the priority status of the action package. Make the appropriate links in CDER's Web site within the following timeframes after receipt of the redacted action package from DIDP:

- 1) Publication Priority 1: one business day
- 2) Publication Priority 2: five business days
- 3) Publication Priority 3: fifteen business days

Office of Communications, Division of Drug Information:

1. Maintain and update the distribution list CDER-APPROVALS.
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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)
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DEFINITIONS

Action Package: A compilation of (1) FDA-generated documents related to the review of an NDA, BLA or efficacy supplement, (2) documents pertaining to the format and content of the application generated during drug development (Investigational New Drug (IND)), and (3) labeling submitted by the applicant.

Applicant: Any person(s) who submits an application, abbreviated application, or supplemental application, to obtain FDA approval of a new drug. Any person who owns an approved new drug or abbreviated new drug application.

Application: The vehicle to seek FDA approval for the sale and marketing of a drug product.

Approval Letter: A letter to an applicant from FDA approving an application or an abbreviated application for marketing a drug product in the United States.

Approvals Distribution List: Internal email system distribution lists, CDER-APPROVALS and CDER-OGDAPPROVALS directed to FDA individuals who require information about just-approved drug products. Lists include staff in the Division of Information Disclosure Policy and the Division of Online Communications.

Approved Labeling: Final approved text and graphics of the prescribing information, generally limited to prescribing information and medication guide for prescription products. For non-prescription drug products, the approved labeling consists of the carton and immediate container labels.

CDER Web site: A public Internet site maintained by CDER's Division of Online Communication, containing information related to CDER's mission.

Division of Information Disclosure Policy (DIDP): CDER division responsible for reviewing and redacting information for release to the public.

Enclosure: Information included with an approval letter that is not in the body of the letter, such as approved labeling and REMs.

Orange Book: The common name for the list of Approved Drug Products with Therapeutic Equivalence Evaluations. Published on the FDA Web site since 1997, this document identifies drug products approved by the FDA on the basis of safety and effectiveness.

Summary Review (21 U.S.C. § 355(l)(2)(C)(iv)): A review that “documents conclusions from all reviewing disciplines about the drug, noting any critical issues and disagreements with the applicant and within the review team and how they were resolved, recommendations for action, and an explanation of any non-concurrence with review conclusions.”

Risk Evaluation Mitigation Strategy: Required risk management plans that use risk minimization strategies beyond the professional labeling to ensure that the benefits of certain prescription drugs outweigh their risks.

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. The delayed effective date is generally because product marketing is blocked by a patent or marketing exclusivity. An approval with a delayed effective date does not become final until FDA issues an approval letter.

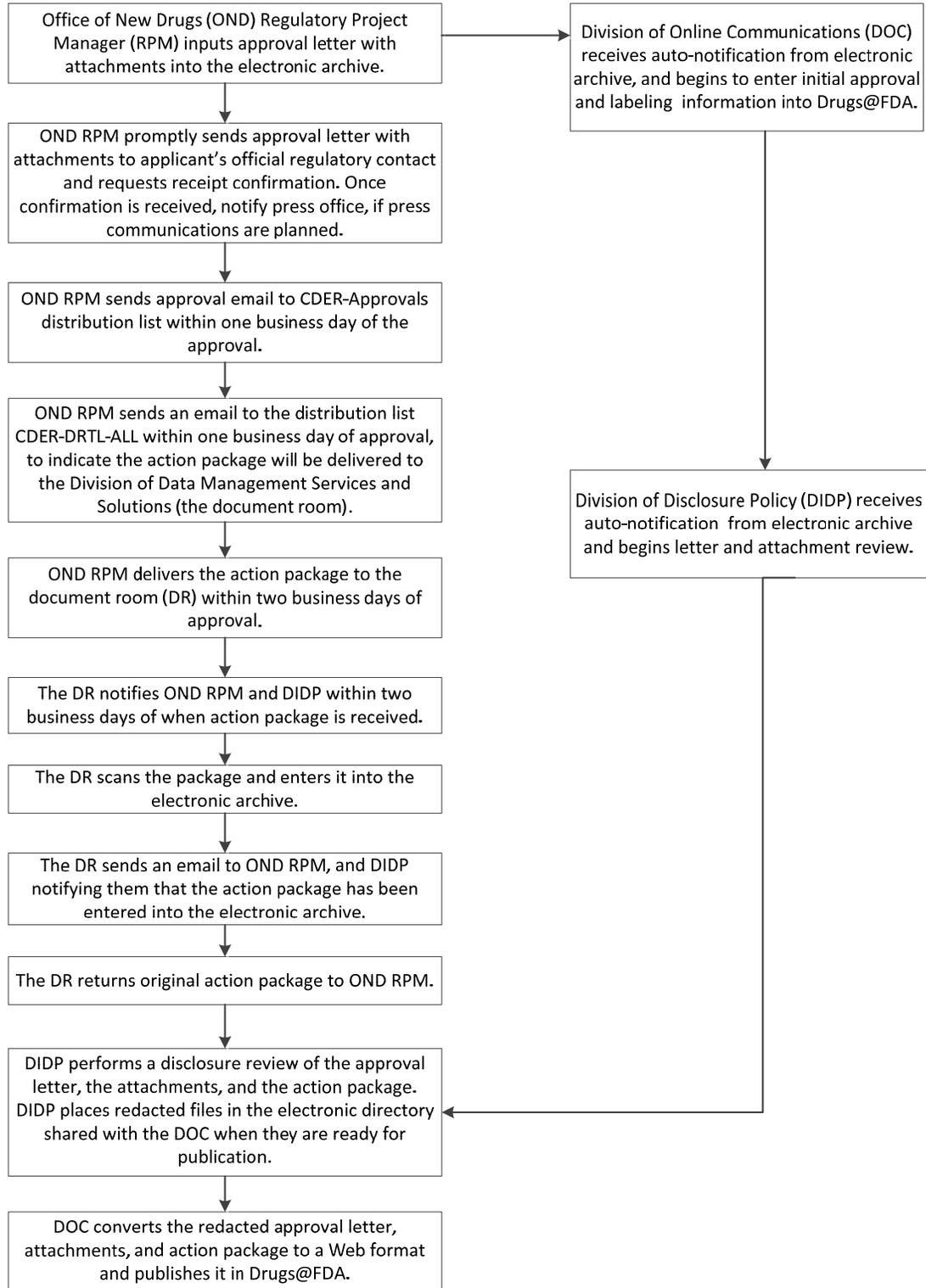
EFFECTIVE DATE

This MAPP is effective upon date of publication.

CHANGE CONTROL TABLE

| Effective Date | Revision Number | Revisions |
|----------------|-----------------|---|
| 3/26/98 | initial | n/a |
| 8/20/14 | Rev. 1 | <ul style="list-style-type: none"> • Scope of MAPP broadened to include BLAs and REMS • Updated all content, to reflect current practices |
| 7/14/17 | Rev. 2 | <ul style="list-style-type: none"> • Decreased the time for webmaster to post change from three to two business days, for approved labeling for drug approvals |
| 11/10/22 | n/a | Document recertified, JD Wyllie, OCOMM Director. |

ATTACHMENT 1: Procedure for Publishing Approval Information for Original NDAs and BLAs



ATTACHMENT 2: Procedure for Publishing Approval Information for NDA/BLA Efficacy Supplements, NDA/BLA Labeling Supplements and Original ANDAs

