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OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

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**CREATING AND MAINTAINING A REFERENCE COPY OF THE CURRENTLY APPROVED LABELING FOR AN APPLICATION (VOLUME 0)**

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**I. PURPOSE**

This document establishes the procedures to create and maintain a reference to the currently approved labeling for an application (Volume 0) that is easily accessible within the administrative file. Other documents describe the review process to determine the appropriate content of approved labeling that is referenced in Volume 0.<sup>1</sup>

**II. BACKGROUND**

In many applications it is difficult to determine what is the currently approved labeling. The reasons for this can be many (e.g., the length of time since the original approval, the number of supplemental approvals over time resulting in components of the labeling being submitted at different times and within numerous volumes of information within the application, etc.). Thus, the Office of New Animal Drug Evaluation's (ONADE) business process includes establishment and maintenance of a "Volume 0" file for each abbreviated new animal drug application (ANADA) or new animal drug application (NADA) that identifies the currently approved labeling components for that (A)NADA.

**III. DESCRIPTION OF VOLUME 0**

"Volume 0" is a listing of the submission(s) containing each of the components of the currently approved labeling for the application. Ultimately, a complete Volume 0 will contain a reference to all of the labeling components for each approved product within an (A)NADA application.<sup>2</sup> A Volume 0 may consist of both paper and electronic labeling components. If a Volume 0 contains paper copies of labeling (i.e., if it was created prior to July 2011 and no new labeling has been approved since that time), it will be in the administrative record in the Document Control Unit (DCU) and will always be the first volume (Volume 0) in sequence for the application. Paper Volume 0 jackets can be identified by their purple colored jacket. All Volume 0s created or

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<sup>1</sup> See P&Ps 1243.6020 or 1243.6030.

<sup>2</sup> It is important to note that reviewers must not presume the Volume 0 is complete and contains up to date copies of all labeling components for the approved product. For example, some products (particularly older products) may have additional sizes approved that are not currently marketed, and have inadvertently not been added to the Volume 0. Such labels should be added to the Volume 0 when they are identified by a reviewer.

updated after July 2011 are available electronically on the ONADE Volume 0 SharePoint site.<sup>3</sup>

#### IV. PREPARER RESPONSIBILITIES

##### A. Determine If a Volume 0 Exists

All electronic Volume 0 Excel files are stored in a SharePoint folder for that specific (A)NADA. To determine if a Volume 0 (electronic or paper) has been created for an approved application, check the Document Overview screen in STARS to see if the Volume 0 indicator is checked. If there is no existing Volume 0 (either paper or electronic) for an approved application, an electronic Volume 0 will be created at the subsequent supplemental approval in which the target animal division (TAD) approves a change to the labeling. For new approvals, the TAD should create a Volume 0 at the time of the original approval. Follow this document as necessary to create, or to reference all revisions to, the approved labeling in the electronic Volume 0.

##### B. Creation of Electronic Volume 0 If No Volume 0 Exists

If a Volume 0 does not exist for an application, follow the steps in this section to create an electronic Volume 0. If a Volume 0 exists, proceed to section C below for instructions to update an existing file. For instructions on how to add new electronic Volume 0 files or to check out an existing Volume 0 file for editing, refer to the Volume 0 user guide posted on the SharePoint site.

If no electronic Volume 0 has been created, prepare a complete electronic Volume 0 to replace the entire paper Volume 0. If all components of labeling have not been updated in the current submission, you may need to examine the administrative file to identify all the approved components of labeling. For (A)NADAs that are Type A medicated articles, there should also be Type B (if applicable) and Type C medicated feed labeling (e.g., Blue Bird labeling) for each approved use (species/class, dosage/duration and indication) on the Type A medicated article label.

TAD personnel will:

1. Use the provided Microsoft Excel template located on the SharePoint site to create the electronic Volume 0 file. Save this edited template to your personal network drive using the file name "\_Volume 0 (A/N)XXXXXX".
2. Complete the Table of Contents (TOC) Sheet.

