
OFFICE OF NEW ANIMAL DRUG EVALUATION
REVIEWERS' CHAPTER

TRANSFER OF OWNERSHIP AND SPONSOR NAME OR ADDRESS CHANGE PROCEDURES IN ONADE FOR NADA, ANADA, INAD, JINAD, OR VMF SUBMISSIONS

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I. PURPOSE

This Guide describes the procedures for Transfers of Ownership and sponsor name or address changes submitted for NADAs, ANADAs, INADs, JINADs, or VMFs.

II. REVIEW PROCEDURE

Basic principles regarding transfer of ownership are described in CVM Policy and Procedures (P&P) Guide 1240.4150, Ownership Transfer or Corporate Identity Change of an Application. This guide gives additional detail for the reviewer responsible for handling these submissions in the Office of New Animal Drug Evaluation (ONADE). Changes in ownership are legal transactions between the buyer and seller. CVM does not participate in these transactions, but merely

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Responsible Office: ONADE Generic Drug Team (HFV-101).
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maintains records of ownership transfers to assure that the authorized persons (who are responsible for each application) are available for contact. Hence, CVM does not issue approvals or incomplete letters on this type of submission.

The Generic Drug Team, HFV-101, is responsible for processing all transfer notifications for NADAs, ANADAs, INADs, JINADs, and VMFs. ATTACHMENT A describes the documentation to be submitted when a transfer occurs. The team leader of HFV-101, signs a letter to the sponsor, which either acknowledges the transfer, or requests additional information or certifications.

III. CVM ACTION ON CHANGE OF SPONSOR IDENTITY

An incoming document notifying FDA of a change of sponsor identity is coded as general correspondence (i.e., "G" submission type) as a part of an application. A response to a submission notifying the Center of a change of sponsor identity usually results in issuance of both an acknowledgment letter and a Federal Register (FR) publication. If an approved application is affected by the name change, FDA will amend the codified approval regulation in the Code of Federal Regulations (CFR) (usually §510, § 520, § 522, or § 558) to change the sponsor name. The acknowledgment letter, signed by the team leader (HFV-101), notes that the change will be published in the FR if the change impacts the regulations. The Director, ONADE, signs the FR publication when it is final. The decision package is routed through the Quality Assurance Team, HFV-102, prior to issuance of the acknowledgment letter and publication of the Federal Register Notice.

IV. CVM ACTION ON TRANSFER OF OWNERSHIP

Draft FR documents for this action are not ordinarily routed to GCF-1 for concurrence. If the ownership transfer is for an NADA or ANADA, the new sponsor submits a signed Form FDA 356V (see ATTACHMENT A).

The incoming document notifying FDA of a transfer of ownership is also coded as general correspondence. CVM's response may either request additional information, or acknowledge the change (see ATTACHMENT A).

A Transfer of Ownership action by the Center usually results in the issuance of both an acknowledgment letter and an FR publication. If an approved application is involved in the transfer, FDA will amend the codified approval regulation in the CFR (usually §510, § 520, § 522 or § 558) to reflect the transfer in ownership. The acknowledgment letter to the sponsor, signed by the team leader (HFV-101), notes that the name change will be published in the FR. The Director, ONADE, signs the FR publication when it is final. The decision package is routed through the Quality Assurance Team, HFV-102, prior to issuance of the acknowledgment letter and publication of the Federal Register Notice.

NOTE: Transfers of Ownership for Medicated Feed Mill Licenses are the responsibility of the Division of Animal Feeds, HFV-220.

V. FINAL ACTION FORM ENTRIES

The reviewer should fill out a Final Action Form requesting a (070) SPNSR CHNG – sponsor change, – which is a final action for both sponsor change and transfer of ownership. With this final action, the submission is "closed," and the status will change from pending to final. If there is a publication of the change in the FR, then the Document Control Unit (DCU) will enter the publication date as an (071) CHNG PUBD "Change Published in Federal Register" as the information publishes. This completes the record.

To summarize, when the letter issues, the Final Action Form entry is:

070, SPNSR CHNG, sponsor change.
071, CHNG PUBD [this is a DCU entry].

