

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/information 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