PREPARING AND PROCESSING AN APPROVAL PACKAGE

I. PURPOSE

This document describes the procedures for preparing and routing approval packages for original and supplemental New Animal Drug Applications (NADAs) and Abbreviated New Animal Drug Applications (ANADAs) other than manufacturing and regulatory supplements.[1,2]

II. OVERVIEW OF THE PROCESS

When an (A)NADA is received that results in an original or supplemental approval, the division assigned the application is responsible for preparing the approval package.[3] The division determines the person(s) responsible for preparing and reviewing the approval package. The approval package takes the place of the standard "final action

[1]See P&P 1243.6020 and 1243.6030 for information on regulatory supplements. Manufacturing supplemental approvals (Chemistry, Manufacturing and Controls) are prepared by the Division of Manufacturing Technologies and signed at the division level.
[2] This P&P does not apply to conditional approvals.
[3]The application is assigned to either the division responsible for review of the Target Animal Safety and Effectiveness sections or the Generic Animal Drugs Team.

package" prepared for most Submission Tracking and Reporting System (STARS) submissions. (A)NADAs may be submitted as "administrative" or "non-administrative." The process for preparing approval packages for administrative or non-administrative (A)NADA is similar.

You (designated division personnel) perform the checks and reviews necessary to determine that the application is approvable, and may prepare the documents for the approval package as described in Section IV.[4] Route the draft and final packages as described in Section V and Section VI.

After the signature authority signs the approval letter, designated personnel will:

- Final out the application in STARS:
- Send a center-wide email notifying CVM of the approval
- Archive the approval documents and files
- Forward the FEDERAL REGISTER (FR) notice to announce the approval and regulation in the FR, and forward the Freedom of Information (FOI) Summary, and if applicable, the Environmental Assessment (EA) and Finding of No Significant Impact (FONSI) for public display.

III. STEPS IN PREPARING A DRAFT APPROVAL PACKAGE

A. Ensure the accuracy of STARS

Administrative (A)NADAs have a STARS due date of 60 days. Non-administrative (A)NADAs have a STARS due date of 180 days. If the package is coded incorrectly, return it to the Document Control Unit (DCU) with a STARS Correction Form, requesting that the application be re-coded. Check with the Animal Drug User Fee Act (ADUFA) Team about ADUFA fee status in the event an application was misidentified.

[4] For purposes of this document, designated division personnel refer to a reviewer, consumer safety officer (CSO), or other individual from the division responsible for preparing and reviewing the approval package for an application.

B. Determine if a Project Day is Needed

Check with your team leader and the Project Management Team to determine if they need to schedule a Project Day or if you need to take care of any other special administrative steps. The ONADE Project Management Team schedules Project Days.

C. Review the application

Review the application to ensure that it, as a whole, meets the requirements for approval set forth in the Federal Food, Drug, and Cosmetic Act and applicable regulations. Issue consulting review requests for a non-administrative (A)NADA if needed.

Do not prepare a review document (or a submission summary) for an administrative (A)NADA; instead, document that the application is approvable in the Memorandum Recommending Approval (MRA). Prepare a review document for non-administrative (A)NADAs using P&P 1243.3009 and the ONADE review template. Include reviews in Folder B of the approval package (see Section IV. below).

D. Request a draft FR notice

If the approval requires a change or addition to the regulations, send an email to the CVM Policy and Regulations Team in the office of the center director requesting that they prepare a draft FR notice. Provide a copy of the draft FOI Summary, labeling, draft MRA, or other information to assist them. If necessary, identify the section(s) of the regulation requiring changes/additions in the email to them. The draft FR notice consists of a cover sheet, the draft FR notice text, and the pre-change and post-change versions of the affected regulation(s).

