OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

REVIEWING, PREPARING, AND ROUTING APPROVAL PACKAGES FOR CERTAIN ABBREVIATED AND NEW ANIMAL DRUG APPLICATIONS

I. PURPOSE

This document describes the procedures for reviewing, preparing, and routing approval packages for the following types of approvals:

- original new animal drug applications (NADAs)
- original abbreviated new animal drug applications (ANADAs)
- B1 supplemental (A)NADAs[1]
- ANADA non-fee (NF) supplements, except for proprietary name change NFs

The process for preparing approval packages for other supplements (manufacturing, non-fee (NF), and non-fee labeling (NL) supplements) is described in other documents.[2,3] This document can also be used to prepare conditional approval packages.

II. OVERVIEW OF THE PROCESS

When CVM receives an (A)NADA that results in an original or supplemental approval, the division assigned the application is responsible for preparing the approval package.[4] (A)NADAs are classified as either "administrative" or "non-administrative." The process for preparing approval packages for an administrative or a non-

[1] B1 supplemental ANADAs are rare.
[2] See P&P 1243.6020 and 1243.6030 for information on regulatory supplements, and the applicable P&Ps/templates for preparing NL approval packages. See P&P 1243.6040 for information on non-fee supplements. Manufacturing supplemental approvals (Chemistry, Manufacturing and Controls (CMC)) are prepared by the Division of Manufacturing Technologies and approved at the division level.
[3] This P&P does not apply to conditional approvals.
[4] Applications are assigned to either the division responsible for review of the Target Animal Safety and Effectiveness sections or the Division of Generic Animal Drugs.

administrative (A)NADA is similar. 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 package" prepared for most Submission Tracking and Reporting System (STARS) submissions.

Designated division personnel perform the initial application review necessary to determine that the application is approvable as described in Section III. Division personnel then prepare the documents for the approval package as described in Section IV,[5] route the draft and final packages as described in Section V and Section VI, and follow the post-approval steps described in Section VII, Section VIII, and Section IX.

III. INITIAL STEPS IN REVIEWING THE (A)NADA SUBMISSION

A. Ensure the Accuracy of STARS

Administrative and non-administrative (A)NADAs have different STARS due dates. Currently, all applications default to the non-administrative A(NADA) timeframe. If the preparer determines that the application is an administrative A(NADA), they should use the "Review Time Change" workflow in Appian to reset the due date.[6]

If an application has been received in paper and accepted and there are other errors in the coding (e.g., OT subclass vs. B1 subclass), submit a STARS Correction Request Form electronically to recode (paper) or void (eSubmitter) the submission.[7,8]

B. Verification of Technical Sections

Prior to final approval of the application, verify that the previously issued technical section complete letters are still valid.

C. Review of 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.[9] If needed, send consulting review requests within the appropriate timeframe for a non-administrative (A)NADA. [10]

[5] For purposes of this document, designated division personnel refer to a reviewer, consumer safety officer (CSO), and/or other individual from the division responsible for preparing and reviewing the approval package for an application.
[6] Refer to the Appian User Guide for instructions on completing the review time change: Internal information redacted.
[7] See P&P 1243.3011 for information on voiding submissions.
[8] Note: for information on handling and rejection paper applications and submissions see P&P 1243.3002
[9] See P&P 1243.2050 and 1243.3100 for information on refuse to file procedures.
[10] See P&P 1243.3200 for information on creating consulting reviews

Sponsors are required by law to submit patent information for NADAs as part of the application.[11] As part of your review, confirm that patent information has been submitted or that the sponsor has provided a statement that no patents exist. If necessary, contact the sponsor to request they provide an amendment with either the patent information or a statement that there is no patent information to include with the application.

