Form Approved: OMB No. 0910-0032; Expiration Date: 09/30/2028
See OMB Statement on Page 3.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

APPLICATION FOR APPROVAL OF A NEW ANIMAL DRUG
(OR SUBMISSION TO SUPPORT NEW ANIMAL DRUG APPROVAL)

(Sections 512 and 571 of FFDCA and Title 21, Code of Federal Regulations, Part 514)

APPLICATION OR INVESTIGATIONAL FILE NUMBER

DATE OF SUBMISSION

APPLICANT INFORMATION

APPLICANT NAME		CONTACT NAME *(authorized representative or U.S. agent)*	
APPLICANT ADDRESS *(Number, Street, City, State, Country, and ZIP or Mail Code)*		CONTACT ADDRESS *(Number, Street, City, State and ZIP Code)*	
		E-MAIL ADDRESS:	
TELEPHONE NUMBER	FACSIMILE (FAX) NUMBER	TELEPHONE NUMBER	FACSIMILE (FAX) NUMBER

PRODUCT DESCRIPTION

ESTABLISHED NAME	PROPRIETARY NAME *(trade name)*, IF ANY
DOSAGE FORM:	PROPOSED MARKETING STATUS *(check one)* ☐ Prescription (Rx) *(section 503(f)(1) of FFDCA)* ☐ Over-the-Counter (OTC) *(section 502(f)(1) of FFDCA)* ☐ Veterinary Feed Directive (VFD) *(section 504 of FFDCA)*
DOSE or DOSE RANGE:	
ROUTE(S) OF ADMINISTRATION	
SPECIES AND, IF APPLICABLE, CLASS	DESIGNATED NEW ANIMAL DRUG? ☐ Yes ☐ No DATE OF DESIGNATION:

PROPOSED INDICATION(S) FOR USE

APPLICATION DESCRIPTION

TYPE OF APPLICATION *(check one, if applicable)*

- ☐ New Animal Drug Application (NADA) *(section 512(b)(1) of FFDCA)*
- ☐ Abbreviated New Animal Drug Application (ANADA) (*section 512(b)(2) of FFDCA)*
- ☐ Application for Conditional Approval *(section 571(a) of FFDCA)*

Administrative Application? ☐ Yes ☐ No

FOR AN ANADA, IDENTIFY THE FOLLOWING INFORMATION FOR THE REFERENCE LISTED DRUG

Proprietary Name

Application Number

Holder of Approved Application

TYPE OF SUBMISSION *(check one)*

- ☐ Submission of data or information to an Investigational File (and Amending Submissions)
- ☐ Submission to a Master File
- ☐ Original Application
- ☐ Supplement requiring review of safety or effectiveness data *(21 CFR §514.8(c)(1))*
- ☐ Chemistry, Manufacturing and Controls: Supplement or Report *(also check specific type)*
  - ☐ Prior Approval *(21 CFR §514.8(b)(2))*
  - ☐ Changes Being Effected (CBE) - 30 day *(21 CFR §514.8(b)(3)(i))*
  - ☐ CBE - Immediate *(21 CFR §514.8(b)(3)(vi))*
  - ☐ Minor Changes and Stability Report (MCSR) *(21 CFR §514.8(b)(4))*
- ☐ Labeling Supplement *(also check specific type)*
  - ☐ Prior approval *(21 CFR §514.8(c)(2))*
  - ☐ CBE *(21 CFR §514.8(c)(3))*
- ☐ Amendment to Pending Application, Supplement or MCSR
- ☐ Reactivation of Application, Supplement, or MCSR
- ☐ Request for renewal of conditionally approved Application *(section 571(d)(1) of FFDCA)*
- ☐ Other *(please describe)*:

SUBMISSION CONTENT *(Check each box that describes a type of information included in your submission)*

