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 copy of 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 placed in Volume 0.[1]

II. BACKGROUND

In many applications it is difficult to determine exactly 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 that have spread portions of the label across time and numerous volumes of information within the application, CVM requests for labeling changes that were submitted to non-target animal divisions or other Offices, ambiguous record keeping, or for medicated feeds, the presence of numerous Type B and C medicated feed labels. Thus, ONADE management has found it necessary to establish what, in fact, the currently approved label is, and to put in place a process to maintain a reference copy of the currently approved label. This paper-based reference copy is a prelude to the later establishment of an electronic repository of the currently approved labeling.

[1] See P&Ps 1243.6020 or 1243.6030.

III. DESCRIPTION OF VOLUME 0

"Volume 0" is the reference copy of all components of the currently approved labeling for the application. Ultimately, a complete Volume 0 will contain all of the labeling components for each approved product within an ANADA or NADA. Each Volume 0 is located in the administrative record (Document Control Unit, DCU) as the first volume (Volume 0) in sequence for the application, unless out on Library Loan. Writing or labels on the jacket will identify the volume as Volume 0 for a specific application. Typically, we will use purple colored jackets to identify Volume 0.

IV. TARGET ANIMAL DIVISION RESPONSIBILITIES

A. Requirement for Volume 0

Target animal division (TAD) personnel will "create" a Volume 0 when an application (NADA or ANADA) is first approved. For purposes of this document, "target animal division" means the Divisions of Therapeutic Drugs for Non-food Animals, Production Drugs, and Therapeutic Drugs for Food Animals and the Generic Animal Drugs Team. If there is no existing Volume 0 for an approved application, TAD personnel will create Volume 0 at the subsequent supplemental approval in which the TAD approves a change to the labeling. TAD personnel will follow this document as necessary to create, or to place all revisions to, the approved label in Volume 0.

B. Creation of Volume 0

The purple jackets will be available from the DCU. In the event that this color jacket is unavailable, use the jackets designated by the Policy Team. The plastic sleeves and tabs will be available from Office (or Division) supplies.

To create Volume 0 for the application, TAD personnel will:

1. Obtain copies of the product labeling that is the subject of the approval

   TAD personnel will use a copy of all labeling components taken from either the duplicate or triplicate copy of the sponsor's submission to populate the Volume 0. If such a copy is not available, TAD personnel may remove a copy from the original copy of the submission PROVIDED at least one complete

set of the submitted labeling remains in the original copy of the submission to maintain a complete administrative record of the labeling components.

2. Permanently mark each component of labeling

   The permanent (ink) marking consists of the application type and number (e.g., N-123456), the submission type and number (e.g., A-0000), and the name of the component. Where possible, use well-placed adhesive labels for the markings. Alternatively, make the markings directly on the labeling component. Place this marking in a conspicuous location while not obscuring (if possible) the legibility of the labeling component. The reverse side of a component is often an ideal place to mark the component. For small label components that may be easily lost, the TAD personnel may affix them to a sheet of paper and place the markings adjacent to the labeling component.

3. Place each marked labeling component in a plastic sleeve

4. Complete the Log of Labeling Component Changes (LLCC) for each labeling component

   Use the provided LLCC format template to create an LLCC for each labeling component specific to the application (Appendix 1). Temporarily save the file to your personal network drive using file name "_Volume 0 LLCC (A/N)XXXXXX". Edit this template to reflect the application type and number of the current application. Save this edited template to your personal network drive. Print this application-specific 'template' as necessary for each labeling component. Write in the name of the component and the tabular information as appropriate on each LLCC.

   After the creation of the Volume 0 is completed, forward this edited template file to the DCU along with the other electronic files as part of finaling out this submission. Delete the application-specific template from your personal network drive after the submission is finaled out.

   ONADE's R:\Drive administrator saves the application-specific LLCC template file that contains (A)NADA specific LLCC to the root directory of the application for ONADE on the R:\Drive as part of the finaling out process.