We are now requesting the addition of an "Approved by FDA" labeling statement based on the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (H.R. 5554). These amendments added a section to the Federal Food, Drug, and Cosmetic Act (FD&C Act) that requires the addition of the statement "Approved by FDA under NADA # XXX-XXX" or "Approved by FDA under ANADA # XXX-XXX" to labeling (except representative [Blue Bird] labeling) of approved new animal drugs and generic new animal drugs, respectively, by September 30, 2023. We are requesting the addition of the labeling statement to all approved and marketed labeling components of these products. We are also encouraging the addition of the statement to Blue Bird labeling to clearly identify that the medicated feed was manufactured in accordance with FDA-approved Blue Bird labeling. If the labeling included in the application does not include the applicable labeling statement, and/or, for supplemental applications, if any of the approved and marketed labeling components identified in the A/NADA's Volume 0 do not include the new statement, refer to the ONADE Policy 'Initial Recommendations for the Addition of Approved by FDA Statements to Labeling' found on the ONADE Policy SharePoint page for information on when and how to ask the sponsor to add or update the statement to the labeling.[12]

We generally do not prepare a review (or a submission summary) for an administrative (A)NADA; instead, document that the application is approvable in the Memorandum Recommending Approval (MRA).[13] If you need to document additional relevant information that is too extensive to be described in the MRA (such as an informal communication with a sponsor or clarification of information in the application), it is acceptable to prepare a brief review document (e.g.,review, submission summary, or memo to file) using P&P 1243.3009 and the applicable ONADE templates. For non-administrative (A)NADAs, prepare a review document using P&P 1243.3009 and the ONADE review template.

For non-administrative (A)NADAs, request minor amendments as needed using the information about amendment requests in P&P 1243.3026.[14]

[11] Under section 512(b)(1) of the FD&C act, sponsors are required to submit this information and under section 512(d)(1)(G), we cannot approve an NADA if the application fails to contain the patent information prescribed by section 512(b)(1).

[12] Link to ONADE Policy on "Approved by FDA…" labeling statements
Internal information redacted.

[13] See 1243.5741 for information regarding the MRA for NADAs

[14] See 1243.3026 for information regarding amendments

If you determine that a minor amendment may be needed for an administrative (A)NADA, talk with your team leader.

IV. PREPARING THE DRAFT APPROVAL PACKAGE

A. Request the Draft Federal Register (FR) Documents

If the approval requires a change or addition to the regulations, complete the ONADE "Request for Federal Notice" template and send it via email to the CVM Policy and Regulations Team in the Office of the Center Director. Attach a copy of the draft Freedom of Information (FOI) Summary, labeling, draft Memorandum Recommending Approval (MRA), or other information to the email to assist them. If necessary, identify the section(s) of the regulation requiring changes/additions. The draft FR package consists of the draft FR document text and includes table entries with basic information pertaining to the approval for the monthly FR document and the text of the amended section(s) of the affected regulation(s), and the pre-change and post-change versions of the affected regulation(s).

The CVM Policy and Regulations Team (HFV-6) prepares the draft FR package and returns it to the preparer by email. Check all parts of the draft FR package to ensure the information is accurate and complete (e.g., that it also includes changes to the sections related to tolerances and medicated feeds, if applicable).

If the approval is for an NADA intended for use in a food-producing species, forward the marked up copy of the draft FR document, via email, to the Division of Human Food Safety (DHFS) for their comments.[15] Upon receipt of all comments on the draft FR package, work with the CVM Policy and Regulations Team to make any needed revisions. Convert the emailed reply from DHFS into a PDF file prior to including it in the approval package.

B. Obtain the Environmental Documents

If a categorical exclusion was granted for the (A)NADA, then there are no environmental documents. If a 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 will contain an EA and 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. Document the Environmental Safety Team's confirmation in the MRA. If confirmation from Environmental Safety Team is required, include a PDF copy of the confirmation email in your approval package.

In the MRA, document the location of the environmental safety reviews, technical section complete letters (if applicable), environmental safety information in the end-game meeting memo (if applicable), any other environmental safety review documents (e.g., FONSI), and the confirmation email. Refer to the MRA template for additional details.

[15] May also be required for certain ANADAs. Consult your team leader for additional information.

Include the electronic files for the signed EA and FONSI in the approval package (they will be uploaded into Appian). The original signed EA and FONSI, which is used to support the approval, can be found in the investigational new animal drug (INAD) file (generally with the Environmental Impact technical section complete letter). On rare occasions, an Environmental Impact Statement (EIS) and Record of Decision (ROD) may replace the EA and FONSI. For the approval package, the procedures are the same for EIS and ROD as for the EA and FONSI.

