OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

NOTIFYING SPONSORS WHEN APPROVED SUPPLEMENTAL LABELING CHANGES IN AN UPSTREAM DRUG APPLICATION ((A)NADA) APPROVED FOR USE IN OR ON ANIMAL FEED WILL REQUIRE REVISIONS TO APPROVED DOWNSTREAM LABELING COMPONENTS

I. Purpose 1
II. Definitions 2
III. Background and scope 2
IV. Labeling changes that may impact a downstream drug application or file 3
V. Identifying downstream drug applications and files 4
VI. Notifying downstream divisions of potentially impactful labeling changes 8
VII. Confirming impactful changes to downstream drug applications and notifying osc 9
VIII. Drafting the prospective change letter and notifying impacted sponsor(s) 10
IX. Following up on the prospective change letter 11
X. References 12
XI. Version history 12
Appendix 1. Flowchart of the process 13

I. PURPOSE

This document establishes procedures for the Office of New Animal Drug Evaluation (ONADE) to consider when supplemental changes to labeling for an approved new animal drug administered in or on feed and subject to 21 CFR 558 (i.e., medicated feeds) may impact other applications or files. Specifically, the procedures encompass the determination of whether the labeling change(s) in the approved parent new animal drug application (NADA) or reference listed new animal drug (RLNAD) application (i.e., upstream drug application) might impact labeling components in any related NADA, abbreviated new animal drug application (ANADA), or veterinary master file (VMF) (i.e., downstream drug application(s) or file(s)) that incorporate the upstream drug application by reference. This document outlines the following steps in this assessment:

- how to identify the type of changes to labeling in upstream drug applications or files that may impact approved labeling components in any related downstream drug application or VMF;
- how to identify whether any related downstream drug application or file exists;
- how the target animal division (TAD) processing the supplemental approval for the upstream drug application will use Appian® and the Downstream Labeling Changes Tracker to notify divisions of labeling changes that may be impactful to approved labeling in any downstream drug application or file;
- how the notified division(s) responsible for evaluation of the downstream drug application or file will confirm that impactful labeling changes exist and how they will use the Downstream Labeling Changes Tracker to notify the Office of Surveillance and Compliance (OSC) that a prospective change letter should be prepared and sent to a sponsor; and

- how the TAD processing the supplemental approval for the upstream drug application will notify the sponsor that changes are required to previously approved labeling maintained in a VMF.

This document also establishes procedures for how the OSC will notify sponsors of prospective changes to their labeling.

II. DEFINITIONS

1. **Upstream drug application:** The new animal drug application (NADA) being changed and upon which one or more related downstream approvals is based. Generally, an upstream drug application may be considered:

    - the parent NADAs incorporated by reference to support approval of a non-fixed ratio of two or more new animal drugs administered in or on feed (e.g., Animal Drug Availability Act of 1996 (ADAA) medicated feed-use combinations);
    - the application serving as the RLNAD for an ANADA; and/or
    - the NADA that holds the approval for medicated feed labeling that is maintained in a VMF.

2. Downstream **drug application (or file):** The NADA, ANADA, or VMF that is directly affected by changes made to the parent NADA or RLNAD (i.e., upstream drug application). For the purposes of this document, a downstream file may be considered:

    - an NADA that includes two or more Type A medicated articles in a non-fixed ratio combination;
    - an ANADA; and/or
    - and a VMF that maintains approved medicated feed labeling.

3. Upstream **target animal division (TAD)**: The division responsible for review of labeling submitted to an upstream drug application.

4. Downstream **division**: The division responsible for review of labeling submitted to a downstream drug **application** or file.

III. BACKGROUND AND SCOPE

The Center for Veterinary Medicine (CVM) is responsible for the approval of labeling for animal drugs and determines when labeling components are in or out of compliance with current laws, regulations, and policies. Once approved, it is the responsibility of the sponsor to ensure that approved labeling components within each of their applications and files are up to date. This includes ensuring that labeling components in their NADAs for medicated feed-use combinations, ANADAs, and/or VMFs are in alignment with approved labeling in each of the individually approved NADAs that serve as the parent application or RLNAD. However, without a process in place for CVM to notify sponsors of supplemental labeling changes recently approved in an upstream drug application, the approved labeling maintained in downstream drug applications (in particular those for medicated feeds) historically have not reflected the most up-to-date information. In some

cases, this has led to the availability of outdated, incorrect, and misleading new animal drug labeling in the marketplace.

