
OFFICE OF NEW ANIMAL DRUG EVALUATION REVIEWER'S CHAPTER

PROCESSING A REQUEST TO OPEN A (J)INAD FILE

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I. PURPOSE

The purpose of this document is to explain:

- what an (J)INAD file is,
- the minimum information we need to complete an A-0000 submission, and
- what to do when we get a request to open a (J)INAD file.

II. WHAT IS A (J)INAD FILE?

The investigational new animal drug (INAD) file contains correspondence and submissions that may be used to support a new animal drug application (NADA)(i.e., phased review submissions). Regulations governing unapproved new animal drugs intended for investigational use are in 21 CFR 511. When the sponsor plans to begin clinical studies, they will submit the information required to maintain their investigational exemption.¹

The generic investigational new animal drug (JINAD) file is the investigational file for generic animal drugs. The information submitted to the file may be used to support an abbreviated new animal drug application (ANADA).

III. WHEN DOES A SPONSOR NEED A (J)INAD FILE?

Sponsors typically submit a request to open an (J)INAD file when they have enough pilot data to start discussing the development process and/or they want to begin using the drug in client-owned animals. In the event that the sponsor is pursuing a supplemental approval, we may request that the sponsor establish a new (J)INAD file so we can better administer review of the data.²

¹ See P&P 1243.4065 Requirements for Investigational New Animal Drug Exemptions.

² See Guidance for Industry 191 Changes to Approved NADAs-New NADAs vs. Category II Supplemental NADAs.

IV. INITIAL ROUTING AND PROCESSING OF A (J)INAD FILE REQUEST

The Document Control Unit (DCU) receives all paper requests to establish (J)INAD files. They will date stamp the submission, record its receipt, cross-check records to verify that it is an original submission, prepare a draft acknowledgement letter with a tentative INAD number, and enter pertinent information into our Submission Tracking and Reporting System (STARS). The submission is then delivered to the appropriate division director, who performs an informal cursory review.

For submissions that are received in paper, the division director will perform an initial assessment of the submission. If the division director believes it is appropriate to open a new (J)INAD file, they initial the copy of the acknowledgement letter prepared by DCU and return the file to the DCU. DCU then mails the acknowledgement letter to the sponsor confirming receipt of the request and telling the sponsor the file number and will then create the A-0000 submission.

All requests to establish (J)INAD files that are received via eSubmitter are automatically created. The sponsor is notified that their file has been created by an acknowledgement issued from the Electronic Submission Gateway. The acknowledgement will contain the file number.

If the submission appears to have deficiencies or errors that could be addressed through an amendment, the sponsor may be contacted to amend it. There may also be situations where the division director may not believe it is appropriate to open a new (J)INAD file, in which case the division director will instruct DCU to convert the file to a General Correspondence (GC) and the respective target animal division will prepare the necessary documentation for this GC submission.

After DCU creates the A-0000 submission for the request, they send the submission to the ADUFA team. If this is the first filing of a (J)INAD by the sponsor, they will be assessed a sponsor fee under either the Animal Drug User Fee Act (ADUFA) or the Animal Generic Drug User Fee Act (AGDUFA), whichever is applicable. Once the ADUFA team has evaluated the submission, the submission is routed to the target animal division for review.

V. REVIEWING THE SUBMISSION

The primary reviewer reviews the submission and identifies any areas in which it is deficient. You may contact the sponsor to get clarification on the information submitted or request they provide additional information through an amendment. Request consulting reviews if appropriate.³ Do this within two working days of your receipt of the submission.

Information that we generally receive in an A-0000 submission:

³ See P&P 1243.3200 for information on how to request a consulting review.

1. Sponsor information including the sponsor name, address, telephone number(s), e-mail address, and contact person or, if they are a foreign sponsor, US agent.
2. Drug identification information. This may include the drug/chemical name or other unique identifier, the pharmacological category, and the dosage form.
3. Treatment information including the species and if applicable, class of animals and the proposed use (e.g. indication, the route of administration, and the dosage regimen if this information is known).

If the sponsor requested that information in the INAD be publicly available, the submission should detail the scope of the disclosure.

Request an amendment or ask the sponsor to clarify if you determine that the submission does not address or include the above information.

Labeling:

The sponsor is not required to submit investigational labeling along with their request to open an (J)INAD file. The acknowledgement letter informs the sponsor of their obligations regarding investigational labeling and "Notices of Claimed Investigational Exemption for a New Animal Drug," in accordance with 21 CFR 511.1.

VI. SPECIFIC INFORMATION ABOUT SUBMISSIONS REQUESTING A JINAD FILE

Requests to establish a JINAD file should include the information in section V above and also contain the following information:

1. Reference listed new animal drug (RLNAD) information: Sponsors are required to identify the RLNAD for their proposed generic drug, including trade name (and/or established name), dosage form, strength, sponsor name, and (A)NADA number;
2. Patent information: Certify the patent information submitted by using the FDA Green Book for listed patents and corresponding expiration dates associated with the RLNAD. Note: If the time to patent expiration is greater than 5 years, consult your team leader for guidance on how to proceed;
3. Marketing exclusivity information: Indicate if exclusivity is applicable to the request. Verify the accuracy of the marketing exclusivity information submitted by the sponsor using the FDA Green Book for listed marketing exclusivities granted the RLNAD. Note: If the period for marketing exclusivity is 5 years, consult your team leader for guidance on how to proceed; and
4. If the sponsor submitted and was granted a suitability petition, a copy of the letter approving the petition should be included with their JINAD request.

VII.COMBINED REQUESTS OR THE SUBMISSION OF OTHER INFORMATION WITH THE A - 0000

Sponsors sometimes include other requests in their request to establish an investigational file (or A-0000). Examples include requests for Food Use Authorization (FUA), protocol review, meetings, bioequivalence waivers, environmental claims (e.g. Categorical Exclusion), and expedited review. If additional requests are made within the A-0000 submission, inform the sponsor that the primary request will be reviewed but additional requests will not be reviewed under the current submission. Instead, have the sponsor submit each additional request separately under the appropriate submission code.

In the AA review and acknowledgement letter, document that the additional requests in the submission were not reviewed under the current submission and the sponsor was notified to submit the additional requests separately under the appropriate submission code.

VIII.PREPARING THE FINAL ACTION PACKAGE

Prepare a review and an acknowledgement letter using the office templates. Follow the procedures described in P&P 1243.3005 and P&P 1243.3030 to prepare clean electronic documents and assemble the final action package.

IX. REFERENCES

Code of Federal Regulations (Title 21)
Part 511 – New Animal Drugs for Investigational Use
CVM Program Policy and Procedures Manual
1243.3005 – Creating Clean Electronic Files
1243.3030 – Completing final Action Packages for STARS Submissions
1243.4065 – Requirements for Investigational New Animal Drug Exemptions
CVM Guidance for Industry
Guidance 191 – Changes to Approved NADAs-New NADAs vs. Category II Supplemental NADAs.

X.VERSION HISTORY

March 31, 2009 – Beta test version

June 30, 2009 – Revised Beta test version

March 15, 2010 – Final Version

December 5, 2011 – Revised version to address bundled submissions