The CVM Policy and Regulations Team prepares the draft FR document, assigns a Federal Register Document Tracking System (FRDTS) number, and returns the draft FR notice to you by email. Check the draft FR document and draft regulation to make sure the information is accurate and complete. Assure that the FR document contains the appropriate National Environmental Policy Act (NEPA) compliance language. If the approval is an NADA intended for use in a food-producing species, forward your marked up copy of the draft FR document, via

email, to the Division of Human Food Safety (DHFS) for their comments. Upon receipt of all comments on the draft document, if you need to make revisions, work with the CVM Policy and Regulations Team to make them. Print and include the draft FR notice in Folder A of the approval package (see Section IV. below). If applicable, include a copy of the email that documents DHFS comments and review of the draft FR notice in the left side of Folder B. From this point, any minor revisions, changes, or corrections made on the printed draft FR notice must be made in pencil and initialed and dated.

E. Determine whether you need a Good Manufacturing Practices (GMP) status check.

GMP status checks are required for original and supplemental (A)NADAs except ADAA feed combination NADAs. See P&P 1243.8500. For administrative (A)NADAs, a GMP status check is requested automatically through DCU when the application is initially entered into STARS. For non-administrative (A)NADAs, request the GMP status check just prior to the forwarding of the draft package. Include the GMP status check results in Folder B of the approval package (see Section IV. below).

F. Request a Bioresearch Monitoring (BIMO) status check.

BIMO status checks are required for original and supplemental (A)NADAs except ADAA feed combination NADAs. See P&P 1243.8225. Include the BIMO status check results in Folder B (see Section IV. below).

G. Perform a Drug Experience Report (DER) status check.

DER status checks are required for original ANADAs, supplemental (A)NADAs, and original and supplemental ADAA feed combination NADAs. DER status checks are not required for original NADAs. Send an email to the Division of Surveillance to request the DER status check. Alternatively, print a Drug Experience Reporting History report from the Corporate Database Portal DER module, and conduct an initial review of the report.[5] If you have concerns, check with the Division of Surveillance for further input. Perform the DER status check

[5] Check with your team leader or division director on appropriate DER status check procedure to use.

just prior to the forwarding of the draft package. Include the DER status check email or DER History report in Folder B (see Section IV. below).

H. Obtain the environmental documents.

If a categorical exclusion was granted for the (A)NADA, then there are no environmental documents. If categorical exclusion was not granted, then the approval package contains the Finding of No Significant Impact (FONSI) and the Environmental Assessment (EA).

If the approval package contains an EA/FONSI, the preparer of the approval package notifies the Environmental Safety Team Leader and requests that they confirm the environmental documents still support the approval. You will document the Environmental Safety Team's confirmation in the MRA.[6]

Include copies of the signed EA/FONSI in Folder A (See Section IV. below). The original signed EA/FONSI, which are used to support the approval, can be found in the (J)INAD file (generally with the Environmental technical section complete letter). On rare occasions, an Environmental Impact State (EIS) and Record of Decision (ROD) may replace the EA/FONSI). For the approval package, the procedures are the same for EIS/ROD as for the EA/FONSI.

I. Prepare the MRA.

The MRA briefs the individual signing the approval (i.e., the center director or office director) on the basis for our recommendation to approve an (A)NADA. Prepare an MRA for all original and supplemental (A)NADAs. Use P&P 1243.5741 (NADA) or P&P 1243.5740 (ANADA) and the appropriate ONADE template.

Include the MRA in Folder A (See Section IV below).

[6] If confirmation from Environmental Safety Team is in writing, include in Folder B.

J. Prepare the FOI Summary.

The FOI Summary provides a summary of the safety and effectiveness data and information used as a basis for the approval. Use P&P 1243.5760 (ANADA); P&P 2143.5761 (NADA); or P&P 1243.5762 (ADAA Feed Combination Drug NADA) and the appropriate ONADE template.

Include the FOI Summary (with a signature page and copy of facsimile or final printed labeling) in Folder A (See Section IV below).

K. Prepare the Approval Letter.

Use the ONADE Approval Letter template appropriate for the type of (A)NADA application.[7] Follow the format described in P&P 1243.3010 and 1243.5820.