The first tab in the template contains the TOC. At the top of the sheet, enter the (A)NADA number, the trade name(s) (i.e., proprietary name(s)), the established name, and the dosage form. For each component of labeling approved for that product, enter the type of labeling (e.g., vial label, package insert) on a separate line. On the next line, enter the name

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<sup>3</sup> Link to Volume 0 SharePoint site  
Internal information redacted.

of each specific component of labeling (e.g., 100 mL presentation). For a medicated feed, the heading might be Type C medicated feed and the specific name "Drug X Finishing Swine Feed" (i.e., the name of the Type B or Type C Blue Bird label). If there are multiple components of labeling under a particular heading, enter each name on a separate line. List all components of approved labeling in the TOC, even if updated labeling is not present in the current submission. For labeling components not provided in the current submission, perform a search of the STARS and the paper administrative file located in the DCU to determine the location of the approved labeling.

Column D of the TOC sheet is entitled "**New "Approved by FDA under..." statement added? Mark "Y" if yes or "NA" if not applicable**". Use this column to identify labeling components to which the "Approved by FDA under A/NADA # XXX-XXX" statement has been added. This statement is required on animal drug labeling (except representative [Blue Bird] labeling) by September 30, 2023, as a result of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (H.R. 5554), signed August 14, 2018. We are requesting the addition of the labeling statement to all approved and marketed labeling components for approved new animal drugs and generic new animal drugs. 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. See the ONADE Office Policy Initial Recommendations for the Addition of Approved by FDA Statements to Labeling for more details on this requirement.<sup>4</sup> Place a "Y" in column D to the right of each labeling component that has been approved with the new statement – including any representative Blue Bird labeling or Veterinary Feed Directives (VFDs) in which a sponsor voluntarily added or updated the statement. If a labeling component is not required to add/update the statement (e.g., Blue Bird labeling, VFDs) and the sponsor did not add/update the statement to these components, place "NA" in the column.

3. Complete the Log of Labeling Component Changes (LLCC) sheet(s)

Complete an LLCC sheet for each labeling component specific to the application. This includes any labeling in the current submission as well as any previously approved labeling components. At the top of the sheet, enter the name of the labeling component. In the table below, enter the submission number for the submission containing the approved labeling and its submission date. If labeling was approved in a reactivation in which the labeling was not resubmitted, use the submission number and submission date for the submission the labeling was submitted under in the "Submission Number" and "Date Submitted" columns. The "Date Approved/Closed Out" column should then list the approval date and submission number for the reactivation the labeling was approved under (e.g., 03/14/2011 (R-0011)). The "Date Approved/Closed Out" column

<sup>4</sup> Link to the Initial Recommendation policy document  
Internal information redacted.

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may contain either the approved date or the FNR date (for final printed labeling) as listed in STARS. Under Type, select FPL (Final Printed Labeling), Facsimile, or Representative (Blue Bird labels only). Under format, select Paper for any labeling that exists only in paper format or Electronic for both scanned and eSubmitter labeling. Complete with the Date Updated and Responsible Individual (preparer of the Volume 0).

Use your judgment on how best to organize the Volume 0 TOC/LLCC file. Strict adherence to the template is not necessary; however, consistency between similar products is desired. If less than all of the approved product's labeling components are used to create Volume 0, indicate this in the Notes section of the template.

4. Complete and submit the Volume 0 Notification form located on the SharePoint site to notify DCU that the Volume 0 flag needs to be activated for the application(s).

After the submission has been finalized, upload the completed electronic Volume 0 file to the appropriate library folder on the Volume 0 SharePoint site. For instructions on how to add new Volume 0 files in SharePoint, refer to the Volume 0 user guide posted on the SharePoint site. Delete the template from your personal network drive.