C. Determine Whether Good Manufacturing Practices (cGMP) Status Check is Needed

GMP status checks are required for original and supplemental (A)NADAs except for Animal Drug Availability Act (ADAA) feed combination NADAs (See P&P 1243.8500). For administrative and non-administrative (A)NADAs, request the GMP status check just prior to routing the package to your supervisor. For non-administrative (A)NADAs, a status check may not be required if a CMC consult is requested for that submission. If the package will be approved within 60 days of the return of a CMC consulting review containing GMP status check results, a new status check does not need to be requested. Include the GMP status check documentation (i.e., a PDF file containing the email from the Division of Manufacturing Technologies and the completed form with the results of the status check) in the approval package.

D. Request a Bioresearch Monitoring (BIMO) Status Check

BIMO status checks are required for original and supplemental (A)NADAs except for ADAA feed combination NADAs. See P&P 1243.8220. Use the Request for BIMO Status Check form on the ONADE Forms SharePoint page to request the BIMO status check. Convert the email and inspectional report into a PDF file and include it in the approval package. If multiple PDFs are included as part of the BIMO status check, combine them into a single PDF file before including it in the draft approval package.

We do not require a BIMO status check for ANADAs granted a waiver from the requirement to conduct *in vivo* bioequivalence studies.

E. 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. For ANADAs, the primary reviewer will do a DER status check of the reference listed new animal drug to determine marketing status. Either of the following procedures are acceptable to perform the DER status check:[16]

1. Send a request to the Division of Surveillance to perform the DER status check. Use the 'DVPS ADE and PD Consult Request Form' and the DVPS Consult Request Instructions on the ONADE Forms SharePoint page to request

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

the DER status check. Request that the status check be completed within 5 days.

2. Print a Drug Experience Reporting History report from the Corporate Database Portal DER module, and conduct an initial review of the report[17]. If there are concerns, check with the Division of Surveillance for further input.

Perform the DER status check just prior to the forwarding of the draft package. Convert the DER status check email or History report to a PDF file prior to including it in the approval package.

F. Prepare and Send the Notice of Pending Approval Email (and Fact Sheet, if required)

Any original or supplemental (A)NADA approval with a letter intended for the Center Director's (CD) signature is a possible candidate for media interest. Prepare a notification email using the "Notice of Pending Approval for (A)NADA" email template on the ONADE Templates SharePoint site. The email also includes instructions for HFV-6 to verify that there are no pending citizen's petitions that could impact the approval. This notification email is not needed for supplemental approvals that will be signed by the Office Director (i.e., an HFV- 6 citizen's petition check is not performed for packages signed by the Office Director).

Any original or supplemental (A)NADA approval with a letter intended for the Center Director's signature will have a Fact Sheet (located on the ONADE Forms page). Include a copy of the Fact Sheet in the approval package. Copies of the Fact sheets will not be loaded into Appian.

The division director (or as delegated) should attach the Fact Sheet, if applicable, to the notification email (Notice of Pending Approval for (A)NADA) and send it prior to forwarding the approval package to QA in draft. HFV-6 will provide a response regarding citizen's petitions.

The preparer should include the email response from HFV-6 in the approval package.

G. Prepare the MRA

The MRA briefs the individual signing the approval (i.e., the CVM 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 using P&P 1243.5741 (NADA) and the appropriate ONADE template.

H. Prepare the FOI Summary

The FOI Summary provides a summary of the data and information used as a basis for the approval (e.g., safety and effectiveness data, bioequivalence studies). Use P&P 1243.5761 (NADA) or P&P 1243.5762 (ADAA Feed Combination Drug NADA) and the appropriate ONADE template.

[17] See SOP 1243.120.001 ONADE Process for Accessing the DER Database to Perform Status Check

I. Prepare the Approval Letter

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

If the applicable "Approved by FDA…" statement is not already included on the labeling in the submission and/or, in the case of supplemental approvals, on previously approved and marketed labeling components identified in the A/NADA's Volume 0, include applicable language from the approval letter template to request addition of the statement in future supplemental applications.