VI. EXAMPLES OF LETTERS

A. SAMPLE LETTER TO ACKNOWLEDGE SUBMISSION OF COMPLETE INFORMATION: **NADA, ANADA**

NADA xxxx
<Sponsor "A">
<Address>

Dear Dr. *<Name>*:

We refer to your letter dated *<insert date>* notifying us of the transfer of ownership of NADA xxxx from *<insert sponsor "A">* to *<insert new sponsor "B">*. We further acknowledge receipt of *<sponsor "B's">* letter dated *<insert date>* confirming this transfer of ownership.

NOTE: Use all or a portion of the following sentence as appropriate:

We are in the process of amending 21 CFR 510.600 *(if applicable)* and 21 CFR *<section>* to reflect the transfer of ownership.

If the transfer is for an approved NADA, use the following language:
The regulations specify that the new owner shall submit a supplemental application under 21 CFR 514.8 for any change in conditions of the approved new animal drug application.

If the transfer is for an NADA that has not been approved, use the following language:
The new owner may submit an amended application under 21 CFR 514.6 for any change in the conditions of use of the new animal drug for which an application is pending. If any further assistance or clarification is needed concerning this action, please contact *<Center contact Staff telephone number.>*

Future correspondence regarding this letter should be identified by this letter's correspondence date and our file number, NADA xxx-xxx G00xx, *<or other appropriate identification.>* This letter is also being sent to the new owner, *<insert sponsor "B.">*

Sincerely yours,

Same letter sent to:
<Owner name>
<Sponsor "B" name>
<Sponsor "B" address>

cc: Orig., HFV-199, NADA 099-999 G0099
HFR-xxx, *<District FDA Offices>*
HFV-212, CVM Drug Listing Coordinator

Identification of reviewer's office

ACK

ec: electronic file information; refer to the SOP on electronic filing located at R:/onade/_sop

NOTE:
A copy should be provided to the FDA DOs identified in the HFV-140 Technical Section Complete letter (as indicated in the cc: block). Guidance on FDA DOs is provided in CVM Policy and Procedures Guide 1243.3300, Copies of Correspondence to FDA District Offices:
www.fda.gov/cvm/index/policy_proced/ppindex.html

B. SAMPLE LETTER TO ACKNOWLEDGE SUBMISSION OF COMPLETE INFORMATION: **INADs, JINADs, or VMFs**

INADA, JINAD, or VMF xxxx
<Sponsor "A">
<Address>

Dear Dr. *<Name>*:

We refer to your letter dated *<insert date>* providing information on the transfer of ownership of INAD, JINAD, or VMF xxxx from *<insert sponsor "A">* to *<insert sponsor "B">*. We acknowledge receipt of the transfer information. We have placed the information that you submitted in the appropriate file.

If a Veterinary Master File, use the following language:
You should notify all sponsors of new animal drug applications that have right of reference to this Veterinary Master File of the change in ownership. If any further assistance or clarification is needed concerning such notification, please contact *<Center contact Division/Staff telephone number.>*

Future correspondence regarding this letter should be identified by this letter's correspondence date and our file number, *<INAD xxxx Submission xxx, or other applicable identification.>* This letter is also being sent to the new owner, *<insert sponsor "B.">*

Sincerely yours,

Same letter sent to:
<Owner name>
<Sponsor "B" name>
< Sponsor "B" address>

cc: Orig., HFV-199, INAD xxxx G xxxx, JINAD, VMF
ONADE division(s): All Divisions affected by action.
HFR-xxx, *<District FDA Offices>*
HFV-212, CVM Drug Listing Coordinator

Identification of reviewer's office

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ec: electronic file information; refer to the SOP on electronic filing located at R:/onade/_sop

NOTE:
A copy should be provided to the FDA DOs identified in the HFV-140 Technical Section Complete letter (as indicated in the cc: block). Guidance on FDA DOs is provided in CVM Policy and Procedures Guide 1243.3300, Copies of Correspondence to FDA District Offices:
www.fda.gov/cvm/index/policy_proced/ppindex.html

C. SAMPLE LETTER FOR ADDITIONAL INFORMATION: **NADA, ANADA, INAD, JINAD, or VMF**, etc.

<Sponsor "A">
<Address>

Dear Dr. *<Name>*:

We refer to your letter dated *<insert date.>* We require additional information as indicated on the Enclosure before we can process the notification of transfer of ownership for your *<insert type of application.>*

In your response, please refer to the date of your notification letter dated *<date>* and our submission number *<or other appropriate identification.>* If you have any questions, you may contact *<Center contact Staff telephone number.>* This letter is also being sent to the new owner, *<insert sponsor "B.">*