The following process is intended to provide a pathway for CVM to notify the sponsors of downstream drug applications and files of labeling changes in upstream drug applications that are pertinent to their downstream labeling.

Given the significant number of new animal drug labeling submissions under CVM's purview, this will undergo an initial test period from October 2024 through September 2025. Applications that involve new animal drugs administered in or on feed will be the target of the test period. Upon conclusion of the test, the success of the process will be evaluated, and a determination made as to whether the process will be expanded to labeling for other new animal drug products.

IV. LABELING CHANGES THAT MAY IMPACT A DOWNSTREAM DRUG APPLICATION OR FILE

Labeling changes that occur under a supplemental application (major supplemental approval (subclass code B1)), a "changes that may be effected immediately" (CBE) labeling supplement (subclass code NL),[1] a prior approval non-fee labeling supplement (subclass code NF),[2] and labeling changes made in a Chemistry, Manufacturing, and Controls (CMC) supplement[3] may impact downstream drug applications or files.

Generally, any labeling change associated with a change to the conditions of use, to safety-, effectiveness-, or CMC-related text, or that adds or deletes labeling components may be potentially impactful to a downstream drug application or file.

The following examples include changes to one or more labeling and related components (e.g., veterinary feed directive (VFD)) in the upstream drug application that are potentially impactful and will require the downstream division(s) to be notified.

- Addition or withdrawal of a VFD.
- Change in marketing status.
- Changes to the approved conditions of use[4], including:
    - Changes to limitations such as cautions, warnings, etc.
    - Changes to directions for use, including dosage level, duration, route of administration, or directions for mixing and feeding/administration.
    - Addition or modification of the indication(s).[5]
    - Withdrawal of approval of an indication(s) or species or class.

[1] See P&P 1243.6020 for more information on NL supplements.
[2] See P&P 1243.6040 for more information NF supplements.
[3] See P&P 1243.6030 for more information on labeling changes in manufacturing supplements.
[4] The downstream divisions should be notified even if marketing exclusivity has been granted for approval of the change. Though the sponsor of an impacted ANADA will not be able to make the change to the product labeling immediately, the sponsor of an NADA for a medicated feed-use combination may be able to do so. The downstream divisions will determine if any additional action is needed.
[5] If Patents or Marketing Exclusivity prohibit the ANADA from adding the change, then DGAD does not need to be notified.

- Changes, additions, or deletions to existing text that may not be directly related to conditions of use that affects effectiveness, target animal safety, user safety, or human food safety.
- Formulation, expiry dates or storage information.[6]
- Changes to the established name.
- CVM initiated changes, including those requested by OSC.

The following examples include changes to one or more labeling and related components in the upstream drug application that will not require the downstream division(s) to be notified.

- Changes to sponsor-specific information.
- Changes in proprietary name.
- Changes to trade dress.
- Changes in existing graphics or addition of new graphics.
- Addition or withdrawal of a "special" labeling component that is substantially different from existing labeling components (e.g., new container size), so long as it does not impact safety (e.g., medication errors).
- Changes that have resulted in the granting of marketing exclusivity.

V. IDENTIFYING DOWNSTREAM DRUG APPLICATIONS AND FILES

If the supplemental application for a new animal drug administered in or on feed is going to be approved, the reviewer of the supplemental application in the upstream TAD will be responsible for determining whether any downstream drug applications or files exist. The reviewer in the upstream TAD should begin completing this step by no later than when their draft review[7] or draft approval package,[8] as appropriate, begins the first round of the division review of the consulting review or draft approval package (i.e., division quality control process). If one or more downstream drug applications or files are identified, the upstream TAD reviewer is responsible for determining whether the changes made to labeling components in the current submission may be impactful to labeling in the downstream drug applications or files identified.

A. Identifying Downstream Drug Applications (NADAs and ANADAs)

1. The upstream TAD reviewer should complete a search of the Submission Tracking and Reporting System (STARS) and Animal Drugs @ FDA[9] (ADAFDA) to determine if any approved downstream new animal drug applications are associated with the upstream application.