Include the approval letter in Folder A (See Section IV. below).

L. Complete the Reviewer's Summary field in STARS.

Before the draft approval package leaves the primary division, complete the Reviewer's Summary field in STARS with a short description of the approval. For example:

Original approval for <PROPRIETARY NAME> (<established name>) <dosage form> for <indications and conditions of use> in <species/class.> *<To identify the proprietary and established names refer to the proprietary and established name boxes on the most recently submitted 356V.>*

For all ANADAs, also include reference product information:

This generic product is a copy of <PROPRIETARY NAME> (<established name>) <dosage form> sponsored by <applicant's name> under (A)NADA <XXXXXX>. *<To identify the proprietary and established names refer to the proprietary and established name boxes on the most recently submitted 356V.>*

[7] If the ONADE template is not available, use the sample letter language in P&P 1243.5820.

M. Send a notification email to the Communications Staff.

Any original or supplemental (A)NADA approval with a letter intended for the center director's signature is a possible candidate for media interest. Prepare a notification email to the Communications Staff using P&P 1240.2325.

IV. ASSEMBLING AND ROUTING THE DRAFT APPROVAL PACKAGE

The draft approval package consists of two pocket folders (designated as Folder A and Folder B) containing the reviews and summary documents and the first volume of the original (A)NADA. Note that not all documents are required for all approvals.

Assemble the draft approval package as follows:

Table 1: Order of placement of review documentation in Folder A for a draft approval package.

Left Pocket of Folder	Right Pocket of Folder
1. Draft Memorandum Recommending Approval (MRA) 2. Draft Freedom of Information (FOI) Summary with labeling at back and Signature Page on top	1. Draft letter for applicant 2. Draft FR Notice with FRDTS cover sheet 3. Copy of original EA and FONSI or EIS and ROD

Table 2: Order of placement of review documentation in Folder B for a draft approval package.

Left Pocket of Folder	Right Pocket of Folder*
1. Final GMP Status Check Email	1. Final Review of Primary Reviewer
2. Final BIMO Status Check Email	2. Final Consulting Reviews
3. Final DER Status Check Email and/or DER History Report	3. Other Pertinent Information (e.g., Memorandum to File)
4. Email from the Division of Human Food Safety documenting their email review of the Draft Regulation (if applicable)	

* For an administrative (A)NADA, the right pocket of Folder B is empty.

1. Staple the final action form printed on yellow paper to the outside of Folder A.[8] Complete the application identification information, final action, and draft approval package routing sections.

    - Check the correct final action box based on the type of approval. Note that a significant supplement (final action code 051) is defined as a supplemental (A)NADA that required substantial review of safety or effectiveness data (including bioequivalence studies) by CVM and provides for a new chemical entity, a new animal drug product, or any of a variety of changes to existing approved NADAs or ANADAs, including additions to the indication section of the label of a new target species, a new significant class of target animals, a new disease indication, a new route of administration, a new tolerance or withdrawal period.

[8] This STARS form is entitled "ONADE Final Action Form for NADA and ANADA Approvals."

- Complete the draft approval package routing section:

  HFV -# (reviewer)
  HFV-# (team)
  HFV-# (division)
  HFV-190 (STARS Trk)
  HFV-150 (concurrence from Division of Human Food Safety, as appropriate)[9]
  HFV-190 (STARS Trk)
  HFV-107 (QA Team)
  HFV-190 (STARS Trk)
  HFV-# (division)

2. Print one copy of the MRA and the FOI Summary and place them in the left pocket of Folder A, in that order. Mark copies as "DRAFT."

   - The primary reviewer, team leader, and division director sign and date the draft column of the concurrence table in the MRA. If applicable, the consumer safety officer (CSO) preparing the MRA may also sign it.