Sincerely yours,

Enclosure: CVM Policy and Procedures Guide 1240.4150

Same letter sent to:
<Owner name>
< Sponsor "B" name>
< Sponsor "B" address>

cc: Orig., HFV-199, *<NADA xxx-xxx G xxxx>*
HFV-212, CVM Drug Listing Coordinator

Identification of reviewer's office

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ec: electronic file information; refer to the SOP on electronic filing located at R:/onade/_sop

NOTE:
A copy should be provided to the FDA DOs identified in the HFV-140 Technical Section Complete letter (as indicated in the cc: block). Guidance on FDA DOs is provided in CVM Policy and Procedures Guide 1243.3300, Copies of Correspondence to FDA District Offices:
www.fda.gov/cvm/index/policy_proced/ppindex.html

VII. REFERENCES

Federal Food, Drug and Cosmetic Act, section 512

CVM Policy and Procedures Guide 1240.4150, Ownership Transfer or Corporate Identity Change of an Application DHHS/PHS/FDA

FDA Correspondence Manual (9/89), Chapter 2, Letters

Code of Federal Regulations 21 CFR 514.1, 514.8 New Animal Drug Applications

21 CFR 314.72, Change in Ownership of an Application (CVM may follow § 314.72(a) as a matter of policy but not law, because § 314.72(a) applies only to human drug applications)

ATTACHMENT A

Information Needed for Transfer of Ownership for an NADA, ANADA, INAD, JINAD, or VMF

Please submit the information or signed statement, as indicated, for each NADA, ANADA, INAD, JINAD, or VMF:

1. For NADA or ANADA:
The former sponsor/owner and the new owner should each submit a letter or other document stating that all rights to the application have been transferred from the former owner, and accepted by the new owner, and the date on which the transfer is (was) effective. Notarized letters are preferred.

The new owner should submit an application form *(Form FDA 356V: go to http://www.fda.gov/cvm/forms/ps356v.pdf*) signed by the new owner (or agent) and a letter or other document containing the following:

- The new owner's commitment to comply with all agreements, commitments, and conditions made by the former owner and contained in the application.

- The date that the change of ownership is (was) effective.

- Either a statement that the new owner has a complete copy of the approved application, including supplements and records that are required to be kept under 21 CFR 510.300, or a request for a copy of the application from FDA's files. FDA will provide a copy of the application to the new owner under the fee schedule in 21 CFR 20.42 of FDA's public information regulations.

- A statement that a supplemental new animal drug application will be submitted by the new owner for any change in the approved NADA. (An approved supplemental application is generally required for a change in the NADA that may result from the transfer of ownership, such as a change in manufacturing methods, facilities, or controls; or a

change in the labeling to reflect the new ownership. The Food and Drug Administration must approve the supplemental application before the drug product may be legally marketed).

- If the former owner granted right of reference to third parties, a statement that either extends or denies CVM's authority to reference information in the application on behalf of third parties.

- Any other relevant information required to complete the transfer of ownership.

2. For INAD, JINAD, or VMF:
The former owner and the new owner should each submit a letter or other document stating that all rights to the file(s) have been transferred from the former owner, and accepted by the new owner (or agent), and the date on which the transfer is (was) effective.

The new owner should submit a letter or other document containing the following:

- The new owner's commitment to comply with all agreements, commitments, and conditions made by the former owner and contained in the file.

- The date that the change of ownership is (was) effective.

- Either a statement that the new owner has a complete copy of the current file, or a request for a copy of the file from FDA. (The Agency will provide a copy of the file to the new owner under the fee schedule in 21 CFR 20.42 of the public information regulations).

- If the former owner granted right of reference to third parties, a statement that either extends or denies CVM's authority to reference information in the application on behalf of third parties.

- Any other relevant information required to complete the transfer of ownership.

ATTACHMENT B

Glossary of Acronyms

ANADA	Abbreviated New Animal Drug Application
CFR	Code of Federal Regulations
CVM	Center for Veterinary Medicine
FDA	Food and Drug Administration
FORM FDA 356V	New Animal Drug Application Form
INAD	Investigational New Animal Drug File
JINAD	Investigational New Animal Drug File for a Generic Product
NADA	New Animal Drug Application
ONADE	Office of New Animal Drug Evaluation
VMF	Veterinary Master File

Responsible Office: ONADE Generic Drug Team (HFV-101).
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