[6] DGAD only needs to be notified of such labeling changes if they will impact the effectiveness of an ANADA, are based on newly identified safety concerns, or are the result of CVM-requested changes.
[7] If the TAD is consulted to review labeling submitted under a CMC supplement.
[8] If the TAD is assigned the primary submission (STARS package ID "AA") and will complete a review of the labeling submitted under any supplement type other than a CMC supplement.
[9] https://animaldrugsatfda.fda.gov/adafda/views/#/search

First, search for referenced applications.

a. Navigate to the “Document Overview” option in STARS, include the “Document Type” and “Document Number” associated with the upstream application, and select “Find”.

b. Determine whether any (A)NADAs are listed in the “Reference Documents” section of the resulting page. For each (A)NADA listed, verify that the drug used in the upstream application is the same drug as in the downstream drug application by STARS and/or ADAFDA:

    1. In STARS: Using the “Document Overview” option, include the “Document Type” and “Document Number” associated with the downstream new animal drug application, and select “Find”. In the resulting page, confirm that (at least one of) the active ingredient(s) listed in the “Chemical” section is the same as the chemical in the upstream new animal drug application.

        Note: It may also be useful to select the last supplemental approval containing labeling from the “List of All Submissions” for the downstream drug application. Open the Memorandum Recommending Approval (MRA) and review the document to confirm that the upstream new animal drug application is listed as the parent or RLNAD of the downstream new animal drug application.

    2. In ADAFDA: Include the (A)NADA number of the downstream drug application in the search bar and review the product description to verify that it is the same drug as in the upstream application.

2. Once a “Referenced Documents” check has been completed in STARS, next verify that no other approved downstream new animal drug applications are associated with the upstream new animal drug application in both STARS and ADAFDA.

    a. In STARS: Using the “Document Search” option, include the active ingredient of the upstream new animal drug application in the “Chemical” section. When completing this search and if applicable, it is recommended that the salt form be excluded from the search terms to ensure that all possible downstream drug applications are identified during the search (e.g., searching “tylosin” will bring up results for “tylosin”, “tylosin phosphate”, and “tylosin tartrate”).

    b. In ADAFDA: Include the active pharmaceutical ingredient of the upstream new animal drug application in the search bar.

        If additional (A)NADAs are identified beyond those listed in the STARS “Referenced Documents” for the upstream drug application, use STARS to identify and review an MRA for a previous approval from the “List of All Submissions” for the downstream drug application to confirm that the upstream drug application is confirmed to be the parent or RLNAD of the downstream drug application.

        In addition, if the “Referenced Documents” section of STARS for either the upstream or downstream drug application includes an incorrect reference or

excludes a correct reference, then STARS should be updated to improve the accuracy of information. If the reviewer does not have STARS editing privileges, then the reviewer should submit a list of identified corrections to the EDSR Mailbox (Internal information redacted.

If the upstream TAD reviewer is uncertain about the existence of a downstream drug application, they should communicate with the appropriate downstream division(s) for help.

3. If the upstream TAD reviewer determines that 1) there are no downstream drug applications relative to the upstream drug application, or 2) the changes made to the labeling and related components of the upstream drug application do not impact the downstream drug application(s), no further action is required.

   If, however, downstream drug applications are identified and considered to be impacted by the changes to the upstream drug application, the upstream TAD reviewer will follow the steps outlined in Sections V.A.3 and VI of this document.

4. For each downstream drug application determined to contain labeling and/or related components that may need to be updated, the reviewer in the upstream TAD will identify and include the following information in the Downstream Labeling Changes Tracker.[10]

   a. Information for the upstream drug application:

      - application number;
      - supplement number for the updated labeling;
      - drug product information, formatted as: Product proprietary name<®™> (product established name) dosage form;[11]
      - sponsor of application;
      - whether the labeling changes were submitted in response to a prospective change letter;
      - a high-level list of the type(s) of labeling components updated as part of the pending approval (for example, if all labeling components are affected, include “all labeling components”, or if only a couple labeling components are affected, provide the name of the components, such as the names listed on a Type C medicated feed blue bird label);
      - a high-level list of potentially impactful changes (this information will be used for internal purposes only and is intended to support the

[10] The Internal information redacted. is located within the CVM Intercenter Consult Request (ICCR) Workspace and is accessible by members of both ONADE and OSC. Since this process is not formally assigned in any CVM databases (e.g., STARS), keeping the Downstream Labeling Changes Tracker up-to-date offers both ONADE and OSC reviewers the ability to identify the current status of any downstream labeling change notification currently in progress.