J. Prepare or Update the Volume 0

Use the instructions in P&P 1243.3810 for the preparation or update of Volume 0.

K. Prepare the Green Book and Animal Drugs (GBAAD) Form

Use P&P 1243.3900 and the office GBAAD[18] form to provide information on the approval that will be included in the Green Book and Animal Drugs @ FDA.

L. Prepare the Notification Email for the Office of Surveillance and Compliance (OSC) for Approvals with a Tolerance Change

When there will be a tolerance change as a result of an approval, prepare a notification email to OSC using P&P 1243.3760 Drug Tolerance Notification Process and the ONADE Drug Tolerance Notification Outlook template.

M. Ensure Section 508 Compliance

All documents should be prepared in compliance with Section 508 of the Rehabilitation Act (29 U.S.C. 794d), as amended by the Workforce Investment Act of 1998 (P.L. 105-220). However, only the FOI Summary created by CVM for public display must be checked for Section 508 compliance prior to moving the draft package forward.[19] Use the information provided on the ONADE Reviewer Reference Page (ORRP)/ONADE Review Aids page in SharePoint to assist in the creation of Section 508 compliant Word documents.

N. Complete the Reviewer's Summary Field in STARS

Complete the Reviewer's Summary field in CDP STARS or CDP Web with a short description of the approval during preparation of the draft approval package. For example:

[18] See P&P 1243.3801 Completing the Green Book and Animal Drugs at FDA (GBAAD Form for information on how to fill out the GBAAD template.

[19] When an EA and FONSI are part of an approval package, they are also made publicly available. The BI Team checks the FONSI for Section 508 compliance prior to uploading it for public display. CVM does not check the EA for Section 508 compliance because it is a sponsor-created (not CVM-created) document.

Original approval for <Proprietary Name®> (<drug product established name>) for <indications and conditions of use> in <species/class.>

For ANADAs, also include reference product information:

This reference listed new animal drug is <Proprietary Name®> (<drug product established name>) sponsored by <applicant's name> under (A)NADA <XXX-XXX>.

V. ASSEMBLING AND ROUTING THE APPROVAL PACKAGE FOR FIRST-PASS REVIEW

Create an electronic folder in the location designated by your division/team procedures) with the (A)NADA code and number (e.g., N123456). Create a subfolder within this folder with the submission code and number (e.g., C1234). Within that subfolder, create two electronic folders named "Folder A" and "Folder B". Note that not all documents are required for all approvals.

Folder A should contain a copy of:
Draft MRA
Draft FOI Summary
Draft approval letter for applicant
Draft FR documents
GBAAD Form
EA and FONSI or EIS and ROD, if applicable

Folder B should contain a copy of:
Final primary reviews for the current submission (generally non-administrative (A)NADAs only)[20]
Other Pertinent Information (e.g., Memorandum to File, copies of email communications with sponsors if applicable, etc.)
GMP Status Check PDF file
BIMO Status Check PDF file
DER Status Check Email or DER History Report (as a PDF)
Email from the DHFS documenting their email review of the Draft FR document (if applicable) or applicable non-administrative (A)NADA documents.
Email from the Environmental Safety Team documenting review of the environmental documents (if applicable)
Email sent to OSC (if a new tolerance will be approved)
Email from HFV-6 confirming that there are no pending citizen's petitions (for packages signed by the Center Director)

In addition to Folder A and Folder B, the main application folder should contain a copy of:
Fact Sheet (if applicable)
Draft Volume 0 Excel sheet

[20] Do not include copies of any referenced documents that were not created as part of the current (A)NADA application review and approval. 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. Reviews from completed submissions are archived in CDMS and the QA team will be able to access them from there if needed.

Appian consult return notification email(s)(if applicable) to allow the QA Team access to the consulting reviews for the current submission.