To support an NADA or application for conditional approval

- ☐ 1. Identification *(21 CFR §514.1(b)(1))*
- ☐ 2. Table of contents and summary *(21 CFR §514.1(b)(2))*
- ☐ 3. Technical sections
  - ☐ a. Labeling *(21 CFR §514.1(b)(3)) (check one)*
    - ☐ Draft (facsimile) labeling
    - ☐ Final printed labeling
  - ☐ b. Chemistry, manufacturing, and controls *(21 CFR §514.1(b)(4) and (5))*
  - ☐ c. Human food safety *(21 CFR §514.1(b)(7) and (8))*
  - ☐ d. Target animal safety (TAS) (21 CFR §514.1(b)(8))
  - ☐ e. Effectiveness *(check one)*
    - ☐ Substantial evidence of effectiveness (21 CFR §514.1(b)(8))
    - ☐ Reasonable expectation of effectiveness (section 571(a)(2)(B) of FFDCA)
  - ☐ f. Environmental impact *(21 CFR §514.1(b)(14))*
  - ☐ g. All other information *(21 CFR §514.1(b)(8)(iv))*
  - ☐ h. Freedom of information summary *(21 CFR §514.11) (for administrative application, submit FOI TSC letter)*
- ☐ 4. Samples *(21 CFR §514.1(b)(6)) (submit only on the request of FDA)*
- ☐ 5. For VFD drugs, submit copies of the VFD *(21 CFR §514.1(b)(9))*
- ☐ 6. Commitments required by 21 CFR §514.1(b)(11) and (12)
  - ☐ a. Labeling and advertising *(21 CFR §514.1(b)(11))*
  - ☐ b. Shipping of approved drug intended for use in the manufacture of animal feeds *(21 CFR §514.1(b)(12)(i))*
  - ☐ c. Good manufacturing practices *(21 CFR §514.1(b)(12)(ii))*
  - ☐ d. Good laboratory practice compliance statement *(21 CFR §514.1(b)(12)(iii))*
- ☐ 7. Patent information on any patent which claims the drug or a method of using the drug *(section 512(b)(1) of FFDCA)*
- ☐ 8. User fee cover sheet *(Form FDA 3546)*

To support an ANADA

- ☐ 9. Identification
- ☐ 10. Table of contents and summary
- ☐ 11. Technical sections
  - ☐ a. Withdrawal period information *(section 512(n)(1)(A)(ii) of FFDCA)*
  - ☐ b. Bioequivalence *(section 512(n)(1)(E) of FFDCA) (check one)*
    - ☐ Documentation supporting a request for waiver
    - ☐ Bioequivalence study or information
  - ☐ c. Labeling *(sections 512(n)(1)(F) and (G) of FFDCA) (check one)*
    - ☐ Draft (facsimile) labeling
    - ☐ Final printed labeling
  - ☐ d. Chemistry, manufacturing, and controls *(section 512(n)(1)(G) of FFDCA)*
  - ☐ e. Patent certification *(section 512(n)(1)(H) of FFDCA)*
  - ☐ f. Environmental impact *(21 CFR §25.15)*
  - ☐ g. Freedom of information summary *(21 CFR §514.11) (for administrative application, submit FOI TSC letter)*
- ☐ Other *(please describe)*:

NUMBER OF VOLUMES SUBMITTED	DESCRIPTION OF ANY ELECTRONIC MEDIA SUBMITTED

CROSS REFERENCES *(list applications or files, (e.g., investigational new animal drug files (INADs), generic INADs (JINADs), NADAs, and master files) referenced in the current application, including by right(s) of reference)*

CERTIFICATIONS

I certify that:

- I have personally reviewed this submission (or received assurances from qualified personnel) and determined that this submission and all supporting data, to the best of my knowledge and belief, are true, accurate, and complete,
- All copies (paper or electronic) of the submission are identical,
- For any information submitted by reference to a master file, investigational file, or application, the reference was made with the belief that the information contained in the referenced file is true, accurate, and complete,
- The services of any person debarred under section 306(a) or (b) of FFDCA have not been used in any capacity related to this submission, and
- I am aware that there are significant penalties for submitting false information, including the possibility of fine and imprisonment for knowing and willful violations (18 U.S.C. § 1001).

If this application is approved, I agree:

- To submit safety update reports as requested by FDA under its statutory authority or as provided for by regulation,
- To comply with all applicable statutes and regulations that apply to approved applications,
- Not to market this drug product until the Drug Enforcement Administration makes a final scheduling decision if this application applies to a drug product that FDA has proposed for scheduling under the Controlled Substances Act, and
- To notify FDA of any change to the conditions established in this approval.