[11] For medicated feed-use combinations, see P&P 1243.5762 (section VII) for the formatting of the drug product information. For all other drug products, see P&P 1243.3015 for the formatting of the drug product information.

downstream reviewer in identifying the presence and/or impact of the changes on the downstream labeling); and

- CVM due date for the supplemental approval.

b. Information for the affected downstream drug application:

- impacted product type (i.e., ANADA for a Type A medicated article (single drug generic), NADA for a medicated feed-use combination (pioneer combination), or ANADA for a medicated feed-use combination (generic combination));
- application number;
- drug product information, formatted as: Product proprietary name<®,™> (product established name) dosage form;[12]
- sponsor of application; and
- a high-level list of the labeling components that may be impacted by the changes made to the upstream labeling components. For example, if all labeling components are affected, include "all labeling components"; or if only a couple labeling components are affected, provide the name of the components, such as the names listed on a Type C medicated feed Blue Bird label.

B. Identifying Downstream Drug Files (VMFs)

Though the approval of labeling occurs under the NADA of the upstream (parent) Type A medicated article, medicated feed labeling may be maintained in a VMF due to differences in sponsorship of two products/files. For such scenarios, CVM has determined that it is the responsibility of the upstream sponsor to notify the VMF holder of recently approved labeling changes and of the VMF holder's responsibility to ensure that their medicated feed labeling aligns with the approved Type A medicated article label.

When CVM intends to approve supplemental changes to Type A medicated article labeling and the Volume 0[12] for that application identifies one or more VMFs containing approved medicated feed labeling (e.g., proprietary free choice medicated feed labeling), the upstream TAD reviewer should ensure the following paragraph is transmitted to the sponsor in the supplemental approval letter:

"This supplemental approval provides for changes to the Type A medicated article label(s) that may directly impact medicated feed labeling approved under NADA xxx-xxx and maintained under a separate veterinary master file (VMF) that is held by another entity. We remind you of your responsibility to inform the holder of each VMF

[12] In support of the success of the process outlined within this document, all VMFs containing previously approved medicated feed labeling were identified and Volume 0s for those VMFs were created. The Table of Contents (TOC) tab within the Volume 0 for each VMF indicates the NADA(s) that hold the approval for the Type A medicated article(s) intended for use in preparation of the proprietary medicated feed. In addition, the TOC tab within the Volume 0 for each NADA that holds an approval for medicated feed labeling that is maintained in a VMF was updated to reference the applicable VMF(s). Therefore, the Volume 0 of the Type A medicated article subject to the current supplemental approval is the only place the upstream TAD reviewer will be expected to check for identification of any downstream VMFs.

of the approved changes described in this letter. If corresponding changes are warranted to the medicated feed labeling, the VMF holder should submit updated feed labeling to their VMF. At the same time, you should submit a minor labeling supplement (NF subclass code) to NADA xxx-xxx to request approval of the labeling submitted to the VMF."

VI. NOTIFYING DOWNSTREAM DIVISIONS OF POTENTIALLY IMPACTFUL LABELING CHANGES

While finalizing the primary submission (STARS package ID "AA") review in Appian®, the reviewer of the submission containing potentially impactful labeling will notify the downstream division(s) by selecting the appropriate options on the Additional Actions screen in Appian®. If the reviewer indicates that the submission contains acceptable labeling and the labeling is maintained in an NADA, then they will select the following option:

1. "This submission includes the approval of changes to Type A medicated article labeling, medicated feed labeling (e.g., Blue Bird or branded), and/or VFD(s). (Selecting this option will notify HFV-120 *(now HFV-130)* and HFV-170 that changes to the labeling may impact downstream combination and/or generic product labeling.)"

   Note that selection of this prompt will send an email to points of contact in both the Division of Food Animal Drugs (DFAD; HFV-130) and the Division of Generic Animal Drugs (DGAD; HFV-170).[13] The email will state: "This submission includes the approval of Type A medicated article labeling, medicated feed labeling (e.g., Blue Bird or branded), and/or VFD(s). You are being notified because the approved changes under this submission may impact one or more applications reviewed by your division, requiring changes to downstream combination and/or generic labeling. Please review and take any further action as required."