Follow your appropriate team or division procedures for the supervisory review of the draft approval package. Note, this is done outside of Appian and Appian sign-off is NOT initiated during the review of the draft approval package. We use informal methods (i.e., email) to notify the next person in the chain that the draft approval package is ready. The review chain for the draft approval package might look like this:

1. The primary reviewer or CSO reviews the package for accuracy and completeness of the information and consistency with current laws and policies, and notifies the team leader.

2. The team leader reviews the package for accuracy and completeness, and notifies the division director.

3. The division director confirms the accuracy and completeness of the package and notifies the preparer.

4. If errors are found during review at the reviewer, team, or division level, the appropriate person is notified for correction.

For non-administrative (A)NADAs for approvals in food-producing animals, the DHFS should review the pertinent parts of the draft package before it moves to the Quality Assurance (QA) Team for review. If the ANADA is granted a waiver from the requirement to demonstrate in vivo bioequivalence, this step is not required. The target animal division (TAD) should make any needed changes before forwarding the package to QA for review. Convert the email documenting the DHFS review/concurrence into a PDF and include it in Folder B.

When the draft package is ready for Quality Control review by the QA Team, follow the procedures in P&P 1243.3210 to add the documents to the S: drive WORKAREA QA Team Approval Packages Draft Folder and send a consulting review request to the QA team to let them know that the draft package is ready for review.

VI. ASSEMBLING AND ROUTING THE APPROVAL PACKAGE FOR FINAL CLEARANCE

The final approval package is electronic, and consists of the documents described above (Folder A and Folder B).

1. When the QA team has verified that the final package is acceptable, they will return the consult in Appian. The TAD should notify the division personnel responsible for checking Section 508 compliance that the FOI summary is ready for review per Division procedures.

2. Once a Section 508 compliant PDF of the FOI Summary has been created, the TAD reviewer should forward the electronic approval package through the appropriate team or division supervisory chain (i.e., primary reviewer, team leader, and division director) following division procedures, and then initiate sign-off in Appian.

3. Choose the relevant final action code in Appian from Table 1:

   Table 1: Final Action Codes for Approval Packages Covered in This P&P

Application Type	Document and Submission Code	Final Action Code in Appian
NADA - original approval	NADA A and E	(ORG APP LD) ORIGINAL APPLICATION APPROVED DATE OF LETTER; LETTER SENT
NADA - B1 supplemental approval	NADA C and R (subclass B1)	(SUP SIG LD) SIGNIFICANT SUPPLEMENT APPROVED DATE OF LETTER; LETTER SENT
ANADA - original approval	ANADA A and E	(ORG APP LD) ORIGINAL APPLICATION APPROVED DATE OF LETTER; LETTER SENT
ANADA – B1 supplemental approval	ANADA C and R (subclass B1)	(SUP SIG LD) SIGNIFICANT SUPPLEMENT APPROVED DATE OF LETTER; LETTER SENT
ANADA – NF supplemental approval	ANADA C and R (subclass NF)	(SUP MIN LD) MINOR SUPPLEMENT APPROVED DATE OF LETTER; LETTER SENT

4. Build the sign-off in Appian according to the longest chain needed for your package. Use the Table 2 as a guide for the signatures needed for each document in the approval package. As described above, the actual documents and signatures required for each package may vary.

Table 2: Signature reference for the approval package components

Document	**PR**	**TL**	**DD**	**DHFS**	**QA**	**OD**	**CD**
MRA	Y	Y	Y	N	Y	*	N
FOI Summary	Y	Y	Y	Y for non admin (A)NADA for food animal	Y	Y	*
Approval letter	Y	Y	Y	N	Y	Y	*
Draft FR documents	Y	Y	Y	N	Y	Y	*
GBAAD form	Y	Y	N	N	N	N	N
Primary reviews	Y	**	**	N	N	N	N

Y = yes and N = no
* means yes, if CD is the signature authority for the letter
** means yes if required by division procedures
PR = primary reviewer, TL = team leader, DD = Division Director, DHFS = Division of Human Food Safety, QA = Quality Assurance, OD = Office Director, CD = Center Director

When including documents in Appian, select "Yes" to answer the question "Should file be sent to the firm?" for the approval letter and the FOI Summary. .