SIGNATURE OF RESPONSIBLE OFFICIAL	NAME AND TITLE *(Printed or Typed)*	DATE
SIGNATURE OF U.S. AGENT *(if applicable)*	NAME AND TITLE *(Printed or Typed)*	DATE

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 5 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Operations
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

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INSTRUCTIONS FOR COMPLETING AND SUBMITTING FORM FDA 356v

GENERAL INSTRUCTIONS

Applicant Information

Provide your name, address, and telephone and facsimile numbers (including the country code if needed). This address will be the address of record we use for all contacts initiated by us and not directly related to a submission. Also provide the name of the individual who will serve as your contact (i.e., your authorized representative or U.S. agent). If you or your authorized representative do not reside or have a place of business within the United States, you must provide the name and address of a U.S. agent as your contact. A U.S. agent is a person who is a permanent resident of the United States and acts as your agent. Your U.S. agent must also sign your application (see 21 CFR §514.1(a)).

Product Description

Include all of the information necessary to identify the drug product that is the subject of your submission. The manufacturer or sponsor of a new animal drug for a minor use or use in a minor species may request designation under section 573(a) of FFDCA. Indicate whether your drug has been declared a designated new animal drug and, if so, the date of designation.

Application Description

Type of Application:

- If you are submitting an application, check the appropriate box to identify whether you are submitting a new animal drug application (NADA), an abbreviated NADA (ANADA), or application for conditional approval. Please check whether the application is an administrative application. If this is an ANADA, identify, for the reference listed new animal drug, the proprietary name of the reference listed drug, its NADA number, and the name of the holder of the approved NADA for the referenced listed drug.

- **DO NOT** check a box under Type of Application if you are submitting information or data to an investigational file or master file. Instead, check the "submission of data or information to an investigational file," "submission to a master file," or "other" under type of submission and the appropriate item(s) from the Submission Content list of items.

Type of Submission: Check the appropriate box.

- **Submission of Data or Information to an Investigational File:** Data or information (including amending data or information) supporting a single technical section submitted for phased review. This submission should include labeling language, and may include Freedom of Information (FOI) information, relevant to the specific technical section.

- **Submission to a Master File:** Data or information submitted to a master file that may be referenced (by the owner or a person granted a right of reference) to support the approval of a new animal drug.

- **Original Application:** A complete application (i.e., containing all applicable technical sections or copies of technical section complete letters for all applicable technical sections) that you have not submitted before.

- **Supplement Requiring Review of Safety or Effectiveness Data:** A supplemental application (21 CFR §514.8(a)) requesting a change to an approved application that requires FDA to review safety or effectiveness data (e.g., the addition of a new claim or species). Note: An applicant may not supplement an application for conditional approval to add indications of use (section 571(g) of FFDCA).

- **Chemistry, Manufacturing, and Controls - Supplement or Report:**

  – **Prior approval:** A supplemental application for any change in the drug, production process, quality controls, equipment, or facilities that has a substantial potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug (21 CFR 514.8(b)(2)).

  – **Changes being effected (CBE) in 30 days**: A supplemental application for any change in the drug, production process, quality controls, equipment, or facilities that has a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug. (See examples in 21 CFR §514.8(b)(3)(ii)). You may commercially distribute the drug made using the change 30 or more days after FDA receives your supplemental application unless FDA informs you otherwise within 30 days of its receipt of the application.

  – **Changes being effected (CBE):** A supplemental application for certain changes in the drug, production process, quality controls, equipment, or facilities that have a moderate potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug (for examples, see 21 CFR 514.8(b)(3)(vi)). You may

commercially distribute the drug when FDA receives your supplemental application.

- **Minor changes and stability report (MCSR):** An annual report that documents changes in the drug, production process, quality controls, equipment, or facilities that have a minimal potential to have an adverse effect on the identity, strength, quality, purity, or potency of the drug as these factors may relate to the safety or effectiveness of the drug (21 CFR §514.8(b)(4)).