   - Attach the FOI signature page to the front of the FOI Summary. Attach the facsimile or final printed labeling, as provided by the applicant, to the back of the FOI Summary. The labeling must be legible and of good quality so that it can produce a legible scanned copy for public display by the Division of Dockets Management.

3. Place one copy each of the approval letter, the draft FR notice, and environmental documents (EA and FONSI or EIS and ROD, if required) in Folder A. See Table 1 for placement of information in Folder A.

   - Print the approval letter on white paper. Each person concurring with the approval action signs and dates the draft column of the concurrence table

   - Print the draft FR notice and the cover sheet (Form FDA 3451) on white paper. Each person reviewing the package signs the cover sheet of the

[9] See Item 6 below for information on routing to DHFS.

draft FR notice to indicate concurrence with the action[10]. The mail code and date of signature accompany each signature.

- Provide a copy of environmental documents on white paper.

4. Place the supporting documents (results of the GMP status check, BIMO status check, and DER status check printed on white paper), reviews created for the current application, and other pertinent information (e.g., memorandum to file to document informal discussions with applicant) referenced in the MRA in Folder B. See Table 2 for placement of information in Folder B.

    - ONADE reviews are printed on yellow paper, signed and dated, as they are considered "final" at this stage.

    - Do not include copies of any referenced documents that were not created as part of the current (A)NADA application. For example, do not include copies of technical section complete letters, reviews associated with previously completed technical sections, FOI Summaries, or FR notices for previous approvals. This applies to reactivations as well.

5. Forward the package through the appropriate team or division supervisory chain.

    - If a CSO has prepared the approval package documents, they forward the package to the primary reviewer.

    - Once the primary reviewer has confirmed the accuracy of the information and completeness of the package and the appropriate documents are signed, the package is forwarded to the team leader.

    - The team leader reviews the package for accuracy and completeness, signs the appropriate documents, and forwards the package to the division director.[11]

[10] In the Quality Assurance Team, only the team leader signs the cover sheet.

- The division director reviews the package for consistency of the approval with current laws and policies, and signs the appropriate documents.

- If errors are found during review at the reviewer, team, or division level, the package is returned to the appropriate person for correction.

6. Once designated team/division level personnel review and sign the draft approval package, send it for quality assurance review as follows:

   - For non-administrative NADA approvals in food-producing species that contain human food safety studies/data or that required a consulting review from the Division of Human Food Safety, the division routes the package through the Document Control Unit (DCU) to the Division of Human Food Safety. The Division of Human Food Safety reviews the human food safety components of the approval package for accuracy and completeness, then routes the package through the DCU to the Quality Assurance Team. If the Division of Human Food Safety finds errors, the package is marked with the changes, and those changes are added to the revisions requested by the Quality Assurance Team.

   - For administrative (A)NADA approvals in food-producing species, do not send the draft approval package to the Division of Human Food Safety for review. Division of Human Food Safety input on the administrative application is limited to the draft regulation and you will handle this is via email.

   - For approvals in non-food producing species and approvals in food-producing species without new human food safety information, the division routes the package through the Document Control Unit to the Quality Assurance Team.

   - Place the electronic documents on the S:drive for review by the Quality Assurance Team.

[11] The team leader is the highest level of review prior to the Quality Assurance Team review for applications that the Generic Animal Drugs Team prepares.

- The Quality Assurance Team reviews the entire package for compliance with regulations, office procedures, boilerplates, and templates, and determines whether there is a need for the Office of Chief Counsel (OCC) to review of the draft approval package.[12]

- If OCC review is necessary, the Quality Assurance Team forwards the package to them for review.

- If OCC review is required, OCC reviews the draft approval package for compliance with the Act, implementing regulations, and agency policies. OCC returns the package to the Quality Assurance Team.

7. The Quality Assurance Team returns the draft approval package with comments to you through the DCU. When you receive it, make the corrections requested during the review of the draft package, as appropriate.

