

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

OMB

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Certifier Shree

Oral Dosage Form New Animal Drugs; Oxytetracycline Hydrochloride

Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for use of oxytetracycline hydrochloride soluble powder in honeybees for the control and treatment of fowlbrood, and in swine drinking water with a reduction in preslaughter withdrawal time to zero days.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV 104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64503, filed a supplement to ANADA 200-247 that provides for use of Oxytetracycline HCl Soluble Powder-343 for making medicated drinking water for the treatment of various bacterial diseases of livestock. The supplemental ANADA provides for use of oxytetracycline hydrochloride soluble powder in honeybees for the control and treatment of fowlbrood, and in swine drinking water with a reduction in preslaughter

withdrawal time to zero days. A new container size, a 4.78-ounce packet, is also being approved. The supplemental ANADA is approved as of November 12, 2003, and the regulations are amended in 21 CFR 520.1660d to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This rule does not meet the definition of “rule” in 5 U.S.C. 804(3)(A) because it is a rule of “particular applicability.” Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 520

Animal drugs.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

■ 2. Section 520.1660d is amended in the third sentence in paragraph (d)(1)(iii)(C) by removing “withdraw 5 days prior to slaughter those products sponsored by No. 059130 and zero days those products sponsored by No. 000069” and by adding in its place “withdraw zero days prior to slaughter those products sponsored by Nos. 000069 and 059130” and by revising paragraphs (a)(7) and (b)(5) to read as follows:

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

(a) * * *

* * * * *

(7) Each 1.32 grams of powder contains 1 gram of OTC HCl (packet: 4.78 and 9.6 oz.; pails: 2 and 5 lb); each 18.1 grams of powder contains 1 gram of OTC HCl (packet: 6.4 oz.; pails: 2 and 5 lb).

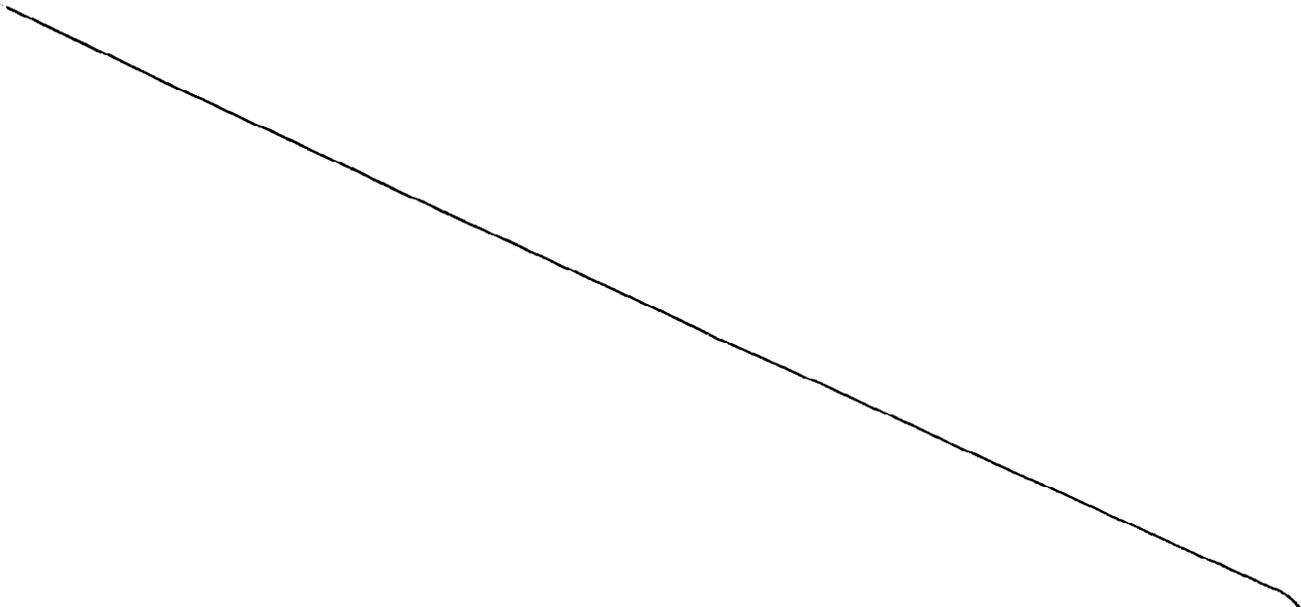
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(b) * * *

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(5) No. 059130 for use of OTC HCl concentration in paragraph (a)(7) of this section in chickens, turkeys, swine, cattle, sheep, and honeybees.