Note that at this time there is an additional prompt available, "This submission includes the approval of changes to the labeling of an NADA for a medicated feed-use combination. (Selecting this option will notify HFV-170 that changes to the labeling may impact labeling.)" Selection of this prompt will send an email to DGAD. Under the test period, the process described within this document only applies to applications that involve new animal drugs administered in or on feed. Selection of this prompt will not elicit further action by DGAD during the test period.

If the approval may have effects on labeling of downstream drug applications reviewed by divisions other than DFAD and/or DGAD, the reviewer may identify other person(s) to be notified by selecting other options on the Additional Actions screen in Appian® (e.g., selecting "Do you want to notify someone else that this submission has been closed?" will allow the reviewer to identify one or more additional persons of the submission being closed). If the reviewer is not sure of the specific downstream reviewer to notify, the reviewer should indicate the leader of the appropriate downstream team (or if necessary, the downstream division's director).

[13] Current points of contact for Appian are identified in P&P 1243.3200.

VII. CONFIRMING IMPACTFUL CHANGES TO DOWNSTREAM DRUG APPLICATIONS AND NOTIFYING OSC

1. When the downstream division points of contact have received the email from Appian®, a reviewer in the downstream division will be assigned the responsibility of confirming whether changes made to the labeling components of the upstream drug application are impactful. The assignment will be made informally (i.e., outside of STARS) following the impacted division's internal processes, and a determination will be made within 30-days of assignment.

2. The reviewer in the downstream division will review the information in the Downstream Labeling Changes Tracker relative to the submission number identified in the email from Appian® to determine if the changes apply to the downstream drug application(s).

3. The reviewer in the downstream division will review the MRA associated with the approved labeling supplement identified in the Downstream Labeling Changes Tracker to review the specific labeling changes made. If appropriate, the reviewer may also review the individual labeling components recently approved in the upstream application.

4. Following a review of the labeling changes, the reviewer in the downstream division will determine whether the changes made to the labeling components of the upstream drug application are impactful and should be relayed to the sponsor(s) of the downstream drug application(s).

5. For each downstream drug application identified as relative to the submission number identified in the email from Appian®, the reviewer will include the following information in the Downstream Labeling Changes Tracker.

    a. An impact determination.

        1. If the labeling changes in the upstream application are not impactful to the labeling in the downstream application, select "No". If "No" is selected, then the process is complete, and no additional action is necessary.

        2. If the labeling changes in the upstream application are impactful to the labeling in the downstream application, select "Yes". If the changes are impactful, select "Yes". If "Yes" is selected, the reviewer in the downstream division will continue with the next step.

    b. If "Yes" is selected for the impact determination, then the reviewer will also include appropriate contact information for the downstream division, based on division practices:

        1. Division name;

        2. Division point of contact for inquiries relative to the letter (typically the team leader), including name and email address; and

        3. Email address for members of the downstream division (in addition to the division point of contact; typically includes the reviewer) that should be

involved in the QC of the draft prospective change letter to confirm the accuracy of the information.

Once the spreadsheet is complete, the reviewer in the downstream division will use the prompts in the Downstream Labeling Tracker to notify the OSC of the need for a prospective change letter to be sent to the sponsor.

VIII. DRAFTING THE PROSPECTIVE CHANGE LETTER AND NOTIFYING IMPACTED SPONSOR(S)

1. Once the OSC reviewer[14] receives the notification, they will review the Downstream Labeling Tracker to identify the sponsor(s) of the application(s) for which a prospective change letter will be prepared. Then, they will access STARS to identify the appropriate sponsor point of contact information for each impacted downstream drug application and will include the sponsor contact information in the Downstream Labeling Changes Tracker.[15]

2. The OSC reviewer will use the information in the Downstream Labeling Changes Tracker to select the appropriate template (i.e., single-drug generic, pioneer combination, or generic combination) to draft a prospective change letter.

   The reviewer will include the ONADE point of contact for letter in both the closing paragraph and electronic carbon copy (eCC) section of the letter.