The remaining documents do not require signature, but if they are part of the approval package, they will need to be uploaded into Appian with the above documents in order to get them correctly archived into FDA's record. These documents include:

- a copy of the EA/FONSI or EIS/ROD
- other pertinent information (e.g., memos to file, copies of sponsor communication emails, etc.)

Save the following documents in PDF format and designate them as "other review related files" when they are uploaded into Appian:

- email from DHFS documenting review of FR notice or other applicable documents in non-administrative (A)NADAs
- email confirmations from the Environmental Safety Team, if applicable
- email sent to OSC if a new tolerance will be approved
- email from HFV-6 confirming that there are no pending citizen's petitions

The following PDF files should be designated as "Status Check (BIMO, DER, GMP)" when they are uploaded into Appian:

- GMP status check document
- BIMO status check document
- DER status check email or DER history report

The following documents, although they were prepared as part of the approval package process, are NOT uploaded in Appian:

- Fact Sheet
- Draft Volume 0 Excel sheet
- Appian consult return notification email(s)(if applicable)

VII. FINALIZING APPROVAL PACKAGES

A. Appian Sign-Off

It is the responsibility of the TAD reviewer to make sure that the correct personnel are available and entered into the Appian concurrence chain and that the package moves through Appian for concurrences in a timely manner. The TAD should initiate communication with the appropriate individuals when the package is stalled.

B. Who Signs Approval Packages if the Office and Center Director are Out?

1. Who signs when the ONADE Office Director (OD) is out?

    - If the ONADE OD is out, either the Deputy Director or the Senior Science Advisor may sign the approval package.
    - If the ONADE OD, Deputy Director, and Senior Science Advisor are out, the ONADE OD will have sent an email letting the office know who is acting OD. The acting OD will sign.

2. Who signs when the CVM Center Director (CD) is out?

    - When the TAD reviewer selects HFV-001 in the Appian clearance chain, the Appian workflow automatically sends the approval package to the Appian queues of the CVM CD, the Deputy Center Director and the Deputy Center Director for Science Policy. Any of these individuals will

pick up the task and sign-off on the approval based upon their availability.

C. Document Control Unit/Business Informatics (BI) Team

When the Document Control Unit (DCU) receives the completed and signed approval package, they:

- mail the letter and enclosures to the applicant for packages received in paper, if applicable[21]; and
- the BI Team updates STARS as appropriate when the approval is finaled, as part of the Green Book/Animal Drugs@FDA monthly update process.

VIII. PREPARING THE NOTIFICATION OF THE APPROVAL AND POSTING THE APPROVAL DOCUMENTS

A. Send the CVM Product Approval Announcement

After the division receives notification that the approval letter is signed, issue the CVM Product Approval Notification email using the ONADE email template. We send this center-wide email 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 and the approval date). The approval date should be the date listed in STARS. This notification also serves to alert the reader that the electronic files for the approval will soon be available in CDMS.

B. Notify OSC if Final Printed Labeling (FPL) was Submitted

If the submission contained FPL as you are closing out the submission in Appian, on the "Additional Actions" screen, check the box next to the option, "Does the submission contain FPL that is acceptable to CVM". Appian will send an email to the CVM OSC FPL Notification mailbox. This email is used to notify OSC that ONADE has received FPL to aid in OSC's maintenance of the DER database.

C. Post the Approval Documents to Animal Drugs @ FDA

The month following the approval of the (A)NADA, the BI Team will prepare and post a Green Book Monthly Update document under the Green Book Reports on the Animal Drugs @ FDA website. In addition, the BI Team will also perform a final Section 508 compliance/accessibility check on the FOI Summary, and if applicable, the FONSI, and upload them, as well as the Environmental Assessment (if applicable) to the Animal Drugs @ FDA website.

[21] If the application was submitted in paper, the project manager associated with the project emails a copy of the approval letter to the sponsor.