5. Create a Table of Contents (TOC) for all submitted labeling components of the application

Use the provided TOC format template to create a TOC specific to the application (Appendix 2). Temporarily save the template to your personal network drive using the file name "_Volume 0 Table of Contents (A/N)XXXXXX". Edit this template (following the general order presented in 4.a. or 4.b. based on the product type) to reflect the labeling components specific to the current application. Place a printed copy of this TOC in a plastic sleeve as the first page of Volume 0. Save this edited template to your personal network drive.

TAD personnel are to use their judgment on how best to organize the Volume 0. Strict adherence to the template is not necessary; however, consistency between similar products is desired. If less than all of the approved products labeling are used to create Volume 0, then the TAD personnel should note that at the bottom of the TOC and include a printed copy of the approved products under this (A)NADA obtained from the Drug Products Listing (DPL) database behind the TOC in it's plastic sleeve.

After the creation of the Volume 0 is completed, forward this edited template file to the DCU along with the other electronic files as part of finaling out the submission. Delete the templates from your personal network drive after the submission is finaled out.

ONADE's R:\Drive administrator saves the application-specific TOC template file that contains NADA specific TOC to the root directory of the application for ONADE on the R:\Drive as part of the finaling out process.

a. Dosage form products

    i. Package insert or outsert,

    ii. Client information sheet,

    iii. Grouped by container size,

        - Immediate container label,
        - Carton label, and
        - Shipping label, and

iv. Other components.

b. Medicated feed products

i. Type A medicated article label,

ii. Type B medicated feed label(s) (Bluebird label(s)), and

iii. Type C medicated feed label(s) (Bluebird label(s)).

6. Label the tabs with their respective labeling component names

7. Assemble Volume 0

The TOC is the first page of Volume 0. Each labeling component (consisting of the labeled tab, the completed LLCC, and the corresponding labeling component in a plastic sleeve) follows in the order established above.

DCU personnel are responsible for writing the application type and number (e.g., N-123456) and the words "Volume 0" on the front jacket cover.

8. Annotate the ONADE Final Action Form

In the "Comments/Instructions to DCU" box, identify from which copy of the submission the copy of the labeling components were removed.

C. Updates to Volume 0

To update the existing Volume 0 for the application, TAD personnel will:

1. Request Volume 0 for the application as a Library Loan from DCU.

If Volume 0 is already out on loan, ask DCU who has it. If there are multiple pending submissions requiring Volume 0, then the TAD personnel must coordinate their competing needs for Volume 0 during the final action and clearance process for the submissions containing labeling.

2. Obtain copies of the product labeling that is the subject of the approval

The TAD personnel will obtain copies of the approvable labeling from the duplicate or triplicate submission copies of the sponsor submitted (A)NADA

to populate the Volume 0. If such a copy is not available, the TAD personnel may remove a copy from the original copy of the submission PROVIDED at least one complete set of the submitted labeling remains in the original copy of the submission to maintain a complete administrative record of the labeling components.

3. Permanently mark each component of labeling (as described above in section IV.B.2) that will replace an existing component or that will be newly added,

4. Place each revised or added labeling component in the plastic sleeve,

5. Complete the LLCC for each labeling component revised or added,

   If the LLCC is full, create an additional page for the LLCC. Keep all existing pages with each component.

6. If necessary, create a labeled tab for each new labeling component added,

7. If necessary, update the TOC,

   Make the appropriate changes to the electronic file (see section IV.B.4 for the name and location of the file). Save the updated TOC with the same filename to your personal network drive and print a copy of the updated TOC for Volume 0. Destroy the outdated paper copy of the TOC from Volume 0.

   You should forward the edited TOC template file to the DCU along with the other electronic files as part of finaling out the submission. Delete the templates from your personal network drive after the submission is finaled out.

   ONADE's R:\Drive administrator will replace the application-specific TOC template file that contains NADA specific TOC to the root directory of the application for ONADE on the R:\Drive as part of the finaling out process.

8. Assemble Volume 0

   The TOC is the first page. Each labeling component (consisting of the labeled tab, the completed LLCC, and the corresponding labeling component in a plastic sleeve) follows in the order established in section IV.B.5. If the sponsor no longer markets a labeling component, do not remove tab or the

LLCC. Indicate on the LLCC and labeling component that the component is no longer marketed and the date of the supplement supporting this decision. Assemble and collate as necessary for each revised or added labeling component, the labeled tab, the LLCC, and the corresponding labeling component.

