OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

TRANSFER OF OWNERSHIP

I. PURPOSE

This document describes how to document and process submissions for notifications of transfers of ownership of (abbreviated) new animal drug applications [(A)NADAs], (generic) investigational new animal drug [(J)INAD] files, general correspondence (GC) files, and veterinary master files (VMFs). These procedures also apply to transfers resulting from corporate mergers and acquisitions.

II. GENERAL INFORMATION

CVM recognizes that changes of ownership may occur as the result of ordinary business decisions, changes in corporate structure, or changes in corporate ownership, among other things. However, sponsors must appropriately notify CVM of these changes so that the accuracy of our official records can be maintained (see 21 CFR 514.8 and 21 CFR 514.106). The Business Informatics (BI) Team in the Office of New Animal Drug Evaluation (ONADE) processes all transfers of ownership of applications or files. The ONADE Office Director is the signature authority for these types of submissions.

III. HOW TRANSFER OF OWNERSHIP SUBMISSIONS ARE CODED IN OUR SUBMISSION TRACKING AND REPORTING SYSTEM (STARS) DATABASE

Transfer of ownership submissions for approved (A)NADAs are coded as supplements (C), per 21 CFR 514.106(b)(1)(iii) and are assigned the AD (Administrative Requests) subclass code. Transfer of ownership submissions for pending (A)NADAs and all other file types are coded as general correspondence (G) submissions and are also assigned the AD subclass code.

IV. HOW SPONSORS SUBMIT TRANSFER OF OWNERSHIP SUBMISSIONS

A. Electronically

Sponsors can submit transfer of ownership submissions electronically for one of their files or applications, more than one, or all of them. If a sponsor transfers ownership of an approved (A)NADA that references data in a (J)INAD but does not transfer

ownership of that (J)INAD file or provide right of reference to it, the new owner's ability to change the product and market it in the future may be limited.

When transferring an approved application, sponsors need to use either the N-C-AD or A-C-AD template in eSubmitter. If a sponsor wishes to transfer an additional file or application along with the approved application, they can create a linked submission using these templates. Creating and submitting linked submissions allows a sponsor to submit the same information to multiple applications without having to create multiple submissions in eSubmitter. The linked submission must also be an approved application because these are all coded as supplements. Otherwise, they need to create a separate submission for the transfer of any file or pending (A)NADA. Sponsors can submit linked submissions for the transfer of pending (A)NADAs using the A-G-AD or N-G-AD template. They can also submit linked submissions for all other file types using either the I-G-AD, J-G-AD, G-G-AD or V-G-AD eSubmitter template.

The BBI Team provides excel spreadsheets that contain approved and unapproved documents, respectively, for the sponsor(s). In instances of transfer of ownership, each sponsor must submit two submissions for the transfer of ownership and the name change. For approved products, this will be a C submission and for unapproved products, a G submission. STARS is updated within two business days of the submission being finalized. Animal Drugs @ FDA (ADAFDA) is updated the month after the transfer is completed in STARS.

When sponsors create their transfer of ownership submission in eSubmitter, they need to identify the name of the new sponsor and include their contact information. In addition, the sponsor must check a box stating; "1) All rights to the file(s) and/or application(s) (INAD, JINAD, GC, VMF, NADA, ANADA) identified in the submission are transferred, and 2) You will provide the New Owner a copy of the submission notifying the FDA of the transfer of ownership of these file(s) and/or application(s)." Lastly, the sponsor needs to attach a letter from the new sponsor indicating that it accepts ownership of the application or file.

B. Paper

Sponsors can also submit transfer of ownership submissions in paper (per P&P 1243.3002) under limited circumstances. If a sponsor would like to submit a transfer of ownership in paper, they should contact ONADE to determine if paper is acceptable. If a sponsor is transferring more than one file, it can provide a list of the files that are being transferred rather than submitting multiple submissions. As stated above, if the sponsor transfers ownership of an approved (A)NADA that references data in a (J)INAD, but does not transfer ownership of the underlying (J)INAD file and/or provide right of reference to it, the new owner's ability to change the product and market it in the future may be limited. The (transferor) sponsor must provide the name of the new (transferee) sponsor and the name and contact information of an individual authorized to speak for the new owner about the transfer of ownership. The new sponsor also needs to submit a letter stating that it accepts ownership of the file(s). Alternatively, the transferor sponsor may include the acceptance letter from the new sponsor in their submission.

V. MEETING TO PLAN FOR LARGE TRANSITIONS

When there will be large transfers of ownership, such as mergers, acquisitions, or spin-offs of companies where a significant number of approved products will transfer from one sponsor or entity to another, ONADE has a process to facilitate the changes. In these circumstances, ONADE recommends that the affected sponsors request a meeting to discuss the upcoming changes before submitting the transfer request(s). The meeting request will be a Z submission with a meeting type of OO (i.e., Other ONADE Meetings).

The assigned ONADE project manager (PM) for the sponsor is the primary reviewer for pioneer Z submissions and is responsible for facilitating the meeting and following up on any action items. The PM schedules and prepares for the meeting following the procedures for OO meetings described in P&P 1243.3024.