V. ASSEMBLING AND ROUTING THE FINAL APPROVAL PACKAGE

The final approval package consists of Folder A and Folder B containing the reviews and revised summary documents, copies of documents needed for distribution, and all volumes of the current application. Note that not all documents are required for all approvals.

Assemble the final approval package as follows:

[12] See CVM Policy and Procedures Guide 1240.2020, Federal Register Document Processing

Table 3: Order of placement of review documentation in Folder A for a final approval package.

Left Pocket of Folder A	Right Pocket of Folder A
1. Final Memorandum Recommending Approval (MRA)	1. Transparent protector sheet
2. Final Freedom of Information (FOI) Summary with labeling at back and Signature Page on top 3. Distribution copies of FOI Summaries in same order as listed in distribution block of FOI Summary (if bulky place in separate folder)	2. Final letter for applicant 3. Applicant copy of Freedom of Information Summary with labeling at back 4. Envelope for Applicant 5. Pink file copy of letter 6. FDA District Office copy of letter 7. Envelope for FDA District Office copy of letter 8. Draft FR Notice with FRDTS Cover Sheet 9. Copy of original EA and FONSI or EIS and ROD 10. Distribution copy of original EA and FONSI or EIS and ROD for Division of Dockets Management

Table 4: Order of placement of review documentation in Folder B for a final approval package.

Left Pocket of Folder B	Right Pocket of Folder B*
1. Final GMP Status Check Email 2. Final BIMO Status Check Email 3. Final DER Status Check Email and/or DER History Report 4. Email from the Division of Human Food Safety documenting their email review of the Draft Regulation (if applicable)	1. Final Review of Primary Reviewer 2. Final Consulting Reviews 3. Other Pertinent Information (e.g., Memorandum to File)

* For an administrative (A)NADA, the right pocket of Folder B is empty.

1. Complete the final approval package routing section of the final action form on Folder A.

   Packages Requiring Center Director Signature:

   HFV -# (reviewer)
   HFV-# (team)
   HFV-# (division)
   HFV-190 (STARS Trk)
   HFV-150 (concurrence from Division of Human Food Safety, as appropriate)[13]
   HFV-190 (STARS Trk)
   HFV-107 (QA Team)
   HFV-190 (STARS Trk)
   HFV-100 (ONADE director)
   HFV-1 (center director)
   HFV-107 (QA Team)
   HFV-190 (STARS Trk)
   HFV-199 (DCU)

[13] See Item 6 below.

Packages Requiring Office Director Signature:

HFV -# (reviewer)
HFV-# (team)
HFV-# (division)
HFV-190 (STARS Trk)
HFV-150 (concurrence from Division of Human Food Safety, as appropriate)
HFV-190 (STARS Trk)
HFV-107 (QA Team)
HFV-190 (STARS Trk)
HFV-100 (ONADE director)
HFV-107 (QA Team)
HFV-190 (STARS Trk)
HFV-199 (DCU)

2. Prepare the final copies of the MRA and the FOI Summary.

   - Type in the names of the reviewing officials and dates that they signed the draft MRA in the concurrence table. Print the first page of the MRA on bond paper displaying the official pre-printed blue letterhead logo of the Department with the government watermark.[14] Print the remaining pages on bond paper. Do not staple the MRA. The primary reviewer, team leader, and division Director sign and date the MRA. If applicable, the CSO preparing the MRA may also sign it.

   - The original copy of the MRA is filed in the application jacket. No pink copy is needed.

   - Initial and date the FOI signature page on the front of the FOI Summary. Attach the FOI signature page to the original FOI Summary (printed on white paper) only.