9. Ensure the outdated labeling components are destroyed

   Only current labeling will reside in Volume 0 and will replace older versions of the same labeling component. Old versions of that same labeling component that are being replaced will be destroyed. Collect and bind the outdated labeling components replaced by the current approval and mark them as such so that DCU can destroy them when the final action package is forwarded.

10. Annotate the ONADE Final Action Form

    In the "Comments/Instructions to DCU" box, identify from which copy of the submission the copy of the labeling components were removed. Indicate that you are returning obsolete labeling components that are to be destroyed.

V. REFERENCES

CVM Program Policy and Procedures Manual

1243.3800, Approval process and approval package

1243.6020, Review of NADA and ANADA labeling supplements

1243.6030, Review of labeling changes in manufacturing supplements

VI. VERSION HISTORY

August 23, 2007 – Original version

APPENDIX 1. LOG OF LABELING COMPONENT CHANGES (LLCC)

(A)NADA* *XXXXXX*

Log of Labeling Component Changes for *insert name or type of labeling component here*

Submission Identification for Most Recent Component (e.g. G0002)	Name of Individual Updating Component's Labeling	Date Labeling Component is added/replaced

**If applicable, include the A for an ANADA. If the A is not applicable, delete the A.*

APPENDIX 2. TABLE OF CONTENTS (TOC)

Table of Contents*

(A)NADA** *XXXXXX* Labeling Components

(Use this TOC for dosage form products)

I. Package Insert or Label Outsert (package insert attached to the vial or container)

II. Patient or Client Information

III. Container Size – xxx xxxxxxxx (*specify; e.g., 55 gal. drum, 250 mL bottle, foil pouch, etc.*)

   A. Immediate Container Label

   B. Carton Label

   C. Shipping Label

IV. (Repeat III for each container size)

V. Other Component (*please specify, separate tab for each, e.g., client information sheet*)

**CSOs are to use their judgment on how best to organize the Volume 0. Strict adherence to the template is not necessary; however, our objective is consistency between similar products.*

***If applicable, include the A for an ANADA. If the A is not applicable, delete the A.*

If less than all of the approved products labeling are use to create Volume 0, then the CSO should note that at the bottom of the TOC and include a printed copy of the approved products under this (A)NADA obtained from the Drug Products Listing (DPL) database.

Table of Contents*

(A)NADA *XXXXXX* Labeling Components

(Use this TOC for medicated feed products)

I. Type A Medicated Article Label

II. Type B Medicated Feed Label (Bluebird Label)

III. Type C Medicated Feed Label (Bluebird Label)

**CSOs are to use their judgment on how best to organize the Volume 0. Strict adherence to the template is not necessary; however, consistency between similar products is desired.*

If less than all of the approved products labeling are use to create Volume 0, then the CSO should note that at the bottom of the TOC and include a printed copy of the approved products under this (A)NADA obtained from the Drug Products Listing (DPL) database.

Table of Contents*

(A)NADA *XXXXXX* Labeling Components

(For medicated feed products)

I. PROPRIETARY NAME

A. Type A Medicated Article Label
- *List all applicable labels*

B. Type B Medicated Feed Label (Bluebird Label)
- *List all applicable labels or put "None" if not applicable*

C. Type C Medicated Feed Label (Bluebird Label)
- *List all applicable labels with descriptors if needed*

II. PROPRIETARY NAME

A. Type A Medicated Article Label
- *List all applicable labels*

B. Type B Medicated Feed Label (Bluebird Label)
- *List all applicable labels or put "None" if not applicable*

C. Type C Medicated Feed Label (Bluebird Label)
- *List all applicable labels with descriptors if needed (e.g., species, if multiple Proprietary names. Designate the Proprietary name associated with each Type C medicated feed label).*

**CSOs are to use their judgment on how best to organize the Volume 0. Strict adherence to the template is not necessary; however, consistency between similar products is desired.*

If less than all of the approved products labeling are use to create Volume 0, then the CSO should note that at the bottom of the TOC and include a printed copy of the approved products under this (A)NADA obtained from the Drug Products Listing (DPL) database.