A. Facilitate the Request

The meeting request is made via eSubmitter and submitted to a GC file. If the sponsor does not already have a GC file, they first submit a request to establish a GC file, followed by the meeting request. Any of the impacted sponsors may request the meeting (i.e., either the acquiring or acquired company may initiate the request). Ideally, all impacted sponsors attend the meeting to discuss the transfer. The meeting request should include the following information:

- which sponsor name(s), labeler code(s), and DUNS number(s) will be retained or replaced;
- plans for maintaining or updating electronic accounts [Electronic Submission Gateway (ESG) and Electronic Submission System (ESS)], including email addresses and digital signatures/certificates;
- impacts on manufacturing facilities and approved product marketing (is the sponsor going to transfer, sell, or withdraw redundant products?);
- proposed labeling updates for approved products resulting from the transfer (e.g., trade dress, “manufactured by” statement), the proposed schedule for submitting labeling supplements [ONADE requests that sponsors plan to submit labeling supplements in batches of no more than 10 supplements per target animal division (TAD) each month following the transfer], and whether any products will require more extensive labeling revisions, including the addition of the “Approved by FDA” statements to labeling required by September 30, 2023;
- proposed plan for the sequence of events and associated timeframes for the transition and proposed submissions. This allows CVM to address user fee considerations;
- pharmacovigilance plans, including how calls and updates will be handled for products that have transitioned from one sponsor to another; and
- specific questions for CVM regarding the transition process.

B. Identify Participants and Send Consults

Upon submission receipt, the ONADE PM reviews the submission to determine who will be invited to and receive consults for the meeting. Typically, the following staff is included in the meeting.

- ONADE participants include:
  - the sponsor's assigned PM;
  - a BI Team member to discuss the logistics of transfer of ownership (e.g., impact on STARS, ADAFDA and electronic submission accounts);
  - a Division of Manufacturing Technologies member to discuss manufacturing site changes; and
  - one representative from each impacted TAD to discuss plans for transitioning from old to new labeling.
- Office of Surveillance and Compliance (OSC) participants include:
  - a member of the Marketed Product Information Team in the Division of Veterinary Product Safety (DVPS) to handle labeler code, drug listing, and DUNS number updates;
  - a member of the Drug and Devices - Compliance Support Team in the Division of Drug Compliance to discuss plans for transitioning from old to new labeling and promotional materials;
  - a member of the Division of Food Compliance to field import questions;
  - a member of DVPS to discuss pharmacovigilance plans, if applicable; and
  - a member of the Division of Animal Food Ingredients to discuss labeling changes to approved animal feeds, if applicable.

C. Facilitation of the Meeting

The PM facilitates the meeting. The PM confirms all parties are present, start the meeting with a short introduction and then facilitates the discussion. Major points covered by the meeting participants may include but are not limited to the following items (this will be driven by the information and questions presented by the sponsor).

- Sponsors will transition to one labeler code, which is updated with the name and address of the acquiring sponsor. The sponsor must confirm all product(s) is out of their distribution warehouses before delisting the associated labeler code. The acquiring sponsor has to revise the current NDC Labeler Code Request SPL file with the new name and possible new DUNS number. The sponsor may contact SPL (spl@fda.hhs.gov) for questions about this process. The ONADE BI Team emails the Policy and Regulations Staff in the Office of the Director for changes requiring publication in the FEDERAL REGISTER (FR).
- Registered ESG users can continue to use their existing electronic submission accounts to submit to transferred files. If the email addresses associated with ESS

accounts are updated, users need send a single, original, signed change letter to CVM. They also need to update their digital signatures by submitting a new manage form per Guidance for Industry (GFI) #108 to the ESS coordinator. If ESG accounts will be updated, the sponsor should keep existing accounts active until they have received all responses to submissions sent through those accounts or amend those submissions to redirect them to the new accounts.

- Depending on the sponsors' circumstances, the sponsor name change could be the only visible change and not the actual location of the manufacturing site. The sponsors would have to update Common Technical Document CTD Section 3.2.P.3.1; Manufacture [name, dosage form]. DMT will let sponsors know when they can file the change(s) for their minor changes and stability report (MCSR). Appropriate CTD sections can be updated per discussion with DMT. The sponsor should be reminded that they are obligated to report any CMC changes, including site changes, per 21 CFR 514.8 and the recommendations in GFI #83.

- For any right of reference transfering from the current sponsor to a new sponsor, CVM needs a new letter granting right of reference to the new sponsor.

- If there are questions related to export certificates, direct the sponsor to email their questions to: CVMExportCertification@fda.hhs.gov.

- Typical labeling changes resulting from a transfer should be submitted as a minor labeling supplement (NL). Acceptable changes to be included in these supplemental applications include: a change in sponsor name, change in manufacturing site information, adding the "Approved by FDA" statement, adding antiparasitic statements, and any other changes that would normally fall under an NL supplement. If the sponsor has any changes beyond the scope of an NL, then they have to submit them in an NF supplement.

