
GENERAL REVIEW AND ENFORCEMENT POLICIES

INITIAL PROCESSING AND FILING OF AN ORIGINAL NADA OR ANADA

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Attachment: CVM letter acknowledging receipt of an application

I. PURPOSE

This guide sets forth the procedures for receipt and initial processing of a New Animal Drug Application (NADA) and Abbreviated New Animal Drug Application (ANADA).

II. REFERENCES

Section 512(b)(1) of the Federal Food, Drug, and Cosmetic Act (FFDCA) sets forth the broad requirements for the content of an NADA.

Section 512(c) of the FFDCA requires the Agency to take an appropriate action within 180 days after the filing of an NADA or ANADA.

Section 512(n) of the FFDCA sets forth the broad requirements for the contents of an ANADA.

21 CFR 514.1 provides the outline for the organization and content of an NADA.

21 CFR 514.110 provides the basis for refusing to file an application.

III. INITIAL PROCESSING OF AN NADA OR ANADA

When an apparent original NADA or ANADA is received, the Document Control Unit (DCU, HFV-199) will date stamp the submission, prepare it for review, and assign it to the appropriate division.

DCU staff will prepare a draft letter to the sponsor acknowledging CVM's receipt of their application and assigning it an NADA or ANADA number.

DCU staff will forward the NADA or ANADA, and accompanying draft letter, to the review division.

The responsible review Division Director, or authorized designee, will immediately perform a cursory review to confirm proper coding of the submission as an original application.

If the submission is an original NADA or ANADA, the Division Director will, within 4 days of delivery to the division, initial the draft letter, identify the responsible review team, and return the submission and letter to HFV-199. DCU staff will then sign and issue the letter, code the submission into STARS, and return the submission to the review team for reviewer assignment.

If the submission is not an original NADA or ANADA, the Division Director will, within 4 days of delivery to the division, return the submission to DCU with an indication of its proper disposition.

IV. EVALUATION OF APPROPRIATENESS FOR FILING

The original NADA or ANADA must be evaluated within 30 days of the date of receipt to determine if it meets the standards for filing by the responsible review team. CVM must notify the sponsor within 30 days of receipt of their application if CVM determines the application is not acceptable for filing and give them reasons for refusing to file their application (21 CFR 514.110(c)).

The application is considered FILED on the date of its receipt if:

- 1) CVM does not notify the applicant within 30 days of receipt of the application that it is unacceptable for filing (21 CFR 514.110(a)), or
- 2) the sponsor files the application over protest (21 CFR 514.110(d)).

If the application is not acceptable for filing, the review division will prepare a letter refusing to file the application. The letter will be signed by the Division Director, will give the reasons for the refusal to file, and will state that CVM is retaining the application. If it is uncertain whether the sponsor will receive this refuse-to-file letter

within 30 days, the Division Director will contact the sponsor with the Center's decision via telephone, email, or facsimile before the 30-day period has elapsed. The refuse-to-file letter should follow within 7 days.

ATTACHMENT

(A)NADA 000000

Today's Date

Drug Sponsor Firm Name
Attention: Signer of Cover Letter
Title of Signer of Cover Letter
Street Address
City, State Zip Code

Dear Dr. Signer of Cover Letter:

We received your [select either New Animal Drug Application or Abbreviated New Animal Drug Application] for the use of [enter drug name or generic drug name] in [enter species] dated [enter correspondence date].

Your application was received on [enter receipt date] and was assigned [select either **NADA** or **ANADA**] **number 000000**. Please refer to this number when submitting any future correspondence pertaining to this application.

We are evaluating your application according to 21 CFR 514.110 to determine if it is acceptable for filing. We will notify you within 30 days after we receive your application if we find that it is not acceptable for filing. If our initial notification is not in writing, we will promptly confirm that notification by letter.

If we do not notify you within 30 days that we are refusing to file your application, the filing date of your application will be the date we received it. You will not receive confirmation that your application was filed successfully.

This is not an approval letter.

Sincerely,

Carol Goolsby
Technical Information Specialist
Document Control Unit, HFV-199
Center for Veterinary Medicine