FREEDOM OF INFORMATION SUMMARY

I. GENERAL INFORMATION

A. File Number
   NADA 065-256

B. Sponsor
   Feed Specialties Co.
   Des Moines, Iowa 50313

C. Proprietary Name
   Chlortet-Soluble-O

D. Established Name
   chlortetracycline soluble powder

E. Dosage Form
   Soluble Powder (for use in drinking water)

F. Dispensing Status
   OTC

G. Route of Administration
   Oral

H. Indication

   SWINE:
   For the control and treatment of bacterial enteritis caused by Escherichia coli and
   Salmonella spp. and bacterial pneumonia associated with Pasteurella spp.,
   Actinobacillus pleuropneumoniae. and Klebsiella spp. susceptible to chlortetracycline
   in swine.

   CHICKENS:
   Control of chronic respiratory disease (CRD, air sac disease) caused by Mycoplasma
   gallisepticum and Escherichia coli; infectious synovitis caused by Mycoplasma
   synoviae susceptible to chlortetracycline.

   TURKEYS:
   Control of infectious synovitis caused by Mycoplasma synoviae; control of
   complicating bacterial organisms associated with bluecomb (transmissible enteritis,
   coronaviral enteritis) susceptible to chlortetracycline.

I. Effect of Supplement

   The effectiveness chlortetracycline soluble powder was reviewed by the National
   Academy of Sciences/National Research Council Drug Efficacy Study Implementation
II. EFFECTIVENESS

NADA 065-256 was originally approved as safe for use as labeled on October 14, 1966. The drug was the subject of National Academy of Sciences/National Research Council (NAS/NRC) reports which were published in the FEDERAL REGISTER of July 21, 1970 (35 FR 11647). The Academy evaluated these products as probably effective for growth promotion and feed efficiency and the treatment of animal diseases caused by pathogens sensitive to chlortetracycline.

The Academy states that:

1. Claims made regarding "for prevention of" or "to prevent" should be replaced with "as an aid in the control of" or "to aid in the control of";
2. Claims for growth promotion or stimulation are disallowed and claims for faster gains and/or feed efficiency should be stated as "may result in faster gains and/or improved feed efficiency under appropriate conditions";
3. Each disease claim should be properly qualified as "appropriate for use in (name of disease) caused by pathogens sensitive to (name of drug)"; if the disease cannot be so qualified the claim must be dropped;
4. Claims pertaining to egg production and hatchability should be changed to "May aid in maintaining egg production and hatchability, under appropriate conditions, by controlling pathogenic microorganisms";
5. The labels should warn that treated animals must actually consume enough medicated water or medicated feed to provide a therapeutic dosage under the conditions that prevail and, as a precaution, state the desired oral dose per unit of animal weight per day for each species as a guide to effective usage of the preparation in drinking water or feed: and
6. Effective blood levels are required for each recommended dosage. The Food and Drug Administration concurs in the findings of the Academy; however, the Administration concludes the appropriate claim for faster weight gains and improved feed efficiency should be "For increased rate of weight gain and improved feed efficiency for (under appropriate conditions of use)."

The Food and Drug Administration concurs with the Academy's findings, interpreting the phrase "...cannot be so qualified..." in paragraph (3) to mean "...is not supported by adequate data..." (See Fed. Reg. vol. 35, NO. 140-Tues., July 21, 1970). FDA proceeded to review all available data relating to the effectiveness of products subject to NADA 065-256 to determine which label claims were supported by the requisite proof of effectiveness. That review resulted in a letter to the sponsor dated April 20, 1992, in which the agency stated that it had concluded that such data supported effectiveness only for the control and treatment of certain bacterial diseases susceptible to chlortetracycline hydrochloride in chickens, turkeys and swine.

Thereafter, the sponsor complied with the evaluation of NAS/NRC and FDA's conclusions in the following manner:

1. Appropriate oral doses of 10 mg per pound body weight daily in swine, 200-800 mg/gallon for chickens and turkeys and 25 mg per pound body weight for turkeys when treating bluecomb disease (transmissible enteritis, coronaviral enteritis) have been established.
2. Claims for inappropriate viral diseases have been deleted from the labeling completely.
3. Each disease claim on the label has been properly qualified with the appropriate genus and species of bacteria susceptible to chlortetracycline hydrochloride. Disease claims which were not so qualified have been deleted.
4. Claims made for prevention have been revised to read "Control of..." where appropriate.
5. The manufacturer's label carries the warning statement that treated animals must have the medicated water adjusted to compensate for variation in age and the weight of animals, the nature and severity of disease signs, and environmental temperature and humidity, each of which affects water consumption.

III. TARGET ANIMAL SAFETY

NADA 065-256 was originally approved as safe on October 14, 1966. No further safety data are required.

IV. HUMAN FOOD SAFETY

The NAS/NRC evaluation of the drug is concerned only with the effectiveness and safety of the drug for the treated animal. FDA's approval of the supplemental application does not involve reevaluation or reaffirmation of the human food safety data in the parent application. The tolerances for residues of chlortetracycline are codified at 21 CFR 556.150.

Withdrawal times: 5 days for swine, 24 hours for chickens and turkeys

V. AGENCY CONCLUSIONS

This supplemental NADA satisfies the requirements of section 512 of the Act and demonstrates that Chlortetracycline Soluble Powder when used under its proposed conditions of use, is safe and effective for the labeled indications. The approval provides for use of Chlortetracycline Soluble Powder for the control and treatment of specific diseases in swine, chickens and turkeys.

The "probably effective" finding of the NAS/NRC regarding chlortetracycline hydrochloride which was published in the FEDERAL REGISTER of July 21, 1970, was subsequently reviewed by FDA, resulting in the upgrade to "effective" status with respect to the claims noted in the previous paragraph. The firm submitted revised labeling to conform and, therefore, this supplemental NADA complies with the NAS/NRC evaluation and FDA's conclusions.

When NADA 065-256 was reviewed under NAS / NRC / DESI program, it was an over-the-counter product and this marketing status remains unchanged. Chlortetracycline Soluble Powders for use in food-producing animals are also currently on the market as over-the-counter products. Therefore, the Center for Veterinary Medicine has concluded that this product should retain over-the-counter marketing status.

Under the Center's supplemental approval policy (21 CFR 514.106(b)(2)), this is a Category II change. The approval of this change is not expected to have any adverse effect on the safety or effectiveness of this new animal drug and, therefore, did not require a reevaluation of the human food or target animal safety data in the parent application.
Under the Generic Animal Drug and Patent Term Restoration Act of 1988, this approval does not qualify for an exclusivity period under section 512(c)(2)(F)(iii) of the Federal, Food, Drug, and Cosmetic Act (21 U.S.C. 360b (c)(2)(F)(iii)) because the supplemental application does not contain reports of new clinical or field investigations (other than bioequivalence or residue studies) and in the case of food producing animals human food safety studies (other than bioequivalency or residue studies) essential to the approval and conducted or sponsored by the applicant.

VI. ATTACHMENTS

7 oz Packet
28.8 oz Packet

Copies of applicable labels may be obtained by writing to the:

Food and Drug Administration
Freedom of Information Staff (HFI-35)
5600 Fishers Lane
Rockville, MD 20857

Or requests may be sent via fax to: (301) 443-1726. If there are problems sending a fax, call (301) 443-2414.

The format of this FOI Summary document has been modified from its original form to conform with Section 508 of the Rehabilitation Act (29 U.S.C. 794d). The content of this document has not changed.