    - We advise sponsors to initially submit one NL supplement reflecting the change(s) so we can discuss and agree on trade dress changes that will be carried through the remaining labeling supplements.

    - Any outstanding agency-initiated changes to the currently approved labeling should be incorporated into the new labeling when the new labeling is submitted to CVM for review and approval. If the sponsor is in doubt about what to include or wishes to have additional discussion about the changes, they should ask to meet with the appropriate office before submitting a supplement for labeling changes.

    - For changes to the trade dress related to change in ownership, sponsors should be aware of P&Ps 1243.6020 and 1243.6040 and meet with ONADE if they have questions.

- User fees are assessed every fiscal year. Each sponsor that has an active investigational file [i.e., (J)INAD], pending application, or approved application is assessed a single sponsor fee. Product fees are assessed for each specific strength or potency of a particular active ingredient or ingredients in final dosage form marketed by a particular manufacturer or distributor, which is uniquely identified by the labeler code. Sponsors are assessed establishment fees for each

manufacturing site that is engaged in the manufacture of a new animal drug in a particular fiscal year.

D. Process the Documentation

The final action code for these meetings is FNR/MEMO. The PM will prepare a review summary which should capture the main points discussed with the sponsor in the meeting, and should be concurred on by the meeting attendees. The clearance chain consists of the project manager and their team leader.

VI. PROCESSING TRANSFER OF OWNERSHIP SUBMISSIONS

The ONADE BI Team processes the transfer of ownership submissions. If the submission is for an approved (A)NADA, the BI reviewer emails the Policy and Regulations Staff (HFV-6) in the Office of the Center Director to request that they draft a FR notice indicating the change of ownership. Transfers of ownership for all other files are not published in the FR. The BI reviewer drafts an acknowledgement letter to the sponsor stating that our records have been updated with respect to ownership of the application.

VII. FINALIZING THE TRANSFER OF OWNERSHIP SUBMISSION IN APPIAN

The final action code for transfer of ownership submissions is OWNER CHG; DOCUMENT OWNER CHANGE; LETTER SENT; FR PUBLICATION IF APPROPRIATE. The clearance chain consists of the reviewer on the ONADE BI Team and the ONADE Director (see P&P 1243.3030 for information on completing final action packages). The review summary should convey from whom and to whom the file or application is being transferred. Only an acknowledgement letter is sent to the sponsor (see P&P 1243.3010 for information on format and style conventions for letters). A review is not required, unless there is something pertaining to the transfer that needs to be retained in the administrative file. When the submission is finalized, the reviewer updates the sponsor name in STARS and Animal Drugs @ FDA (see P&P 1243.3900 for information on maintaining the Animal Drugs @ FDA Website and Green Book).

VIII. FOLLOW-UP ACTIVITIES FOR LARGE TRANSITIONS

Following a large transition, the PM ensures the sponsor provides regular forecasts of their planned labeling supplements. As stated above, these should be divided into batches of no more than 10 supplements per TAD each month following the transfer. The PM utilizes SOP 1243.180.424 to share these forecasts with the appropriate TADs. In order to properly plan for labeling supplements, the PM utilizes SOP 1243.180.325. Non-PMs utilize SOP 1243.186.002 to access information that the PM's have incorporated into the Sponsor's timelines.

OSC updates and merge the firms in the inspectional database to ensure accuracy for future surveillance inspection.

IX. REFERENCES

Code of Federal Regulations (Title 21)

21 CFR 514.8

21 CFR 514.106

Guidance for Industry

GFI #108 Registering with CVM's Electronic Submission System

GFI #83 Chemistry, Manufacturing and Controls Changes to Approved NADA/ANADA

CVM Program Policies and Procedure Manual – ONADE Reviewer's Chapter

1243.3010 – Format and Style Conventions for Letters

1243.3030 – Completing Final Action Packages for Submission Tracking and Reporting Systems (STARS) Submissions

1243.3900 – Updating the Animal Drugs @ FDA Website and Green Book

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

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

X. VERSION HISTORY

March 19, 2018 – Original version (supersedes P&P 1240.4150 Ownership Transfer or Corporate Identity Change of an Application and replaces P&P 1243.2340 Transfer of Ownership and Sponsor Name or Address Change Procedures in ONADE for NADA, ANADA, INAD, JINAD or VMF Submissions). The creation of this P&P is solely for transfer of ownership processing. There is also a new P&P that is solely for change of sponsor name and address processing (P&P 1243.2342).

May 18, 2018 – Updated to contain information about linked submissions.

January 7, 2021 – Updated to contain information about process surrounding the meeting to plan for large transitions and the follow up tasks after a large transition.

July 22, 2022 – Quality systems review for minor formatting updates.

May 24, 2023 - Quality system review conducted of the document and no updates or revisions were necessary at this time. To bring all office quality system documentation into compliance with the FDA Visual Identity Program approved fonts, ONADE has adopted Arial 11-point font. The font of this document was changed from Verdana 10-point font to Arial 11-point font.