IX. PRESENT SUMMARY PRODUCT INFORMATION AT THE QUARTERLY MONITORED ADVERSE REACTION COMMITTEE (MARC) MEETING, IF APPROPRIATE

Contact your division representative during the approval process to determine if a presentation at the MARC meeting will be appropriate. If a MARC meeting presentation is appropriate, prepare a summary of significant findings from the studies conducted, mechanism of action, any adverse reactions noted, and any pharmacokinetic data at a MARC meeting after the (A)NADA approval. This data may be helpful to the OSC as they evaluate promotional and advertising materials and adverse drug event reports for the product.

X. REFERENCES

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

FDA Staff Manual Guides (SMGs)

1410, Regulatory Delegations of Authority

CVM Program Policy and Procedures Manual

1243.2050 – Refuse to File and Refuse to Review

1243.3002 - Handling and Rejecting Paper Applications and Submissions

1243.3005 - Creating Clean Electronic Documents

1243.3009 - Format and Style Conventions for Reviews and Submission Summaries

1243.3010 - Format and Style Conventions for Letters

1243.3011 – Voiding Submissions and Discontinuing the Review of Pending Submissions and Applications

1243.3026 – Amending and Resetting the Clock on STARS Submissions

1243.3100 – BETA TEST - Refuse to Review (RTR) and Refuse to File Assessments (RTF) Assesments of Submissions and Applications

1243.3200 – Routing a Request to Obtain a Consulting Review of a Submission Tracking and Reporting System (STARS) Submission

1243.3210 - Requesting a QC Review from the Quality Assurance Team

1243.3760 – Drug Tolerance Notification Process

1243.3801 – Completing the Green Book and Animal Drugs at FDA (GBAAD) Form

1243.3810 – Creating and Maintaining a Reference Copy of the Currently Approved Labeling for an Application (Volume 0)

1243.3900 – Maintaining the Animal Drugs @ FDA Database and Website

1243.5741 - Memorandum Recommending Approval (MRA) for Original and Supplemental New Animal Drug Applications (NADA)

1243.5761 - Freedom of Information Summary (FOI) for Original and Supplemental New Animal Drug Applications (NADA)

1243.5762 - Freedom of Information (FOI) Summary for Animal Drug Availability Act (ADAA) Feed Combination New Animal Drug Applications

1243.5820 - Approval Letters

1243.6020 - Review of NADA and ANADA Labeling Supplements NL Subclass

1243.6030 - Review of Labeling Changes in Manufacturing Supplements

1243.6040 - Review of A NADA 60-Day NF Qualifying Labeling Supplements

1243.8220 - Requesting a Bioresearch Monitoring (BIMO) Status Check

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

ONADE Office Policy Page

Initial Recommendations for the Addition of Approved by FDA Statements to Labeling

XI. 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

August 31, 2010 – Revised to incorporate the ERA process, GBAAD forms, and Volume 0 information, and to incorporate current Office practices.

August 17, 2011 – Revised to incorporate new electronic review and sign-off procedures.

September 7, 2012: Revised to improve flow of the document, incorporate the Fact Sheet process, incorporate 508 compliance process, and incorporate additional Appian information.

April 12, 2013: Clarified the Fact Sheet/Communications email procedures.

June 28, 2017: Revised to incorporate new and updated procedures.

August 29, 2017 - Revised to clarify procedures to state if a FONSI is prepared for the approval a copy is included with the approval letter sent to the sponsor and update the information on posting approval information to Animal Drugs @ FDA.

August 2, 2018 – Revised to add clarification of final action codes and information about the new process for preparing draft CVM updates for new chemical entities. Removed reference to outdated P&P 1240.2325 from Section IV. I and added instruction that for supplemental approvals sgned by the ONADE OD the notification email is not necessary. Added information on who signs the approval if the ONADE OD and CVM CD are out creating a new part B in Section VII. Added reference to the new P&P on how to fill out the GBAAD form P&P 1243.3801. Revised the title.

April 04, 2019 – Revised to to add instructions on when and how to ask for addition of "Approved by FDA…" statements to labeling. Revised to reflect the Finding of No Significant Impact (a.k.a. FONSI) is no longer sent to the sponsor. Updated information regarding the Fact Sheet to reflect that all approvals going to the Center Director for signature are required to have a Fact Sheet.