OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

CHANGE OF SPONSOR NAME OR ADDRESS

I. PURPOSE

This document describes how to document and process submissions for changes in sponsor name or address.

II. GENERAL INFORMATION

CVM recognizes that changes in sponsor name or address 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 514.106). The Business Informatics (BI) Team in the Office of New Animal Drug Evaluation (ONADE) processes all submissions for changes in sponsor name or address. The Office Director is the signature authority for these types of submissions.

III. HOW CHANGE OF SPONSOR NAME OR ADDRESS SUBMISSIONS ARE CODED IN OUR SUBMISSION TRACKING AND REPORTING SYSTEM (STARS) DATABASE

When sponsors submit change of sponsor name or address submissions to CVM, they should identify all of the files and applications that are affected by such change. Sponsor name or address change submissions for approved (abbreviated) new animal drug applications [(A)NADAs] are coded as supplements (C), per 21 CFR 514.106(b)(1)(i), and are assigned the Administrative Requests (AD) subclass code. Sponsor name or address change submissions for pending (A)NADAs, (generic) investigational new animal drug [(J)INAD] files, general correspondence (GC) files, and veterinary master files (VMFs) are coded as general correspondence (G) submissions and are assigned the AD subclass code.

IV. HOW SPONSORS SUBMIT CHANGE OF SPONSOR NAME OR ADDRESS SUBMISSIONS

Sponsors can use eSubmitter to create change of sponsor name or address submissions and submit these electronically. If a sponsor owns an approved application that is affected by the change, they use either the N-C-AD or A-C-AD eSubmitter template to create their submission. If they own more than one 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. When creating a linked submission for an approved application, all of the linked documents must also be approved.

If a sponsor owns pending applications that are affected by a sponsor name or address change, they use either the A-G-AD or N-G-AD template to create their submission. Sponsors may also use the I-G-AD, J-G-AD, G-G-AD or V-G-AD eSubmitter template to create submissions for their respective files. Similar to above for approved applications, if a sponsor owns more than one pending application or other file type that is affected by the sponsor name or address change, they can create a linked submission using the appropriate eSubmitter template.

V. PROCESSING CHANGE OF SPONSOR NAME OR ADDRESS SUBMISSIONS

The BI Team processes change of sponsor name or address submissions. To ensure the accuracy of our records, the BI reviewer verifies in STARS that the sponsor has identified all of their files and applications. If there is a discrepancy between the STARS database and what the sponsor has submitted, the BI reviewer contacts the sponsor to resolve it and request an amendment if needed.

The BI reviewer drafts an acknowledgement letter stating that our records have been updated with respect to the sponsor name or address. Only an acknowledgement letter is drafted and sent to the sponsor (see P&P 1243.3010 for information on letter format and style conventions). A review is not required, unless there is something pertaining to the submission needs to be retained in the administrative file.

If the change of sponsor name or address submission impacts a sponsor that is currently listed in 21 CFR 510.600, the BI reviewer emails the Policy and Regulations Staff in the Office of the Center Director to request that they draft a FEDERAL REGISTER (FR) notice reflecting the change. If the impacted sponsor is not currently listed in 21 CFR 510.600, an FR notice is not published.

After the submission is finalized, the BI reviewer updates the sponsor name or address in STARS and Animal Drugs @ FDA if applicable (see P&P 1243.3900 for information on maintaining the Animal Drugs @ FDA Website and Green Book).

VI. FINALIZING THE SUBMISSION IN APPIAN

The final action code for sponsor name change submissions is SPONSOR NAME CHANGE; LETTER SENT; FR PUBLICATION IF APPROPRIATE. The final action code for sponsor address change submissions is SPONSOR ADDRESS CHANGE; LETTER SENT; FR PUBLICATION IF APPROPRIATE. If both the sponsor name and address are changed, choose one final action code. The Appian clearance chain consists of the reviewer on the BI Team and the Office Director (see P&P 1243.3030 for information on completing final action packages). The Review Summary field details the change of sponsor name and/or address.

VII. REFERENCES

Code of Federal Regulations (Title 21)

21 CFR 510.600

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

May 1, 2018 – Original version (supersedes and replaces P&P 1240.4150 Ownership Transfer or Corporate Identity Change of an Application and 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 change of sponsor name and/or address processing. There is also a new P&P that is solely for transfer of ownership processing (P&P 1243.2341).

April 27, 2021 – Updated to remove a paragraph describing how to submit in paper.

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.