DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION	**NEW ANIMAL DRUG APPLICATION** (Drugs for Animal Use) (Title 21, CFR 514)	*Form Approved: OMB No. 0910-0032* *Expiration Date: July 31, 2004* **NADA**

DRUG PRODUCT

ESTABLISHED NAME *(e.g. USP/USAN)*	PROPRIETARY NAME

DOSAGE FORM	PROPOSED INDICATIONS FOR USE	SPECIES

PROPOSED MARKETING STATUS *(Check one)*: ☐ PRESCRIPTION PRODUCT (Rx) ☐ OVER-THE-COUNTER PRODUCT (OTC)

NAME OF APPLICANT	ADDRESS *(Street Number, City, and ZIP Code)*

NOTE: No application may be filed unless a completed application form has been received.

- ☐ ORIGINAL APPLICATION (21 CFR 514.1(a))
- ☐ ABBREVIATED ORIGINAL APPLICATION
- ☐ AMENDMENT TO AN UNAPPROVED ORIGINAL APPLICATION *(21 CFR 514.6)*
- ☐ SUPPLEMENT TO AN APPROVED APPLICATION (21 CFR 514.8(a))
- ☐ AMENDMENT TO AN UNAPPROVED SUPPLEMENT TO AN APPROVED APPLICATION (21 CFR 514.6)
- ☐ SPECIAL SUPPLEMENT TO AN APPROVED APPLICATION --CHANGES BEING EFFECTED *(21 CFR 514.8(e))*

REASON FOR SUBMISSION:

Paperwork Reduction Act Statement

A federal 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 control number. Public reporting burden for this collection of information averages 242.6 hours per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the necessary data, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information to:

Food and Drug Administration
Center for Veterinary Medicine (HFV-12)
Attn.: Assistant Records Control Officer
7500 Standish Place
Rockville, MD 20855

INSTRUCTIONS FOR PREPARING AND SUBMITTING THE NEW ANIMAL DRUG APPLICATION

i. Prepare three identical copies of the submission.

ii. Identify front cover of each copy with the name of the applicant, the proprietary name (if available), the name of the new animal drug and the dosage form.

iii. Use separate pages for each numbered heading consistent with the sub-paragraphs of this application form. (See reverse side of this page).

iv. Number the pages of the new animal drug application. Each copy should bear the same page numbering.

v. Submit separate applications for each different dosage form of the proposed drug.

vi. Basic information pertinent to a dosage form should be made by reference to volume and page of the application containing such information. Include in each application information applicable to the specific dosage form, such as, labeling, composition, stability data, efficacy data, method of manufacture and references to appropriate investigational new animal drug applications and master file(s).

vii. Submit applications to: Food and Drug Administration
Center for Veterinary Medicine (HFV-199)
7500 Standish Place
Rockville, MD 20855

viii. Prepare amendments, supplements, reports and other correspondence in the above format. Identify the submission with the assigned NADA number.

ix. If the submission is a supplemental application, full information shall be provided on each proposed change concerning any statement made in the approved application.

x. Submit page 1 and 2 of this form with each submission.

FOR FDA USE ONLY

The following information in the cited section of 21 CFR 514 shall constitute the requirements of this application. Please check the information submitted.

NOTE: 1. An original application shall include all of the following sections.
2. A supplement or amendment shall include only those sections necessary.

☐ **1. IDENTIFICATION** 21 CFR 514.1(b)(1)

☐ **2. TABLE OF CONTENTS AND SUMMARY** 21 CFR 514.1(b)(2)

A table of contents and summary of information to describe the chemistry of the proposed drug and product, the clinical purpose and a summary of laboratory and clinical studies.

☐ 3. **LABELING** 21 CFR 514.1(b)(3)

Copies of each proposed label.

☐ **4. COMPONENTS AND COMPOSITION** 21 CFR 514.1(b)(4)

A list of all articles used as components of the drug product.
A statement of composition of the drug product.
A complete description of the fermentation of antibiotic drug substances.

☐ **5. MANUFACTURING METHODS, FACILITIES, AND CONTROLS** 21 CFR 514.1(b)(5)

A detailed description of the manufacturer, personnel, facilities/equipment, new animal drug substance synthesis, raw material controls (specifications, tests and methods), manufacturing instructions, finished product analytical controls (specifications, tests and methods), stability program, container/packaging, and lot control number system.

☐ **6. SAMPLES** 21 CFR 514.1(b)(6)

Samples to be submitted only upon the Center's request.

☐ **7. ANALYTICAL METHODS FOR RESIDUES** 21 CFR 514.1(b)(7)

Method(s) and data to enable determination of residues of the drug in food-producing animals.

☐ **8. EVIDENCE TO ESTABLISH SAFETY AND EFFECTIVENESS** 21 CFR 514.1(b)(8)

Data/information to permit evaluation of the safety and effectiveness of the drug product for the claim(s) proposed in the proposed species.

☐ **9. GOOD LABORATORY PRACTICE COMPLIANCE** 21 CFR 514.1(b)(12)(iii)

A statement of compliance or non-compliance to good laboratory practices (21 CFR 58) of each nonclinical laboratory study.

☐ **10. ENVIRONMENTAL ASSESSMENT** 21 CFR 514.1(b)(14)

An environmental assessment (21 CFR 25.40) containing data/informaiton to permit evaluation of the environmental safety of the drug product or a claim for a categorical exclusion from preparing an environmental assessment (21 CFR 25.33), as appropriate.

☐ **11. FREEDOM OF INFORMATION SUMMARY** 21 CFR 514.11

A summary prepared according to Agency guidelines.

☐ **12. OTHER** *(Specify)*

The undersigned official submits this application for a new animal drug pursuant to section 512(b) of the Federal Food, Drug, and Cosmetic Act. It is understood that the labeling and advertising for the new animal drug will prescribe, recommend, or suggest its use only under the conditions stated in the labeling which is part of this application and if the article is a prescription new animal drug, it is understood that any labeling which furnishes or purports to furnish information for use or which prescribes, recommends, or suggests a dosage for use of the new animal drug will also contain, in the same language and emphasis, information for its use including indications, effects, dosages routes, methods, frequency, and duration of administration, any relevant hazards, contraindications, side effects, and precautions contained in the labeling which is part of this application in accordance with 21 CFR 201.105. It is understood that all representations in this application apply to the drug produced until changes are made in conformity with 21 CFR 514.8. It is further understood that new animal drugs as defined in 21 CFR 510.3, intended for use in the manufacture of animal feeds in any State will be shipped only to persons who may receive such drugs in accordance with 21 CFR 510.7. Furthermore, the applicant certifies that the services of any person debarred under FFDCA, subsection 306(a) or (b), have not and will not be used in any capacity with this application.

NOTE: This application must be signed by the applicant or by an authorized attorney, agent, or official. If the applicant does not have a place of business within the United States, the application must also provide the name and address of and be countersigned by an authorized agent or official residing or maintaining a place of business within the United States.

(**WARNING:** A willfully false statement is a criminal offense. U.S.C. Title 18, sec. 1001.)

SIGNATURE OF RESPONSIBLE OFFICIAL OR AUTHORIZED AGENT	TITLE OF AUTHORITY	DATE