   - Make distribution copies (white paper) of the FOI Summary as indicated in the cc: block (NOTE: distribution copies for the applicant, FOI Staff, and Division of Dockets Management do not contain the cc: block or other

[14] Do not use computer-created facsimiles of the letterhead logo for the MRA.

internal administrative information). Staple distribution copies of the FOI Summary. Attach copies of the facsimile or final printed labeling, as provided by the applicant, to the back of the original and all copies of the FOI Summary. The labeling must be legible and of good quality so that it can produce a legible scanned copy for public display by the Division of Dockets Management. Write the intended recipient's name and mail code in pencil in the upper right-hand corner on the first page of each copy. The DCU will distribute these copies as part of processing the final action package. If the DCU needs to mail the copy, such as to an FDA district office, provide an addressed envelope in the final action package.

- Place the MRA and the original FOI Summary (with signature page and labeling attached) in the left pocket of Folder A, in that order. Place additional copies in a separate folder (marked "distribution copies") if they do not fit in Folder A.

3. Prepare the final copies of the approval letter, envelope(s), the draft FR notice, and environmental documents (if required).

   - On copies where cc: blocks are included, list the distribution copies in the cc: blocks of each document in the package. Do not add any recipients to the cc: blocks. In order to maintain document version control and information integrity, the agency does not support the retention or distribution of additional paper copies.

   - Type in the names of the reviewing officials and dates that they signed the draft approval letter in the concurrence table. Print the first page of the original approval letter on bond paper displaying the official pre-printed blue letterhead logo of the Department and the government watermark.[15] Print the remaining pages of the letter on quality bond paper. Do not include the cc: block or concurrence table on the original letter. Do not staple the letter. Print a copy on pink paper (including the cc: block and concurrence table) for the administrative file. If applicable, print a copy on white paper (no cc: block or concurrence table) for the FDA District Office (DO). Each person concurring with the approval action initials and dates the concurrence table on the pink copy.

[15] Do not use computer-created facsimiles of the letterhead logo for the letter.

- Print an envelope for the applicant's letter and enclosures and for the FDA DO copy of the letter, if applicable.[16] Use envelopes with the pre-printed return address for the Department and make certain the envelopes are the appropriate size for the material you are sending. On the applicant's letter have an address that matches the address of the letter. On both the applicant and the FDA DO envelopes, and have the DCU mail code (HFV-199), added by hand or printer, above the return address of the envelope to allow proper return of the letter if the postal service is unable to deliver it.

- Obtain a clean corrected copy of the draft FR notice from the Policy and Regulations Team if the Quality Assurance Team requests one. Otherwise, include the same copy (with minor revisions marked) that was forwarded with the draft approval package.

- Include a distribution copy of the environmental documents for the Division of Dockets Management on white paper.

- Place the original copy of the letter, covered with a transparent protector sheet, and the applicant's copy of the FOI Summary, in the inside right pocket of Folder A. Place the envelope for the applicant's letter and FOI Summary, other copies of the letter (with an envelope for the FDA DO copy), the draft FR notice, and the environmental documents (if required) behind the applicant's letter and FOI Summary in the right pocket of Folder A, in that order.

4. There are typically no requested changes to the documents in Folder B. Assemble the documents in this folder as described in Section V.

5. Submit the final package through the appropriate team or division supervisory chain as described in Section V.

6. Once designated team/division personal have reviewed and signed the final approval package, route it for signature as follows:

[16] See P&P 1243.5820 for instructions on when the FDA DO needs a copy of the letter. A list of the District Office addresses is available on the Center for Food Safety and Applied Nutrition Intranet.

- If anyone made or requested substantive changes to the human food safety components of the draft approval package, the division routes the final approval package through the DCU to the Division of Human Food Safety. The Division of Human Food Safety reviews the revised human food safety components of the approval package for accuracy and completeness, then routes the package through the DCU to the Quality Assurance Team. If no one made changes to the human food safety components in the draft approval package, do not route the final package through the Division of Human Food Safety.

- For approvals in non-food producing species, the division routes the package through the DCU to the Quality Assurance Team.

- The Quality Assurance Team reviews the final documents to ensure that the requested changes were made. If the Quality Assurance Team finds errors, they will return the package to you for correction. Otherwise, the Quality Assurance Team signs off on the final approval package and routes the package through the DCU to the ONADE Director.