* * * * *



Dated: November 21, 2003

November 21, 2003.

Steven D. Vaughn DVM

Steven D. Vaughn,
Director,
Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 03-????? Filed ??-??-03; 8:45 am]

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CONFIRMED ORIGINAL

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HFA 305

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Approval Date: _____

FREEDOM OF INFORMATION SUMMARY
SUPPLEMENTAL ABBREVIATED NEW ANIMAL
DRUG APPLICATION (ANADA)

ANADA 200-247

OXYTETRACYCLINE HCL SOLUBLE POWDER – 343
(oxytetracycline HCl)

**Indications for use: For control and treatment of specific diseases in
poultry, cattle, sheep, swine and honeybees.**

Sponsored by:

Phoenix Scientific, Inc.
3915 South 48th St. Terrace
St. Joseph, MO 64503

FREEDOM OF INFORMATION SUMMARY

I. General Information:

- a. File Number: ANADA 200-247
- b. Sponsor: Phoenix Scientific, Inc.
3915 South 48th St. Terrace
St. Joseph, MO 64503

Drug Labeler Code: 059130
- c. Established Names: Oxytetracycline HCl
- d. Proprietary Name: OXYTETRACYCLINE HCL SOLUBLE
POWDER-343
- e. Dosage Form: Soluble powder
- f. How Supplied: 4.78 oz (135.5 g) & 9.6 oz (272.2 g)
- g. How Dispensed: OTC
- h. Amount of Active Ingredients: Each packet contains 102.4 or 204.8 grams of
oxytetracycline HCl
- i. Route of Administration: Oral
- j. Species/Class: Poultry, cattle, sheep, swine, and honeybees
- k. Recommended Dosage: SWINE-10mg/lb/day, up to 14 days

CALVES, Beef cattle and non-lactating dairy
cattle- 10 mg/lb/day, up to 14 days

SHEEP- 10 mg/lb/day, up to 14 days

HONEYBEES- 200 mg/colony, administered in 3
applications of sugar syrup or 3 dustings at 4- to 5-
day intervals in early spring or fall.

CHICKENS-

Infectious synovitis caused by *Mycoplasma synoviae* - 200-400 mg/gal

Chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *E.coli* - 400-800 mg/gal

Fowl cholera caused by *Pasteurella multocida* - 400-800 mg/gal

TURKEYS-

Hexamitiasis caused by *Hexamita meleagridis* - 200-400 mg/gal

Infectious synovitis caused by *Mycoplasma synoviae* - 400 mg/gal

Growing turkeys- complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis) - 25 mg/lb body weight daily

For chickens and turkeys medicate continuously at the first clinical signs and continue for 7-14 consecutive days.

l. Pharmacological Category:

Antibacterial

m. Indications:

OXYTETRACYCLINE HCL SOLUBLE POWDER – 343 is indicated for a variety of bacterial infections in cattle, sheep, swine, chickens, turkeys, and honeybees associated with organisms susceptible to oxytetracycline. CALVES, BEEF CATTLE AND NON-LACTATING DAIRY CATTLE: Control and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*.

SHEEP: Control and treatment of bacterial enteritis caused by *Escherichia coli* and bacterial pneumonia (shipping fever complex) caused by *Pasteurella multocida*.

SWINE: Control and treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis* and bacterial pneumonia caused by *Pasteurella multocida*. For Breeding Swine: Leptospirosis (reducing the incidence of abortions and shedding of leptospira) caused by *Leptospira pomona*.

CHICKENS: Control of infectious synovitis caused by *Mycoplasma synoviae*, chronic respiratory disease (CRD) and air sac infection caused by *Mycoplasma gallisepticum* and *Escherichia coli*, and fowl cholera caused by *Pasteurella multocida*.

TURKEYS: Control of hexamitiasis caused by *Hexamita meleagridis* and infectious synovitis caused by *Mycoplasma synoviae*. Growing turkeys-complicating bacterial organisms associated with bluecomb (transmissible enteritis, coronaviral enteritis).