3. A draft copy of the letter will be shared via the CVM Intercenter Consult Request (ICCR) Workspace.[16] Once a draft copy of the letter has been placed in the "Downstream Labeling Change Notifications" folder, an email will be sent to the ONADE contact(s) identified in the ONADE Contact Information section of the Downstream Labeling Changes Tracker requesting that they ensure that all information included in the letter is accurate.

4. Once the OSC reviewer has received concurrence from the ONADE point(s) of contact, and the letter is in its final version, the OSC reviewer will convert the letter to PDF and acquire a signature from the Director of the Division of Pharmacovigilance and Surveillance.

5. The OSC reviewer will email an electronic copy of the signed letter to the sponsor using the Division of Surveillance email box.

6. To ensure that the ONADE downstream division is aware that the letter has been sent, a copy of the signed letter will be emailed to the individual identified as the point of contact for the letter.

7. The OSC reviewer will also send a copy of the signed letter to the DCU mailbox (HFV-199@fda.hhs.gov) to be logged into the virtual drug experience report (vDER) folder ("Other" section of the DER module in STARS) with a purpose code – "Prospective Change Annual".

[14] The OSC reviewer is located within the Division of Pharmacovigilance and Surveillance. Carly Oeller (Carly.Oeller@fda.hhs.gov) is the current contact.

[15] This information may be found in the Drug Development section of STARS. If there are any questions, consider contacting the ONADE project manager for the application.

[16] Internal information redacted.

Once logged into the vDER database, the letter will be available for viewing by anyone in CVM.

8. The OSC reviewer will update the "Prospective Change Letter" section of the Downstream Labeling Changes Tracker to identify:

    - The date the prospective change letter was sent to the sponsor.

    - The date the prospective change letter was sent to DCU for inclusion in the vDER.

IX. FOLLOWING UP ON THE PROSPECTIVE CHANGE LETTER

The prospective change letter informs the sponsor of a downstream drug application of the recommendation to contact the downstream division within 30 days if clarification is needed regarding the specific required revisions to the labeling or the administrative process to submit the supplemental application to ONADE. If the firm contacts the downstream division in ONADE for information regarding the specific required revisions, the assigned reviewer will rely on the MRA in the upstream drug application to identify the specific labeling changes, as well as the labeling components impacted by these changes. If appropriate, the reviewer may share a copy of any approved, non-proprietary labeling with the sponsor of the downstream drug application. As a reminder, most Blue Bird labeling for Type B and Type C medicated feeds are non-proprietary and are made publicly accessible at ADAFDA soon after the approval.

The prospective change letter also informs the sponsor that they will have 60 days to comply with the prospective change letter. CVM will consider the sponsor to have complied with the letter when the amended labeling has been submitted to the downstream division in ONADE.

1. Once the labeling submission is received, the downstream reviewer assigned to evaluate the supplemental application will update the Downstream Labeling Changes Tracker with the following information:

    - The submission number for the labeling supplement.

    - The date the labeling supplement was received.

2. The reviewer will also update the STARS Review Summary to include: "The effect of the supplement is to align the labeling with changes made to labeling approved in the <*insert either: parent NADA or RLNAD*>, XXX-XXX." Additional details may be incorporated in the Review Summary, if appropriate.

Upon updating the Downstream Labeling Changes Tracker and STARS Review Summary, the process is considered complete.

X. REFERENCES

CVM Policies and Procedures Manual – ONADE Reviewer's Chapter

1243.3015 – Proprietary Names

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

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

1243.5741 – MRA for Original and Supplemental (A)NADAs

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

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

1243.6030 - Review of Labeling Changes in Manufacturing Supplements

1243.6040 - Review of Abbreviated and New Animal Drug Application 60- and 180-Day Non-fee Prior Approval Labeling Supplements

ONADE Standard Operating Procedures

1240.106.004 – Office of New Animal Drug Evaluation's Intra- and Intercenter Consult Request (ICCR) Process

Other

CVM Electronic Document Submission and Review (EDSR): CVM ONADE Final Action/Consult Return Application in Appian® User Guide

CVM Downstream Labeling Changes Tracker

XI. VERSION HISTORY

March 29, 2024 – Original version.

April 1, 2024 – Corrected a typographical error in a heading and add the appendix with the flowchart.

APPENDIX 1. FLOWCHART OF THE PROCESS