- The ONADE Director signs the approval letter, or signs off on the approval package documents and routes the package to the center director for approvals requiring the center director's signature.[17] In the rare instance, the office director finds errors, the office director returns the package to you for correction.

- After the approval letter is signed, the approval package is returned to the Quality Assurance Team for processing and forwarded to the DCU for final action as described in Section VII.

[17] Generally, the center director signs original applications and supplemental applications which include new species, significant new indications, and changes in marketing (Rx/OTC) status.

VI. FINALING OUT APPROVAL PACKAGES

A. Quality Assurance Team

When the completed and signed approval package is returned to the Quality Assurance Team from the signature authority, the Quality Assurance Team:

- stamp dates the approval letter, distribution copies of the approval letter, and the FOI Summary;
- faxes a copy of the stamp dated letter (without the cc: block and other internal administrative information) to the applicant;
- sends the draft FR notice to the Policy and Regulations Team to be put into final;
- sends a distribution copy of the FOI Summary and environmental documents, if any, to the Division of Dockets Management.
- notifies the primary division by email that the approval letter has been signed; and
- hand carries the approval package to the DCU.

B. DCU

When the DCU receives the completed and signed approval package, they:

- assure that the division has entered the necessary information correctly into the STARS database;
- enter the final action code and date;
- assure proper filing of the FR document, FOI Summary, labeling, approval letter, MRA, and other documents into the NADA file;
- mail the letter and enclosures to the applicant and FDA DO if applicable;

- distribute the copies of the FOI Summary;
- notify ONADE Document Archive mailbox manager of the final action date to be put on the electronic copy of the approval letter and FOI Summary; and
- update STARS as appropriate, when the approval publishes in the FEDERAL REGISTER[18].

VII. PREPARING AND SENDING ELECTRONIC FILES FOR ARCHIVING

There should be an electronic file for each ONADE review document included in the approval package. All electronic files should be "clean" and identical to the printed version.[19] If you have not gotten an email from the manager of the "CVM ONADE Records" mailbox confirming receipt of the requested consults by the time you are ready to final out the application, contact the necessary reviewers and instruct them to email an electronic copy of their document(s) to the "CVM ONADE Records" mailbox.

Once you receive the email confirming receipt of all the electronic files for the requested consulting reviews from the "CVM ONADE Records" mailbox and the approval letter has been signed, send the electronic files for all the remaining documents in the approval package using the following procedures:

- Create an email addressed to the "CVM ONADE Records" mailbox. The subject of this email should be the document type code, the document number, the submission type code, the submission number, the subclass code, and the package ID of the final approval package (for example, "**N-987654-A-0000-OT (AA)**").[20] For final actions that involve more than one administrative file, send a separate email for each administrative file.
- Attach your electronic files to the email.

[18] DCU has an SOP that describes the information they enter into the STARS database once an approval publishes in the FR. See DCU personnel if you have questions.
[19] See P&P 1243.3005 on how to create clean electronic files
[20] If the subject line is not in the correct format, the email will be returned to you by the manager of the "CVM ONADE Records" mailbox for correction of the subject line.

- Complete the text of the email. The text of the email must include the name of the reviewer assigned the application in STARS and how many files are attached.

- Send the e-mail.

The ONADE Records Drive mailbox manager adds the necessary correspondence dates to the files before archiving them.

The archived electronic copy is our official electronic copy. In order to maintain document version control and information integrity, the agency does not support the retention or distribution of additional electronic copies.

VIII. PREPARING THE NOTIFICATION OF THE APPROVAL AND THE AVAILABILITY OF ELECTRONIC FILES

Once the division receives notification that the approval letter is signed, they send an email announcement center-wide. We send a center-wide approval notice for any approval that has a Freedom of Information Summary. All of the information in the email comes from the title page of the FOI Summary (with the exception of the submission code). This notification also serves to alert the reader that the electronic files for the approval will soon be available in our archive.