### **C. Update That Converts a Paper Volume 0 to an Electronic Volume 0**

To update an existing paper Volume 0 and convert to an electronic Volume 0 for the application, the preparer will:

1. Request the paper Volume 0 jacket for the application.

If Volume 0 is already out on loan, ask the Records and Information Management (RIM) Team to assist you in locating it. If there are multiple pending submissions requiring Volume 0, then coordinate the competing needs for Volume 0 during the final action and clearance process for the submissions containing labeling.

2. Use the provided Microsoft Excel template located on the SharePoint site to create the electronic Volume 0 file. Save this edited template to your personal network drive using the file name "\_Volume 0 (A/N)XXXXXX".
3. Complete the TOC Sheet.

The first tab in the template contains the TOC. At the top of the sheet, enter the (A)NADA number, the trade name(s) (i.e., proprietary name(s)), the established name, and the dosage form. For each component of labeling approved for that product, enter the type of labeling (e.g., vial label, package insert) on a separate line. On the next line, enter the name of each specific component of labeling (e.g., 100 mL presentation). For a medicated feed, the heading might be Type C medicated feed and the specific name "Drug X Finishing Swine Feed" (i.e., the name of the Blue Bird label). If there are multiple components of labeling under a particular

heading, enter each name on a separate line. List all components of approved labeling in the TOC, even if updated labeling is not present in the current submission. For labeling components not provided in the current submission, perform a search of the Submission Tracking and Reporting System (STARS) and the paper administrative file located in the DCU to determine the location of the approved labeling.

Column D of the TOC sheet is entitled **"New "Approved by FDA under..." statement added? Mark "Y" if yes or "NA" if not applicable"**. Use this column to identify labeling components to which the "Approved by FDA under A/NADA # XXX-XXX" statement has been added. This statement is required on animal drug labeling (except representative [Blue Bird] labeling) by September 30, 2023, as a result of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (H.R. 5554). We are requesting the addition of the labeling statement to all approved and marketed labeling components for approved new animal drugs and generic new animal drugs. 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. See the ONADE Office Policy Initial Recommendations for the Addition of Approved by FDA Statements to Labeling for more details on this requirement. Place a "Y" in column D to the right of each labeling component that has been approved with the new statement – including any representative Blue Bird labeling or VFDs in which a sponsor voluntarily added or updated the statement. If a labeling component is not required to add/update the statement (e.g., Blue Bird labeling, VFDs) and the sponsor did not add/update the statement to these components, place "NA" in the column.

4. Complete the LLCC sheet(s)

Complete an LLCC sheet for each labeling component specific to the application. This includes any labeling in the current submission as well as any previously approved labeling components. At the top of the sheet, enter the name of the labeling component. In the table below, enter the submission number for the submission containing the approved labeling and its submission date. If labeling was approved in a reactivation in which the labeling was not resubmitted, use the submission number and submission date for the submission the labeling was submitted under in the "Submission Number" and "Date Submitted" columns. The "Date Approved/Closed Out" column should then list the approval date and submission number for the reactivation the labeling was approved under (e.g., 03/14/2011 (R-0011)). The "Date Approved/Closed Out" column may contain either the approved date or the FNR date (for final printed labeling) as listed in STARS. Under Type, select FPL (final printed labeling), Facsimile, or Representative (Blue Bird labels only). Under format, select Paper for any labeling that exists only in paper format or Electronic for both scanned and eSubmitter labeling. Complete with the Date Updated and Responsible Individual (preparer of the Volume 0).

5. Use your judgment on how best to organize the Volume 0 TOC/LLCC file. Strict adherence to the template is not necessary; however, consistency

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between similar products is desired. If less than all of the approved product's labeling components are used to create Volume 0, indicate this in the Notes section of the template.

6. Update paper LLCC documents.

As paper labeling is replaced with electronic versions, the preparer should add a note on the paper LLCC documents located in the paper Volume 0. Mark through any remaining open lines on each LLCC document and add the note "Future updates located in electronic Volume 0".