- **Labeling Supplement:**
  - **Prior approval:** A supplemental application requesting labeling changes that requires approval before the drug may be distributed (for examples, see 21 CFR §514.8(c)(2)).
  - **Changes being effected (CBE):** A supplemental application requesting labeling changes that can be placed into effect before approval. These supplements request changes in labeling that increase the assurance of drug safety (21 CFR §514.8(c)(3)(i)) or that do not decrease the safety of drug use (21 CFR §514.8(c)(3)(ii)).

- **Amendment to a Pending Application, Supplement, or MCSR:** Any submission that provides additional information to an application or report while it is under review.

- **Reactivation of an Application, Supplement, or MCSR:** Resubmission of an application or report to address the deficiencies described in an incomplete letter from FDA.

- **Other:** Any submission that does not fit within one of the types of submissions described above.

Submission Content: Please check each box that describes a type of information that is included in your submission. Note that items 1-7 apply to the submission of NADAs and applications for conditional approval (or to their supporting investigational files), item 8 applies specifically to NADAs, and items 9-11 apply to ANADAs (or to their supporting investigational files).

- A complete NADA and application for conditional approval must include information and any right(s) of reference to information for items 1-7 (21 CFR §514.1; section 571(a)(2)(A), (B) and (C) of FFDCA). A supplemental NADA may omit statements made in the application concerning which no change is made. If you are submitting information required by sections 571(a)(2)(D) - (F) of FFDCA to support conditional approval, check "other" and describe the information you are submitting. Indicate the order in which these sections appear in your submission in your table of contents. A completed User Fee Cover Sheet (item 8) should accompany each NADA and supplemental NADA subject to fees. To determine if your NADA or supplemental NADA is subject to an application fee, see section 740(a)(1) of FFDCA.

- For submissions other than applications (e.g., a submission to an investigational file for phased review), check only those items that apply and indicate the order in which these sections appear in your submission in your table of contents. Do not check Labeling or Freedom of Information Summary if the submission contains such information only as it relates to a technical section. For administrative applications, submit a copy of your FOI technical section complete letter.

- A complete ANADA should include items 9-11. A supplemental ANADA may omit statements made in the approved application concerning which no change is made.

- The "other" category should be checked and include a description of the submission when you are submitting certain information supporting a conditional approval (see instructions above) or when your submission does not fall into the above categories.

Description of Submission

Enter the number of volumes you are submitting. Describe any electronic media in your submission.

Cross References

List all investigational new animal drug files (INADs, JINADs), new animal drug applications (NADAs, ANADAs, applications for conditional approval), master files (VMFs, DMFs, PMFs), or other applications or files referenced in your current submission, including by "right of reference." If you reference data or information in any file you don't own, make sure a copy of your authorization to reference such data or information is included with your submission or has already been submitted to the file in which you referenced it.

Signature

After carefully reading the certifications, sign and date the form. Ordinarily only one person must sign the form, i.e., the applicant, or the applicant's attorney, agent, or other authorized official. However, if you do not reside or have a place of business within the United States, your U.S. agent must also sign the application.

INSTRUCTIONS FOR SUBMITTING AN APPLICATION

1. Include a completed and signed Form FDA 356v (pages 1 through 3) with all submissions relating to

new animal drug approval (i.e., NADAs, ANADAs, applications for conditional approval, submissions of data or information to an investigational file, supplements, amendments, reactivations, and MCSRs). The completed form should be placed before the cover letter, table of contents, and submission.

2. Submit three identical copies of your submission (21 CFR §514.1(b)). A copy of the Form FDA 356v should accompany each copy of your submission.

3. Place the applicant's name and address and the proprietary name(s) (if available) and established name(s) of the new animal drug on the front cover of each copy of your submission (21 CFR §514.1(b)).

4. Fully describe the submission in your cover letter (e.g., for a supplemental application, describe the change(s) you are seeking to the approved application).

5. Include a comprehensive table of contents in your submission (21 CFR §514.1(b)(2)).

6. Format your submission so each of your sections begins on a new page.

7. Sequentially number the pages of the submission.

8. Send your submission and copies to:

   Document Control Unit (HFV-199)
   Center for Veterinary Medicine
   Food and Drug Administration
   7500 Standish Place
   Rockville, MD 20855

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