The subject line of the email reads "ONADE Product Approval - <PROPRIETARY NAME of the new animal drug>".

The body of email consists of the following information:

NOT FOR PUBLIC DISTRIBUTION

FOR CVM EMPLOYEES ONLY

For information only; do not reply to this message.

DO NOT make this information publicly available until the approval has published in the FEDERAL REGISTER.

We announce the approval of an <*insert original or supplemental*> <*if applicable abbreviated*> New Animal Drug Application <*insert NADA or ANADA number and submission code*>.

Proprietary name: <*insert necessary information*>

Established name: <*insert necessary information*>

Dosage form: <*insert necessary information*>

Species and class: <*insert necessary information*>

Indications or effect of supplement: <*insert necessary information*>

Applicant's name: <*insert necessary information*>

IX. ROUTING FOR THE CODIFICATION AND PUBLIC DISPLAY OF AN APPROVAL

The following describes the last steps in the approval process and are provided for your information.

- The regulation sent by the CVM Policy and Regulations Team is logged through the FRDTS to the Regulation Editorial Staff (RES, HF-27), which prepares the final FR document (regulation) for publication in the FR.

- The final FR document is sent back through FRDTS and is returned through the CVM Policy and Regulations Team to obtain appropriate signatures.

- The final FR document goes to The QA Team and is forwarded to RES for publication.

- The final FR document goes back through FRDTS to RES. RES forwards the following:

    1. The final FR document to the Office of the Federal Register (OFR) for publication in the FR and codification in the Code of Federal Regulations (CFR), and

2. The public display documents (FOI Summary with attached labeling, appropriate environmental documents, and any regulatory analytical methods for residue) to the Division of Dockets Management (HFA-305).

- The final FR document and the public display documents (FOI Summary with attached labeling, appropriate environmental documents, and any regulatory analytical methods for residue) are placed in the appropriate docket and are available for the public in the Dockets' reading room and on the Dockets' website.

- The final FR document is published in the FR and the approval regulation is codified in the CFR. The Green Book is updated following publication of the approval in the FR.

XI. REFERENCES

Section 512 of the Federal Food, Drug, and Cosmetic Act

Staff Manual Guides

1410, Regulatory Delegations of Authority

Program Policy and Procedure Manual

1240.2020 - FEDERAL REGISTER Document Processing

1243.3005 - Creating Clean Electronic Documents

1243.3009 - Format and Style Conventions for Reviews

1240.3125 - Preparation of Draft FEDERAL REGISTER Notice of Approval of a New Animal Drug Application (FR Notice)

1243.3300 - FDA District Office Mail Codes

1243.5740 - Abbreviated New Animal Drug Application Memorandum Recommending Approval

1243.5741 - New Animal Drug Application Memorandum Recommending Approval

1243.5760 - Freedom of Information Summary for an ANADA

1243.5761 - Freedom of Information Summary for an NADA

1243.5762 - Freedom of Information Summary for an ADAA Feed Combination Drug NADA Approval

1243.5820 - Approval Letters

1243.6020 - Review of NADA and ANADA Labeling Supplements

1243.6030 - Review of Labeling Changes in Manufacturing Supplements

1243.8225 - Document Routing and Copy Distribution for Bioresearch Monitoring in ONADE

1243.8500 Making a Request for a Current Good Manufacturing Practice (cGMP) Status for Approval Package

XII. VERSION HISTORY

November 16, 2001 – original version

August 15, 2003 – revised

December 11, 2007 - revised to incorporate format and style conventions, changes and boilerplate language agreed upon by ONADE Management, incorporating active voice where possible, and revised overall format.

March 12, 2008 – revised to incorporate information on the Division of Human Food Safety's review of the draft regulation for administrative NADAs and how to document this in the approval package. Also includes instructions to refer to the most recent 356V to determine the proprietary and established name when filling out the Reviewer's Summary field in STARS