HONEYBEES: Control and treatment of American and European foulbrood caused by *Bacillus larvae*.

n. Pioneer Product:

TERRAMYCIN-343 Soluble Powder, (oxytetracycline HCl); NADA-8-622, Pfizer, Inc.

o. Effect of Supplement:

This submission for OXYTETRACYCLINE HCL SOLUBLE POWDER - 343 is a supplement to the original ANADA 200-247 providing for: (a) a zero- day slaughter withdrawal period for swine; the pioneer sponsor was approved on April 25, 2001, and did not qualify for marketing exclusivity for the zero-day withdrawal period for swine (b) additional pouch size, 4.78 ounce (135.5 g) (c) claim for the treatment and control of foulbrood in honeybees.

2. TARGET ANIMAL SAFETY AND DRUG EFFECTIVENESS:

Under the provisions of the Federal Food, Drug, and Cosmetic Act, as amended by the Generic Animal Drug and Patent Term Restoration Act (GADPTRA) an Abbreviated New Animal Drug Application (ANADA) may be submitted for a generic version of an approved new animal drug (pioneer product). New target animal safety and effectiveness data and human food safety data (other than tissue residue data) are not required for approval of an ANADA.

Ordinarily, the ANADA sponsor shows that the generic product is bioequivalent to the pioneer, which has been shown to be safe and effective. If bioequivalence is demonstrated through a clinical

endpoint study, then a tissue residue study to establish the withdrawal time for the generic product should also be conducted. For certain dosage forms, the agency will grant a waiver from the requirement of an *in vivo* bioequivalence study. (55 FR 24645, June 18, 1990; Fifth GADPTRA Policy Letter; Bioequivalence Guideline, October 9, 2002).

Based on the formulation characteristics of the generic product, Phoenix Scientific, Inc. was granted a waiver from the requirement of an *in vivo* bioequivalence study for the generic product OXYTETRACYCLINE HCL SOLUBLE POWDER - 343. The generic product is administered as an oral solution, contains the same active ingredient in the same concentration and dosage form as the pioneer product, and contains no inactive ingredients that may significantly affect the absorption of the active ingredients. The pioneer product, TERRAMYCIN-343 Soluble Powder (oxytetracycline HCl), sponsored by Pfizer, Inc., NADA 8-622, was approved on September 18, 1952.

3. **HUMAN SAFETY:**

- **Tolerance**

Tolerances are established in 21 CFR 556.500 for the sum of residues of the tetracyclines, including chlortetracycline, oxytetracycline, and tetracycline, in tissues and milk, beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, as follows: 2 parts per million (ppm) in muscle, 6 ppm in liver, 12 ppm in fat and kidney, and 0.3 ppm in milk. The acceptable daily intake (ADI) for total oxytetracycline is 25 micrograms per kilogram of body weight per day.

- **Withdrawal Times**

Because a waiver of *in vivo* bioequivalence study was granted, the withdrawal times are those previously assigned to the pioneer product.

The withdrawal time for swine is zero-day. This withdrawal period is codified at §520.1660d (d)(1)(iii)(C).

- **Regulatory Method for Residues**

The regulatory analytical method for detection of residues of the drug is a microbiological test using *Bacillus cereus* var. *mycoides* (ATCC 11778). The method is as published by the Food and Drug Administration, "Antibiotic Residues in Milk, Dairy Products and Animal Tissues: Method, Reports, and Protocols," revised October 1968, reprinted December 1974.

4. AGENCY CONCLUSIONS:

This supplemental ANADA submitted under section 512(b) of the Federal Food, Drug, and Cosmetic Act satisfies the requirements of section 512(n) of the act and demonstrates that OXYTETRACYCLINE HCL SOLUBLE POWDER – 343 (oxytetracycline HCl), when used under its proposed conditions of use, is safe and effective for its labeled indications.

5. ATTACHMENTS:

Facsimile generic labeling (ANADA 200-247) and currently approved pioneer labeling (NADA 8-622) are attached as indicated below:

Foil Pouch Label (Pioneer)-TERRAMYCIN-343 Soluble Powder
(9.55oz)

Foil Pouch Label (Generic)-OXYTETRACYCLINE HCL SOLUBLE POWDER – 343
(4.78 oz & 9.6 oz)