7. Ensure the outdated labeling components are destroyed

Only paper labeling not currently available in an electronic format will reside in Volume 0. Paper versions of the labeling components will be destroyed as updated electronic versions are received. The preparer should collect and bind the outdated labeling components replaced by the current approval, mark them as outdated, and attach them to the front of the jacket with a completed Volume 0 Notification form so that DCU knows which documents to destroy. Return the paper jacket when you are notified that the approval package has been signed.

8. Final the submission following Office policies

Upload the Volume 0 spreadsheet to the Volume 0 SharePoint site. For instructions on how to add new Volume 0 files in SharePoint, refer to the Volume 0 user guide posted on the SharePoint site. Delete the template from your personal network drive after the submission is finalized out.

#### **D. Update an Existing Electronic Volume 0**

To update the existing electronic Volume 0 for the application, the preparer will:

1. Locate the Volume 0 spreadsheet file for the application located on the SharePoint site. Check out the file and save it to your personal network drive using the existing file name ("\_Volume 0 (A/N)XXXXXX"). For instructions on how to check out existing files in SharePoint, refer to the Volume 0 user guide posted on the SharePoint site.
2. Update the electronic LLCC sheet for each labeling component revised or create new a LLCC sheet(s) for any new labeling component(s) added in the current approval submission. Do not delete any entries in the existing LLCC sheets. Move to the next line in the sheet to add the updated labeling information.
3. Update the TOC if necessary.

If not already added, insert a new "column D" to the TOC page entitled "New "Approved by FDA under..." statement added? Mark "Y" if yes or "NA" if not applicable". Be sure to "wrap text" so that the entire title is visible and add the bold lower border. Use this column to identify labeling components to which the "Approved by FDA under A/NADA # XXX-XXX"

statement has been added. This statement is required on animal drug labeling (except representative [Blue Bird] labeling) by September 30, 2023, as a result of the Animal Drug and Animal Generic Drug User Fee Amendments of 2018 (H.R. 5554). We are requesting the addition of the labeling statement to all approved and marketed labeling components for approved new animal drugs and generic new animal drugs. 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. See the ONADE Office Policy Initial Recommendations for the Addition of Approved by FDA Statements to Labeling for more details on this requirement. Place a "Y" in column D to the right of each labeling component in the submission that has been approved with the new statement – including any Blue Bird labeling or VFDs in which a sponsor voluntarily added or updated the statement. If a labeling component is not required to add/update the statement (e.g., Blue Bird labeling, VFDs) and the sponsor did not add/update the statement to these components, place "NA" in the column.

4. Final the submission following Office policies

Upload the updated electronic Volume 0 file to the Volume 0 SharePoint site and check it back in. For instructions on how to check in the existing file in SharePoint, refer to the Volume 0 user guide posted on the SharePoint site. Delete the file from your personal network drive after the submission is finalized out.

## V. REFERENCES

CVM Program Policy and Procedures Manual

1243.3800 – Reviewing, Preparing, and Routing Approval Packages for Certain Abbreviated and New Animal Drug Applications

1243.6020 - Review of New Animal Drug Application (NADA) and Abbreviated New Animal Drug Application (ANADA) Labeling Supplements (NL Subclass)

1243.6030 - Review of Labeling Changes in Manufacturing Supplements

ONADE Office Policy Page

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

## VI. VERSION HISTORY

August 23, 2007 – Original version

October 7, 2011 – Updated to remove all references to paper copies of labeling and update for electronic labeling procedures.

February 10, 2012 – Updated to incorporate the Volume 0 Notification form.

April 8, 2014 – Updated to include the SharePoint site and remove references to the ONADE Records network drive.

July 8, 2016 – minor formatting revisions and redaction of internal information for the FDA.gov version.

April 4, 2019 – Updated to remove information about updating the Volume 0 tracking sheet on SharePoint site, because we are no longer doing that and add instructions for completing Column D of the electronic Volume 0 TOC sheet.