SUPPLEMENTAL POLICIES

OWNERSHIP TRANSFER OR CORPORATE IDENTITY CHANGE OF AN APPLICATION

Background:

Submissions involving a transfer of ownership or a change in corporate identity (a name change) are routinely submitted to CVM, informing the Center of changes in the following official files: New Animal Drug Applications (NADAs) (including abbreviated New Animal Drug Applications (ANADAs)), Investigational New Animal Drug Applications (INADAs), Medicated Feed Mill Licenses, Master Files (MFs), and Food Additive Petitions (FAPs). As property, the applications may be transferred from one sponsor to another. The corporate name (identity) may also change either through a change in corporate structure or change in corporate ownership.

1. Purpose:

This guide sets forth the procedures for documenting and processing a transfer of ownership of an application or a change in the corporate identity of the owner of an application.

2. Policy:

It is the policy of FDA not to become involved in the transfer of ownership of an application or change in corporate identity, but the Agency requires the submission of certain information to acknowledge the change and amend the official records.

3. Transfer of Ownership:

a. Required Information: **NADA/ANADA** Transfer of Ownership.

At the time of the transfer, the new and former owners should submit information to FDA as follows:

(1) The former owner and the new owner should each submit a letter or other appropriate document which states that all rights to the application(s) have been transferred and specifies the date on which

the transfer is (or was) effective. The former owner should state if all applications have been transferred so that CVM can revise the information in 21 CFR 510.600, Names, Addresses, and Drug Labeler Codes of Sponsors of Approved Applications.

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

(a) A commitment to comply with all agreements, promises and conditions made by the former owner and contained in the application;

(b) Either a statement that the new owner has a complete copy of the application including, in the case of an approved NADA, 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.

(c) A statement which either extends or denies CVM's authority to reference information in the application on behalf of third parties, where the former owner granted right of reference to third parties.

(3) A signed New Animal Drug Application Form FDA 356V for each NADA.

(4) A commitment by the new owner to submit a supplement under 21 CFR 514.8 (for an approved application) or an amendment under 21 CFR 514.6 (for an unapproved application) to describe any change in the conditions of the application that may occur or be necessary due to the change in ownership. The supplement or amendment must include information regarding the manufacture of the product and any proposed labeling. The supplement to an approved application must be approved by CVM before the product may be legally marketed.

b. **Required Information: INADA, Medicated Feed Mill License, Master File, Food Additive Petition Transfer of Ownership.**

(1) The former owner and the new owner should each submit a letter or other document stating that all rights to the application have been transferred and the date on which the transfer is (was) effective. The former owner should state if all applications have been transferred so that CVM can revise the information in 21 CFR 510.600, Names, Addresses, and Drug Labeler Codes of Sponsors of Approved Applications.

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

(a) A commitment to comply with all agreements, promises, and conditions made by the former owner and contained in the file;

(b) The date that the change of ownership is (was) effective; and

(c) Either a statement that the new owner has a complete copy of the current file, or a statement that a request for a copy of the file from FDA has been (or is being) made. 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.

(d) A statement which either extends or denies CVM's authority to reference information in the application on behalf of third parties, where the former owner granted right of reference to third parties.

c. FDA Action on a Transfer of Ownership

(1) Because a transfer of ownership may involve multiple applications and official actions cross Division lines, a Consumer Safety Officer designated by the Director, Office of NADE, will process all such requests.

(2) Since a change in ownership of an application is not a change subject to FDA approval, the incoming documents should be treated as general correspondence. FDA's response, whether requesting additional information or acknowledging the change, should be in the form of an acknowledgement letter. The decision package will be routed from Division to HFV-102 prior to issuance of the acknowledgement letter.

(3) For approved NADAs/ANADAs, if there is information in the submission suggesting a change in the conditions of the application, such as a new manufacturing facility, then the owner should be reminded in the acknowledgement letter that a supplemental application for any change in the conditions of the approved new animal drug application must be approved before the drug product may be legally marketed.

(4) In the case of an approved NADA/ANADA which is codified in the CFR, FDA will publish in the FEDERAL REGISTER a notice of the change of ownership pursuant to section 512(i) of the Act. If the approved NADA is not codified or is an unapproved NADA, no publication is necessary. Draft FEDERAL REGISTER documents for this action are not ordinarily routed to GCF-1 for concurrence.

(5) A copy of the change in ownership should be forwarded to each relevant division in ONADE, to CVM's Drug Listing Coordinator, and to the appropriate FDA District Offices.

d. Once CVM has received the information described above, the Center will honor a request that ownership not be transferred, or, after the effective date of the change of ownership, that the transfer be withdrawn, only if both the former owner and the new owner formally request such action.

4. Corporate Identity:

a. Required Information:

The owner of an application for which the identity of the owner is being changed shall submit for each application a letter giving both the old and new names and addresses of the owner and the date on which the change is (was) effective. The letter should include a statement of the reason for the change (e.g., corporate reorganization).

b. FDA Action:

(1) As with a transfer of ownership, the designated Consumer Safety Officer will process all requests for change in identity (name/address).

(2) FDA cannot approve or deny the change. Therefore, the incoming documents should be treated as general correspondence. FDA's response should be in the form of an acknowledgement letter. The decision package will be routed from the Consumer Safety Officer to HFV-102 prior to issuance of the acknowledgement letter.

(3) If the change in identity or address requires a change in the listing under 21 CFR 510.600(c), FDA will publish an amendment in the FEDERAL REGISTER to reflect the change. Draft FEDERAL REGISTER documents for this action are not ordinarily routed to GCF-1 for concurrence.

(4) A copy of the change will be forwarded to each relevant Division in ONADE and to CVM's Drug Listing Coordinator.

References: 21 CFR 20.42; §314.72; §510.300; §510.600; §514.6; §514.8.