
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

TRANSFER OF OWNERSHIP

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I. PURPOSE

This document describes our procedures for documenting and processing submissions for notifications of transfers of ownership of new animal drug applications (NADAs), abbreviated new animal drug applications (ANADAs), investigational new animal drug (INAD) files, generic investigational new animal drug (JINAD) 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.¹

The Business Informatics (BI) Team in the Office of New Animal Drug Evaluation (ONADE) processes all transfers of ownership of applications or files. The 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) submission classification 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 submission classification code.

¹ See 21 CFR 514.8 and 21 CFR 514.106

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 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.

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 when using eSubmitter. The linked submission must also be an approved application, because these will all be 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 files types using either the I/G/AD, J/G/AD, G/G/AD or V/G/AD eSubmitter template.

When sponsors create their transfer of ownership submission using eSubmitter, they need to identify the name of the new sponsor and include their contact information. In addition, the sponsor is required to 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 until October 1, 2018. 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 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. PROCESSING TRANSFER OF OWNERSHIP SUBMISSIONS

The BI Team is responsible for processing 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 FEDERAL REGISTER (FR) notice indicating the change of ownership. Transfers of ownership for all other files are not published in the FR. Also, the BI reviewer drafts an acknowledgement letter stating that our records have been updated with respect to ownership of the application.

VI. FINALIZING THE 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 BI Team and the ONADE Director (see P&P 1243.3030 for additional information on completing final action packages).² The review summary should convey from whom and to whom the file or application is being transferred. Only an acknowledgement letter is drafted and sent to the sponsor (see P&P 1243.3010 for more information on format and style conventions for letters).³ 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 BI reviewer updates the sponsor name in STARS and Animal Drugs @ FDA (see P&P 1243.3900 for more information on maintaining the Animal Drugs @ FDA Website and Green Book).⁴

VII. REFERENCES

Code of Federal Regulations (Title 21)

21 CFR 514.8

21 CFR 514.106

CVM Program Policies and Procedure Manual

1243.3010 - Format and Style Conventions for Letters

1243.3030 - Completing Final Action Packages for STARS Submissions

1243.3900 - Maintaining the Animal Drugs @ FDA Website and the Green Book

VIII. 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

² P&P 1243.3030 Completing Final Action Packages for STARS Submissions

³ P&P 1243.3010 Format and Style Conventions for Letters

⁴ P&P 1243.3900 Maintaining the Animal Drugs @ FDA Website and the Green Book

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.